

# **The evaluation of new MRLs for flupyradifurone and DFA in or on various commodities**

## **UK Competent Authority Evaluation Report and Reasoned Opinion**

- Prepared under Article 8 of Assimilated Regulation 396/2005 and Data Requirements of Assimilated Regulation 544/2011
- Application Reference Number: COP 2024/01085

**April 2026**



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## Summary

In accordance with Article 6 of Assimilated Regulation 396/2005,<sup>1</sup> HSE received an application from Bayer AG on 21 May 2024 to set import tolerances for the active substance flupyradifurone and its metabolite DFA in or on various commodities. This was to accommodate authorisations in the EU, the USA and Canada.

The applicant submitted a dossier in accordance with the data requirements outlined in Assimilated Regulation 544/2011.

In accordance with Article 8 of Assimilated Regulation 396/2005, HSE evaluated the dossier in accordance with the uniform principles as outlined in Article 29(6) of Assimilated Regulation 1107/2009.<sup>2</sup>

Based on the assessment HSE prepared an Evaluation Report that included its Reasoned Opinion on the risk to consumers associated with amending the MRLs. HSE also took into account the data assessed for the approval of the active substance and previous Reasoned Opinions.

Sufficiently validated analytical methods for the determination of flupyradifurone and its metabolite DFA in plant and animal commodities, in line with the enforcement residue definition for products of plant and animal origin, are available to support the products under consideration in the MRL application.

Toxicological reference values for flupyradifurone were established for the approval of the active substance: an ADI of 0.064 mg/kg bw/day and an ARfD of 0.15 mg/kg bw. The reference values of flupyradifurone are also applicable to the metabolite DFA, as stated in the EFSA Conclusion (EFSA Conclusion, 2015).

Metabolism in primary crops was investigated following foliar spray in fruits (apple), pulses/oilseeds (cotton) and cereals (rice) and following bare soil application in fruit (tomato), root/tuber (potato) and cereals (rice) for the approval of flupyradifurone (EFSA, 2015). As a consistent metabolic pathway was observed across crops from at least 3 crop groups, the available data are sufficient to support all crops groups.

The residue definition for risk assessment (RD-RA) in plants has been agreed as:

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<sup>1</sup> [Assimilated Regulation No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin](#) as it applies in Great Britain, where Great Britain ("GB") refers to England, Scotland and Wales

<sup>2</sup> [Assimilated Regulation No 1107/2009 concerning the placing of plant protection products on the market](#) as it applies in Great Britain, where Great Britain ("GB") refers to England, Scotland and Wales.

- Sum of flupyradifurone and DFA expressed as flupyradifurone

The residue definition for enforcement (RD-Enf) in plants has been agreed as:

1. Flupyradifurone
2. DFA (expressed as DFA)

Sixteen greenhouse trials on strawberries, 26 outdoor trials on potatoes, 16 outdoor trials on flowering brassicas (8 cauliflower and 8 broccoli), 12 outdoor trials on head cabbage, 8 outdoor trials on Brussels sprouts, 6 outdoor trials on kale, 4 outdoor trials on kohlrabi, 22 outdoor trials on lettuce, 20 outdoor trials on soyabean and 8 trials on olives were submitted. The trials are supported by validated analytical methods and storage stability data.

It should be noted that the notified use on table olives and olives for oil production is covered by the CXLs adopted as GB MRLs in February 2026 (HSE, 2026), for both flupyradifurone and DFA.

Hydrolysis of flupyradifurone under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation were assessed for the approval of the active substance (EFSA, 2015). The hydrolysis data demonstrate that flupyradifurone is stable under standard conditions, therefore specific residue definitions for processed commodities are not required. No data are available on the stability of the major metabolite DFA under processing conditions (EFSA, 2015). However, as concluded during the active approval, the structural similarity between DFA and trifluoroacetic acid (TFA), which is very stable under hydrolysis conditions, suggests that DFA is unlikely to degrade under hydrolysis conditions (DAR, NL, 2015).

Newly submitted data on the magnitude of residues in processed commodities of soyabean and olive have been evaluated as part of this assessment.

For import tolerance based MRLs, residues in rotational crops are not typically considered. However, specific MRLs are established in the GB MRL Statutory Register for DFA that may arise in both primary and rotational crops from the use of flupyradifurone. Therefore, residues in rotational crops need to be considered further.

Flupyradifurone is very persistent in soil and has the potential to accumulate from year-on-year use. DFA is persistent in soil. As the approval of flupyradifurone was assessed in accordance with the data requirements outlined in Assimilated Regulation 544/2011, the accumulation of residues of flupyradifurone and its metabolite DFA in the soil has not been considered within this assessment. In addition, there are specific MRL supplementary requirements to address this issue, as outlined as footnotes in the GB MRL Statutory Register. Therefore, the consideration of the MRL supplementary information requirements

for the accumulation and plateau concentrations will be addressed and considered separately.

Residues in rotational crops were considered for the approval of the active substance. The metabolism studies demonstrated that residues of flupyradifurone in rotational crops are expected to be  $>0.01$  mg/kg. Metabolism in rotational crops was found to be via a similar pathway to primary crops therefore specific residue definitions for rotational crops are not required.

The magnitude of flupyradifurone and its metabolite DFA in rotational crops was investigated for the approval of the active substance. After application to bare soil at 200 – 250 g a.s./ha, residues of flupyradifurone are expected to be  $<0.01$  mg/kg in all food commodities except lettuce (leafy veg) and barley straw (cereal straw), while residues of metabolite DFA, expressed as DFA, are expected to be  $>0.01$  mg/kg in all food commodities. As there is a separate residue definition for enforcement for the metabolite DFA, further consideration of rotational residues was made for the import tolerances.

New data on the magnitude of residues in rotational crops have been submitted on commodities relevant to the notified uses and have been evaluated as part of this application. After application to bare soil at 175 – 300 g a.s./ha, residues of flupyradifurone are expected to be  $<0.01$  mg/kg in root and tuber vegetables, flowering brassicas, head brassicas and oilseeds. Residues of DFA, expressed as DFA, are expected to be  $>0.01$  mg/kg in root and tuber vegetables, flowering brassicas, head brassicas and oilseeds.

For the consideration of rotational residues present in crops imported from the USA/Canada (potatoes, tropical root and tuber vegetables and soyabean), rotational residues are scaled to the critical USA/Canadian GAP (1 x 410 g a.s./ha) notified under a previous ER/RO (HSE, 2025b). This results in expected rotational residues of flupyradifurone of  $<0.01$  mg/kg and residues of DFA, expressed as DFA of  $>0.01$  mg/kg in these crops.

For the consideration of rotational residues present in crops imported from the EU (flowering brassicas, head brassicas, Brussels sprouts, kale, Chinese cabbage, kohlrabi and leafy vegetables and herbs), rotational residues are scaled to the notified critical EU GAP (2 x 125 g a.s./ha) with a 25% crop interception. This results in expected rotational residues of flupyradifurone of  $<0.01$  mg/kg in these crops except for leafy vegetables and herbs in which residues of flupyradifurone of  $>0.01$  mg/kg are expected. Rotational residues of DFA, expressed as DFA,  $>0.01$  mg/kg are expected in these crops.

The maximum livestock dietary burden for flupyradifurone exceeded the trigger of 0.1 mg/kg dry matter for all animals. The maximum livestock dietary burden for the metabolite DFA, expressed as flupyradifurone, exceeded the trigger of 0.1 mg/kg dry matter for all animals. On this basis further consideration of the residues in products of animal origin (POAO) was required.

Metabolism of flupyradifurone in livestock was considered for the approval of the active substance. The approval assessment concluded that the metabolic pathways in rodents and ruminants are comparable; the findings in ruminants can therefore be extrapolated to pigs.

The residue definition for risk assessment (RD-RA) in animals has been agreed as:

- Sum of flupyradifurone and DFA, expressed as flupyradifurone

The residue definition for enforcement (RD-Enf) in livestock has been agreed as:

1. Flupyradifurone
2. DFA (expressed as DFA)

A data gap was identified during approval of flupyradifurone (EFSA, 2015) for the submission of new animal feeding studies conducted with DFA. New feeding studies to address this data gap were submitted and evaluated under a previous ER/RO (HSE, 2025a).

Due to an increase in the livestock dietary burden and by consideration of the available feeding studies, MRLs for various POAO (products of animal origin) are recommended to be amended.

The highest UK NEDI for the sum of flupyradifurone and DFA, expressed as flupyradifurone was 75% of the ADI (toddler). The highest PRIMo IEDI was 62% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with flupyradifurone.

The highest UK NESTI for the sum of flupyradifurone and DFA, expressed as flupyradifurone was 64.3% of the ARfD (infant/head cabbage). The highest PRIMo IESTI was 97% of the ARfD (children/lettuces). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with flupyradifurone.

It should be noted that the adoption of the CXL for cauliflowers results in a PRIMo IESTI and NESTI of 100.4% of the ARfD (for children and infants, respectively). The adoption of the CXL for soyabeans results in a NESTI of 105.2% of the ARfD (4-6 year olds). Therefore, the adoption of the CXLs for cauliflowers and soyabean is not recommended.

HSE concludes that sufficient data have been provided to support the setting of new MRLs for the notified uses of flupyradifurone on strawberries, potatoes, tropical root and tuber vegetables, flowering brassicas, Brussels sprouts, head cabbage, kale, Chinese cabbages/pe-tsai, kohlrabi, lettuces and salad plants (except escaroles/broad-leaved endives), spinach and similar leaves, herbs and edible flowers and soyabean. The data are also sufficient to support new MRLs for products of animal origin. The new MRLs will



not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected.

As noted previously, the import tolerance request for olives is covered by the CXL adopted for flupyradifurone in 2025 and adopted as a GB MRL in February 2026 (HSE, 2026). The notified GAP is covered by both the flupyradifurone CXL and the DFA MRL linked to the flupyradifurone CXL.

HSE recommends that the MRLs outlined in Tables 0.1 and 0.2 are amended in the GB MRL Statutory Register.

**Table 0.1 MRLs recommended by HSE (flupyradifurone)**

| Product code                                                                           | Product                            | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                                       |
|----------------------------------------------------------------------------------------|------------------------------------|-------------------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| <b>Enforcement residue definition for products of plant origin:</b><br>Flupyradifurone |                                    |                         |                               |                                                                                                                                |
| 0152000                                                                                | Strawberries                       | 0.4                     | 1.5                           | The MRL is based on the CXL.<br><br>No health effects are expected.                                                            |
| 0211000                                                                                | Potatoes                           | 0.01*                   | 0.05                          | The MRL is based on the CXL.<br><br>No health effects are expected.                                                            |
| 0212000                                                                                | Tropical root and tuber vegetables | 0.01*                   | 0.05                          | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on potato.<br><br>No health effects are expected. |

| <b>Product code</b> | <b>Product</b>           | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>                                                                                                                                         |
|---------------------|--------------------------|--------------------------------|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0241000             | Flowering brassicas      | 0.01*                          | 0.6                                  | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on broccoli and cauliflower.</p> <p>No health effects are expected.</p> |
| 0242010             | Brussels sprouts         | 0.01*                          | 0.09                                 | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p>                     |
| 0242020             | Head cabbages            | 0.01*                          | 1.5                                  | <p>The MRL is based on the CXL.</p> <p>No health effects are expected.</p>                                                                              |
| 0243010             | Chinese cabbages/pe-tsai | 0.01*                          | 4                                    | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on kale.</p> <p>No health effects are expected.</p>                     |

| <b>Product code</b> | <b>Product</b>              | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>                                                                                                                                              |
|---------------------|-----------------------------|--------------------------------|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0243020             | Kales                       | 0.01*                          | 4                                    | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p>                          |
| 0244000             | Kohlrabies                  | 0.01*                          | 0.09                                 | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p>                          |
| 0251010             | Lamb's lettuces/corn salads | 0.03                           | 6                                    | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on lettuce (open leaf varieties).</p> <p>No health effects are expected.</p> |
| 0251020             | Lettuces                    | 5                              | 6                                    | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p>                          |

| Product code                                                                            | Product                                                            | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                                            |
|-----------------------------------------------------------------------------------------|--------------------------------------------------------------------|-------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0251040                                                                                 | Cresses and other sprouts and shoots                               | 0.03                    | 6                             | The MRLs are based on the IT request.                                                                                               |
| 0251050                                                                                 | Land cresses                                                       | 0.03                    | 6                             | The MRLs are extrapolated from data on lettuce (open leaf varieties).                                                               |
| 0251060                                                                                 | Roman rocket/rucola                                                | 0.03                    | 6                             | No health effects are expected.                                                                                                     |
| 0251070                                                                                 | Red mustards                                                       | 0.03                    | 6                             |                                                                                                                                     |
| 0251080                                                                                 | Baby leaf crops (including brassica species)                       | 0.03                    | 6                             |                                                                                                                                     |
| 0251990                                                                                 | Others - Lettuce and other salad plants including brassica species | 0.03                    | 6                             |                                                                                                                                     |
| 0252000                                                                                 | Spinach and similar leaves                                         | 0.03                    | 6                             |                                                                                                                                     |
| 0256000                                                                                 | Herbs and edible flowers                                           | 0.03                    | 6                             |                                                                                                                                     |
| 0401070                                                                                 | Soyabeans                                                          | 0.01*                   | 1.5                           | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |
| <b>Enforcement residue definition for products of animal origin:</b><br>Flupyradifurone |                                                                    |                         |                               |                                                                                                                                     |

| Product code | Product                                             | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                          |
|--------------|-----------------------------------------------------|-------------------------|-------------------------------|-----------------------------------------------------------------------------------|
| 1011010      | Muscle – swine                                      | 0.01*                   | 0.015                         | The MRL is sufficiently supported by data.<br><br>No health effects are expected. |
| 1011030      | Liver – swine                                       | 0.04                    | 0.06                          | The MRL is sufficiently supported by data.<br><br>No health effects are expected. |
| 1011040      | Kidney – swine                                      | 0.05                    | 0.08                          | The MRL is sufficiently supported by data.<br><br>No health effects are expected. |
| 1011050      | Edible offals (other than liver and kidney) – swine | 0.05                    | 0.08                          | The MRL is extrapolated from swine kidney.<br><br>No health effects are expected. |

\* Indicates that the MRL is set at the limit of quantification/determination

**Table 0.2 MRLs recommended by HSE (difluoroacetic acid (DFA) (from the use of flupyradifurone)**

| Product code                         | Product                             | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments             |
|--------------------------------------|-------------------------------------|-------------------------|-------------------------------|----------------------|
| <b>Enforcement</b><br>DFA, expressed | <b>residue definition</b><br>as DFA | <b>for</b>              | <b>products of</b>            | <b>plant origin:</b> |

| Product code | Product                            | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                                                         |
|--------------|------------------------------------|-------------------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 0152000      | Strawberries                       | 0.03                    | 2                             | The MRL is linked to the CXL for flupyradifurone.<br><br>No health effects are expected.                                                         |
| 0211000      | Potatoes                           | 0.09                    | 0.5                           | The MRL is linked to the CXL for flupyradifurone.<br><br>No health effects are expected.                                                         |
| 0212000      | Tropical root and tuber vegetables | 0.09                    | 0.5                           | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on potato.<br><br>No health effects are expected.                   |
| 0241000      | Flowering brassicas                | 0.02*                   | 0.5 <sup>†</sup>              | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on broccoli and cauliflower.<br><br>No health effects are expected. |

| Product code | Product                  | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                                            |
|--------------|--------------------------|-------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0242010      | Brussels sprouts         | 0.02*                   | 0.3 <sup>†</sup>              | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |
| 0242020      | Head cabbages            | 0.02*                   | 0.5                           | <p>The MRL is linked to the CXL for flupyradifurone.</p> <p>No health effects are expected.</p>                                     |
| 0243010      | Chinese cabbages/pe-tsai | 0.02*                   | 0.5 <sup>†</sup>              | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on kale.</p> <p>No health effects are expected.</p> |

| Product code | Product                     | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                                                                     |
|--------------|-----------------------------|-------------------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0243020      | Kales                       | 0.02*                   | 0.5 <sup>†</sup>              | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p>                          |
| 0244000      | Kohlrabies                  | 0.02*                   | 0.4                           | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p>                          |
| 0251010      | Lamb's lettuces/corn salads | 0.04                    | 0.3                           | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on lettuce (open leaf varieties).</p> <p>No health effects are expected.</p> |



| <b>Product code</b> | <b>Product</b>                                                     | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>                                                                          |
|---------------------|--------------------------------------------------------------------|--------------------------------|--------------------------------------|------------------------------------------------------------------------------------------|
| 0251020             | Lettuces                                                           | 0.09                           | 0.4                                  | The MRL is linked to the CXL for flupyradifurone.<br><br>No health effects are expected. |
| 0251040             | Cresses and other sprouts and shoots                               | 0.04                           | 0.3                                  | The MRLs are based on the IT request.                                                    |
| 0251050             | Land cresses                                                       | 0.04                           | 0.3                                  | The MRLs are extrapolated from data on lettuce (open leaf varieties).                    |
| 0251060             | Roman rocket/rucola                                                | 0.04                           | 0.3                                  | No health effects are expected.                                                          |
| 0251070             | Red mustards                                                       | 0.04                           | 0.3                                  |                                                                                          |
| 0251080             | Baby leaf crops (including brassica species)                       | 0.04                           | 0.3                                  |                                                                                          |
| 0251990             | Others - Lettuce and other salad plants including brassica species | 0.04                           | 0.3                                  |                                                                                          |
| 0252000             | Spinach and similar leaves                                         | 0.04                           | 0.3                                  |                                                                                          |
| 0256000             | Herbs and edible flowers                                           | 0.04                           | 0.3                                  |                                                                                          |

| Product code | Product   | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                                            |
|--------------|-----------|-------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0401070      | Soyabeans | 0.05                    | 0.6                           | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |

\* Indicates that the MRL is set at the limit of quantification/determination

† It should be noted that the higher MRL in the exporting country is owing to the impact of accumulation from year-on-year use being considered. GB MRLs at this time have not applied this consideration as it is not required by the data requirements that are applicable to flupyradifurone. Consideration of accumulation from year-on-year use will be addressed separately as part of the MRL supplementary information assessment.

## Background

Assimilated Regulation No 396/2005 outlines the rules for setting MRLs in GB. Article 6 covers the submission of applications for MRLs, including the parties which can submit an application. Article 7 outlines that a dossier in accordance with the data requirements of Regulation (EC) No 1107/2009 must be provided.

On 21 May 2024 HSE accepted an application from Bayer AG to set new MRLs for flupyradifurone and DFA in or on various commodities.

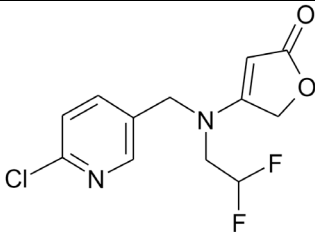
HSE evaluated the information submitted to uniform principles, as defined by Article 8 of Assimilated Regulation No 396/2005 and prepared an Evaluation Report. HSE also took into account EFSA Reasoned Opinions and Conclusions on the peer review relating to decisions implemented in GB.

The Evaluation Report is the basis of HSE's Reasoned Opinion.

## The active substance and its use pattern

Information on the active substance flupyradifurone is outlined in Table 0.3.

**Table 0.3 Information on the active substance**

|                       |                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------|
| Common name (ISO)     | Flupyradifurone                                                                   |
| Chemical name (IUPAC) | 4-[(6-chloro-3-pyridylmethyl)(2,2-difluoroethyl)amino]furan-2(5H)-one             |
| CAS number            | 951659-40-8                                                                       |
| Structural formula    |  |
| Molecular formula     | C <sub>12</sub> H <sub>11</sub> ClF <sub>2</sub> N <sub>2</sub> O <sub>2</sub>    |
| Molecular mass        | 288.68 g/mol                                                                      |

Flupyradifurone is an approved active substance in GB. An EFSA conclusion is available (EFSA, 2015). The MRLs for flupyradifurone and the metabolite DFA were reviewed under Article 12 of Regulation (EC) No 396/2005 (EFSA RO, 2020).

MRLs are established for flupyradifurone and DFA in Part 3a of the GB MRL Statutory Register.

A copy of the current national legislation in the exporting country related to the MRLs under consideration and evidence of the authorisation of the respective uses of the plant protection product in the EU, the USA and Canada was provided by the applicant and is summarised in Appendix E.

Appendix A outlines the GAPs (Good Agricultural Practices) supported in this application.

The following CXLs are available for flupyradifurone for the notified uses (Codex Pesticide Residues in food online database).

**Table 0.4 CXLs relevant to the notified uses**

| Commodity              | CXL (mg/kg) | Comments | Year of adoption |
|------------------------|-------------|----------|------------------|
| <b>Flupyradifurone</b> |             |          |                  |

|                           |      |                                                                                                                                                                                                                                                 |      |
|---------------------------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| FB 0275<br>Strawberry     | 1.5  | <p>The CXL is higher than the current GB MRL (0.4 mg/kg) and the proposed MRL (0.6 mg/kg).</p> <p>As the dietary exposures are below the toxicological reference value, HSE recommends the adoption of the CXL for strawberries.</p>            | 2017 |
| VR 0589<br>Potato         | 0.05 | <p>The CXL is higher than the current GB MRL (0.01* mg/kg) and the same as the proposed MRL (0.05 mg/kg).</p> <p>As the dietary exposures are below the toxicological reference value, HSE recommends the adoption of the CXL for potatoes.</p> | 2017 |
| VB 0404<br>Cauliflower    | 6    | <p>The CXL is higher than the current GB MRL (0.01* mg/kg) and the proposed MRL (0.6 mg/kg).</p> <p>The CXL results in dietary exposures above the toxicological reference value. Therefore, the adoption of the CXL is not recommended.</p>    | 2017 |
| VB 0041<br>Cabbages, head | 1.5  | <p>The CXL is higher than the current GB MRL (0.01* mg/kg) and the proposed MRL (0.3 mg/kg).</p> <p>As the dietary exposures are below the toxicological reference value, HSE recommends the adoption of the CXL for head cabbages.</p>         | 2017 |
| VL 0482<br>Lettuce, head  | 4.0  | <p>The CXL is lower than the current GB MRL (5 mg/kg) and the proposed MRL (6 mg/kg).</p> <p>Therefore, the adoption of the CXL is not recommended.</p>                                                                                         | 2017 |

|                                      |     |                                                                                                                                                                                                                                                                                                                                                                                                                        |      |
|--------------------------------------|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| VD 0541<br>Soya bean (dry)           | 1.5 | <p>The CXL is higher than the current GB MRL (0.01* mg/kg) and the same as the proposed MRL (1.5 mg/kg).</p> <p>Despite being the same as the proposed GB MRL, the CXL results in dietary exposures above the toxicological reference value due to the JMPR RD-RA including an additional metabolite which is not included in the GB RD-RA (see Table 0.5). Therefore, the adoption of the CXL is not recommended.</p> | 2017 |
| FT 0305<br>Table olives              | 5   | The CXL was adopted by GB in 2026 (HSE, 2026).                                                                                                                                                                                                                                                                                                                                                                         | 2025 |
| SO 0305<br>Olives for oil production |     |                                                                                                                                                                                                                                                                                                                                                                                                                        |      |

As outlined in Table 0.5 the residue definitions for risk assessment are not comparable between the JMPR and GB. Using the STMR supporting the CXL will lead to an overestimation of the exposure compared to the GB residue definition as it includes an additional metabolite (6-CAA), and hence a further consideration is not required.

The difference in the RDs for enforcement between GB and the JMPR requires additional consideration. The CXLs are established on a RD-Enf of flupyradifurone only. However, in GB two separate RD-Enf have been established for flupyradifurone and the metabolite DFA that may arise in primary and rotational crops following the application of flupyradifurone.

As treated commodities imported into GB will need to comply with the MRLs for flupyradifurone and DFA, HSE has estimated the MRLs required for DFA associated with the CXLs recommended for adoption in Table 0.4. The MRLs estimated for DFA are based on the data available in the JMPR evaluation.

To adopt the CXLs for flupyradifurone, the MRLs for DFA outlined in Table 0.6 must also be adopted.

**Table 0.5 Residue definitions**

| Commodity | Residue definition type | JMPR | GB | Are the residue |
|-----------|-------------------------|------|----|-----------------|
|-----------|-------------------------|------|----|-----------------|

|        |                 |                                                                        |                                                              | <b>definitions compatible</b>                                                                                            |
|--------|-----------------|------------------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| Plants | Enforcement     | Flupyradifurone                                                        | Flupyradifurone                                              | Yes, although GB includes a separate definition for DFA                                                                  |
|        |                 |                                                                        | DFA, expressed as DFA                                        |                                                                                                                          |
|        | Risk assessment | Sum of flupyradifurone, DFA and 6-CAA, expressed as parent equivalents | Sum of flupyradifurone and DFA, expressed as flupyradifurone | Yes, although JMPR definition includes an additional metabolite and so is considered a more extensive residue definition |

**Table 0.6 MRLs required for DFA associated with the CXLs for flupyradifurone recommended for adoption**

| Commodity                | CXL (mg/kg) | Comments                                                                                                                                                                                                                                                                                  | Year of adoption                                                                                   |
|--------------------------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <b>DFA, expressed as</b> | <b>DFA</b>  |                                                                                                                                                                                                                                                                                           |                                                                                                    |
| FB 0275<br>Strawberry    | 2           | <p>The proposed MRL is calculated from JMPR data used to set the CXL for flupyradifurone and includes primary and rotational residues.</p> <p>The proposed MRL is higher than the current GB MRL (0.03 mg/kg) and the proposed MRL calculated based on the notified use (0.05 mg/kg).</p> | JMPR residue definitions for enforcement do not include DFA, therefore CXLs have not been adopted. |

|                        |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |
|------------------------|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|                        |     | As the proposed MRL is higher, and the dietary exposures are below the toxicological reference value, HSE recommends the adoption of the proposed MRL.                                                                                                                                                                                                                                                                                                                |  |
| VR 0589<br>Potato      | 0.5 | <p>The proposed MRL is calculated from JMPR data used to set the CXL for flupyradifurone and includes primary and rotational residues.</p> <p>The proposed MRL is higher than the current GB MRL (0.09 mg/kg) and is the same as the proposed MRL calculated based on the notified use (0.5 mg/kg).</p> <p>As the proposed MRL is higher, and the dietary exposures are below the toxicological reference value, HSE recommends the adoption of the proposed MRL.</p> |  |
| VB 0404<br>Cauliflower | 0.4 | <p>The proposed MRL is calculated from JMPR data used to set the CXL for flupyradifurone and includes primary and rotational residues.</p> <p>The proposed MRL is higher than the current GB MRL (0.02* mg/kg) but is lower than the proposed MRL calculated based on the notified use (0.5 mg/kg).</p> <p>Therefore, HSE does not recommend the adoption of the proposed MRL.</p>                                                                                    |  |



|                            |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------------------|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| VB 0041<br>Cabbages, head  | 0.5 | <p>The proposed MRL is calculated from JMPR data used to set the CXL for flupyradifurone and includes primary and rotational residues.</p> <p>The proposed MRL is higher than the current GB MRL (0.02* mg/kg) and the proposed MRL calculated based on the notified use (0.3 mg/kg).</p> <p>As the proposed MRL is higher, and the dietary exposures are below the toxicological reference value, HSE recommends the adoption of the proposed MRL.</p> |
| VL 0482<br>Lettuce, head   | 0.4 | <p>The proposed MRL is calculated from JMPR data used to set the CXL for flupyradifurone and includes primary and rotational residues.</p> <p>The proposed MRL is higher than the current GB MRL (0.09 mg/kg) and the proposed MRL calculated based on the notified use (0.2 mg/kg).</p> <p>As the proposed MRL is higher, and the dietary exposures are below the toxicological reference value, HSE recommends the adoption of the proposed MRL.</p>  |
| VD 0541<br>Soya bean (dry) | 4   | <p>The proposed MRL is calculated from JMPR data used to set the CXL for flupyradifurone and includes primary and rotational residues.</p>                                                                                                                                                                                                                                                                                                              |

|                                                                              |      |                                                                                                                                                                                                                                                                                                     |
|------------------------------------------------------------------------------|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                              |      | <p>The proposed MRL is higher than the current GB MRL (0.05 mg/kg) and the proposed MRL calculated based on the notified use (0.6 mg/kg).</p> <p>However, the dietary exposures are above the toxicological reference value, therefore HSE does not recommend the adoption of the proposed MRL.</p> |
| <p>FT 0305<br/>Table olives</p> <p>SO 0305<br/>Olives for oil production</p> | 0.09 | <p>The proposed MRL is calculated from JMPR data uses to set the CXL for flupyradifurone.</p> <p>The proposed MRL was adopted by GB in 2026 (HSE, 2026).</p>                                                                                                                                        |

The CXL database is available at the following link:

<http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/>

# Assessment

## 1 Methods of analysis

### 1.1 Methods for enforcement and monitoring of residues in food of plant origin

Analytical methods for the determination of flupyradifurone and its metabolite DFA in plant commodities, in line with the enforcement residue definition for products of plant origin, were assessed for the approval of the active substance (DAR, NL, 2015).

HPLC-MS/MS method 01330 (including its modification M001) for monitoring flupyradifurone and its metabolite DFA in high water (lettuce), high oil (rape seed), high acid (orange) and dry (wheat grain) commodity groups has been fully validated for the approval of the active substance with a flupyradifurone LOQ of 0.01 mg/kg and a DFA LOQ of 0.02 mg/kg. The method was also validated for hops (difficult matrix) with a flupyradifurone LOQ of 0.05 mg/kg and a DFA LOQ of 0.10 mg/kg. Acceptable ILV data were provided. Extraction efficiency for this method was addressed for the approval of the active substance.

The crop groups under consideration in the MRL application: high acid (strawberry), high water (potatoes, root and tuber vegetables, flowering brassicas, head brassicas, Brussels sprouts, kale, Chinese cabbage, kohlrabi, leafy vegetables, and herbs and edible flowers) and high oil (soyabean and olive) are covered by the available analytical method.

### 1.2 Methods for enforcement and monitoring of residues in food of animal origin

Analytical methods for the determination of flupyradifurone and metabolite DFA in animal commodities, in line with the enforcement residue definition for products of animal origin, were assessed for the approval of the active substance (DAR, NL, 2015).

HPLC-MS/MS method 01214 for monitoring flupyradifurone and its metabolite DFA in animal matrices was fully validated for the approval of the active substance with a flupyradifurone LOQ of 0.01 mg/kg and a DFA LOQ of 0.02 mg/kg in fat, liver, kidney,

muscle, egg and milk. Acceptable ILV data were provided. Extraction efficiency for this method was addressed for the approval of the active substance.

The products of animal origin under consideration in the MRL application are covered by the analytical method available.

## 2 Mammalian toxicology

The toxicological end points established for the approval of the active substance are summarised in Table 2.1.

**Table 2.1 Overview of the toxicological reference values for flupyradifurone**

| TRVs | Source | Year | Value            | Study relied upon           | Safety factor |
|------|--------|------|------------------|-----------------------------|---------------|
| ADI  | EFSA   | 2015 | 0.064 mg/kg bw/d | Rat, two-generation study   | 100           |
| ARfD | EFSA   | 2015 | 0.15 mg/kg bw/d  | Rabbit, developmental study | 100           |

The toxicological end points of the parent are also considered applicable to the metabolite, DFA (EFSA, 2016) as summarised in Table 2.2.

**Table 2.2 Overview of the toxicological reference values for DFA**

| TRVs | Source | Year | Value            | Study relied upon           | Safety factor |
|------|--------|------|------------------|-----------------------------|---------------|
| ADI  | EFSA   | 2015 | 0.064 mg/kg bw/d | Rat, two-generation study   | 100           |
| ARfD | EFSA   | 2015 | 0.15 mg/kg bw/d  | Rabbit, developmental study | 100           |

## 3 Residues in plants

### 3.1 Nature of residues in primary crops

Metabolism in primary crops was investigated following foliar spray treatment in fruits (apple), pulses/oilseeds (cotton) and cereals (rice) for the approval of the active substance (EFSA, 2015). Metabolism in primary crops was also investigated following soil application in fruits (tomato), root vegetables (potato) and cereals (rice) for the approval of the active substance (EFSA, 2015). Metabolism in primary crops was also investigated following seed treatment on root vegetables (potato) for the approval of the active substance (EFSA, 2015).

A summary of the available primary crop metabolism data is presented below (EFSA, 2015):

*“Flupyradifurone metabolism in primary crops was investigated in four crop groups either by foliar applications (apple, cotton, rice), by soil granule/drench applications (tomato, potato, rice) and by seed dressing (potato). Studies were conducted using <sup>14</sup>C-flupyradifurone labelled on the pyridinyl or furanone moiety and using application rates representative of the supported uses. One study on tomato using soil drench application and a <sup>14</sup>C-labelling on the difluoroethyl amino group was also submitted. The metabolism in primary crops was seen to be similar in all plant groups investigated. Flupyradifurone was consistently observed as the major component of the radioactive residues, accounting for ca. 25% to 88% TRR in all plant parts analysed. Besides flupyradifurone, the following metabolites were identified in different plant matrices:*

- *the conjugate flupyradifurone-hydroxy-glycoside, up to 36%TRR in apple leaves,*
- *the conjugate CHPM-diglycoside, up to 37% TRR (0.06 mg/kg) and the metabolite 6-CNA in the range of 13% to 22% TRR in tomato fruit, potato tuber and cotton seed at ca. 0.02 mg/kg, both resulting from the cleavage of the molecule at ethylamine bond and containing the pyridinyl moiety.*

*In contrast, metabolites containing the furanone moiety were almost not detected and the radioactivity in the <sup>14</sup>C-furanone studies was mostly recovered as incorporated in natural glucoside and carbohydrate components, indicating an extensive degradation of the furanone counterpart. In addition, information was given by the study conducted on tomato with the <sup>14</sup>C-labelling on the difluoroethyl amino group that, following soil drench application, significant proportions (87% TRR) and levels (0.17 mg/kg) of difluoroacetic acid (DFA) are present in tomato fruits. Samples from the radiolabelled studies were therefore re-analysed for non-radiolabelled DFA and residues, expressed as DFA*

*equivalent, were measured in the range of 0.04 to 0.23 mg/kg in apple fruits, potato tuber, cotton seed and rice grain, irrespective of the mode of application.”*

A summary of the available primary crop metabolism data considered during the approval of flupyradifurone taken from the DAR (DAR, NL, 2015) is presented below.

**Table 3.1-1 Summary of the primary plant metabolism studies**

| Crop groups         | Crop(s) | Applications                                                                               | DAT <sup>(a)</sup> (days)     |
|---------------------|---------|--------------------------------------------------------------------------------------------|-------------------------------|
| Fruit               | Apple   | Foliar<br>a) 1 x 86 g/ha metre canopy height (CH); BBCH 69<br>b) 2 x 86 g/ha/m CH; BBCH 69 | a) 89 DAT<br>b) 14 DALA       |
|                     | Tomato  | Soil drench, 2 x 300 g/ha, BBCH 14 – 15, interval 14 days                                  | 56 – 73 DALA                  |
| Root vegetables     | Potato  | In furrow, 1 x 626 g/ha, BBCH 03                                                           | 97 DAT                        |
|                     |         | Seed treatment, 1 x 254 g/ha, BBCH 03                                                      | 97 DAT                        |
| Cereals             | Rice    | Foliar, 175 g/ha, BBCH 13/15 + 240 g/ha, BBCH 87 – 89                                      | 29 DALA                       |
|                     |         | Soil granule at planting, 1 x 409 – 434 g/ha, BBCH 13/15                                   | 127 DAT                       |
| Pulses and oilseeds | Cotton  | Foliar<br>a) 1 x 210 g/ha, BBCH 15 – 18<br>b) 210 + 175 g/ha, BBCH 15 – 18                 | a) 169 DAT<br>b) 14 – 15 DALA |

(a) DAT where identification/characterisation of the residues has been investigated (*interim samplings with information limited to TRR levels only, can be omitted*)

As a consistent metabolic pathway was observed across crops from at least 3 crop groups, the available data are sufficient to support all crop groups. The application type in 3 of the studies is foliar spray, which is the same as the application type for the notified uses. On this basis all notified uses are supported by the available metabolism data.

The residue definition for risk assessment (RD-RA) in plants has been agreed as:

- Sum of flupyradifurone and DFA expressed as flupyradifurone

The residue definition for enforcement (RD-Enf) in plants has been agreed as:

- 1) Flupyradifurone
- 2) DFA (expressed as DFA)

## 3.2 Magnitude of residues in primary crops

The notified uses are outlined in Appendix A.

### Residue trials

Trials conducted in northern and southern Europe have been considered where there are authorised uses in northern and southern EU MS for the same GAP. Northern and southern European datasets have been combined when they are similar (Mann-Whitney U-test, 5%).

Summaries of the residues arising from the residue trials evaluated under Appendix C.3.1.2 are presented in Table 3.2-2 for residues of flupyradifurone and DFA.

The trials were conducted in accordance with the relevant guidance documents (OECD 509), and no significant deviations were noted in the trials.

### 0152000 Strawberries

The authorised critical GAP in the EU on strawberries is for a protected use with foliar spray application at a rate of 2 x 0.125 kg a.s./ha with an RTI of 10 days, a PHI of 3 days and with application at BBCH 12 – 89.

The applicant has submitted 16 greenhouse trials on strawberry in the context of this application undertaken using an SL formulation.

Eight of the submitted trials were conducted with foliar applications at 2 x 0.125 kg a.s./ha, with a 9/10 day RTI, a 3 day PHI and with the last application at BBCH 85 – 87.

The remaining eight trials were conducted with a foliar application at 1 x 0.124 – 0.130 kg a.s./ha, with a 3 day PHI and with application at BBCH 73 – 87.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 71 onwards), therefore half of the trials should be decline trials. All 16 of the available trials were decline trials, therefore this is sufficient to support the proposed MRL.

As set out in the GB Extrapolation Guidance 2024, strawberries are a major crop. As eight trials on strawberry carried out at the notified cGAP are available, sufficient data are available to support the notified use on strawberries.

Sufficient residue trials are available to support the proposed MRL for strawberries at the notified GAP.

### 0211000 Potatoes

### 0212000 Tropical root and tuber vegetables



The authorised critical GAP in the USA and Canada on potatoes and tropical root and tuber vegetables is foliar spray application at a rate of 2 x 0.205 kg a.s./ha with an RTI of 7 days, a PHI of 7 days and with application at all growth stages.

The applicant has submitted 26 USA outdoor trials on potatoes in the context of this application undertaken using as SL formulation. The foliar applications were conducted at 2 x 0.201 – 0.221 kg a.s./ha, with a 6 – 8 day RTI, a 7 day PHI and last application at BBCH 43 – 95.

The notified GAP for potatoes and tropical root and tuber vegetables includes timing of application at all growth stages. Therefore, the most critical BBCH of application is considered to be the latest possible growth stage before normal commercial harvest (BBCH 89). Nineteen of the 26 trials were carried out with last application at BBCH 89 onwards, therefore are considered supportive of the notified GAP. The remaining 7 trials were carried out with last application at BBCH 43 – 74. Although not within the same principal growth stage, the reported residues from these trials (flupyradifurone: <0.01 – 0.037 mg/kg; DFA: <0.017 – 0.024 mg/kg) were comparable to those from the trials with last application at BBCH 89 onwards (flupyradifurone: <0.01 – 0.022 mg/kg; DFA: <0.017 – 0.029 mg/kg). In addition, the RTIs and PHIs in all trials matched or were within  $\pm 25\%$  of the notified GAP. Therefore, the submitted trials are considered acceptable to support the notified GAPs on potatoes and tropical root and tuber vegetables.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 19 onwards), therefore half of the trials should be decline trials. Four of the 26 trials were decline trials, which is sufficient given there is only a requirement to provide a total of 8 trials and hence only 4 of which need to be decline trials.

Please note that in some instances residue trials have been carried out at the same location and therefore cannot be considered independent. For further details, see Section C.3.1.2.2.

As set out in the GB Extrapolation Guidance 2024, potatoes are a major crop. As 26 trials on potatoes which support the notified cGAP are available, sufficient data are available to support the notified use on potatoes. As data on potatoes can be extrapolated to the whole subgroup (b) tropical root and tuber vegetables before and after formation of the edible part, sufficient data is available to support the notified use on tropical root and tuber vegetables.

Sufficient residue trials are available to support the proposed MRLs for potatoes and tropical root and tuber vegetables at the notified GAP.

## **0241000 Flowering brassica**

The authorised critical GAP in the EU on flowering brassicas is foliar spray application at a rate of 2 x 0.125 kg a.s./ha with an RTI of 10 days, a PHI of 3 days and with application at BBCH 12 – 49.

The applicant has submitted 8 outdoor trials on cauliflower and 8 outdoor trials on broccoli in the context of this application undertaken using an SL formulation. For both cauliflower and broccoli, 4 trials were carried out in northern Europe and 4 in southern Europe. The trials were conducted with a foliar spray application at 2 x 0.125 kg a.s./ha, with a 10 – 12 day RTI, a 3 day PHI and with last application at BBCH 45 – 49. As all final applications were carried out in the same principal growth stage as specified in the notified cGAP, and as the RTIs and PHIs are within  $\pm 25\%$  of the notified cGAP, the trials are considered acceptable to support the notified GAP on flowering brassicas.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 19 onwards), therefore half of the trials should be decline trials. All of the trials were decline trials, therefore this is sufficient to support the proposed MRL.

As set out in the GB Extrapolation Guidance 2024, cauliflower is a major crop. Trials on cauliflower (4 northern, 4 southern) and broccoli (4 northern, 4 southern) can be extrapolated to the whole subgroup (a) flowering brassica before and after formation of the edible part. As 8 trials on cauliflower and 8 trials on broccoli are available, the requirements of the agreed extrapolation have been met and sufficient data are available to support a GB MRL for the notified use on flowering brassicas.

Sufficient residue trials are available to support the proposed MRL for flowering brassicas at the notified GAP.

### **0242020 Head cabbage**

The authorised critical GAP in the EU on head cabbage is foliar spray application at a rate of 2 x 0.125 kg a.s./ha with an RTI of 10 days, a PHI of 3 days and with application at BBCH 12 – 49.

The applicant has submitted 12 outdoor trials on head cabbage in the context of this application undertaken using a SL formulation. Eight of the trials were undertaken in northern Europe and the remaining 4 in southern Europe. The trials were conducted with foliar spray applications at 2 x 0.125 – 0.135 kg a.s./ha, with a 8 – 12 day RTI, a 3 day PHI and with the last application at BBCH 43 – 49. As all final applications were carried out in the same principal growth stage as specified in the notified cGAP, and as the RTIs and PHIs are within  $\pm 25\%$  of the notified cGAP, the trials are considered acceptable to support the notified GAP on head cabbage.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 19 onwards), therefore half of the trials should be decline trials. All of the trials were decline trials, therefore this is sufficient to support the proposed MRL.

As set out in the GB Extrapolation Guidance 2024, head cabbage is a major crop. As 12 trials on head cabbage are available which support the notified cGAP, sufficient data are available to support the notified use on head cabbage.

Sufficient residue trials are available to support the proposed MRL for head cabbage at the notified GAP.

### **0242010 Brussels sprouts**

The authorised critical GAP in the EU on Brussels sprouts is foliar spray application at a rate of 2 x 0.125 kg a.s./ha with an RTI of 10 days, a PHI of 3 days and application at BBCH 12 – 49.

The applicant has submitted 8 outdoor trials on head cabbage in the context of this application undertaken using a SL formulation. All 8 of the trials were undertaken in northern Europe. The trials were conducted with foliar spray applications at 2 x 0.125 – 0.1369 kg a.s./ha, with a 9 – 10 day RTI, a 3/4 day PHI and with the last application at BBCH 48 – 49. The trials are considered acceptable to support the notified GAP on Brussels sprouts.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 19 onwards), therefore half of the trials should be decline trials. All of the trials were decline trials, therefore this is sufficient to support the proposed MRL.

As set out in the GB Extrapolation Guidance 2024, Brussels sprouts are a minor crop. As 8 trials on Brussels sprouts are available which support the notified cGAP, sufficient data are available to support the notified use on Brussels sprouts.

Sufficient residue trials are available to support the proposed MRL for Brussels sprouts at the notified GAP.

### **0243010 Chinese cabbages/pe-tsai**

#### **0243020 Kales**

The authorised critical GAP in the EU on kale and Chinese cabbage is foliar spray application at a rate of 2 x 0.125 kg a.s./ha with an RTI of 10 days, a PHI of 3 days and application at BBCH 12 – 49.

The applicant has submitted 6 outdoor trials on kale in the context of this application undertaken using a SL formulation. All 6 of the trials were undertaken in northern Europe. The trials were conducted with foliar spray applications at 2 x 0.119 – 0.127 kg a.s./ha,

with a 10 – 13 day RTI, a 3 day PHI and with the last application at BBCH 48 – 49. Only one of the 6 trials was carried out using an RTI of 13 days, all other RTIs were within  $\pm 25\%$  of the notified cGAP. The residue data show that it is the second application that drives the residues, and as the residues from the trial using a 13 day RTI are similar or higher than the trials undertaken with a 10 day RTI, the trials are considered acceptable to support the notified cGAP on kale and Chinese cabbage.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 16 onwards), therefore half of the trials should be decline trials. All of the trials were decline trials, therefore this is sufficient to support the proposed MRL.

As set out in the GB Extrapolation Guidance 2024, kale is a minor crop. As 6 trials on kale are available, which can be extrapolated to Chinese cabbage before and after formation of the edible part, sufficient data are available to support the notified use on kale and Chinese cabbage.

Sufficient residue trials are available to support the proposed MRL for kale and, by extrapolation, Chinese cabbage at the notified GAP.

#### **0244000 Kohlrabies**

The authorised critical GAP in the EU on kale is foliar spray application at a rate of 2 x 0.125 kg a.s./ha with an RTI of 10 days, a PHI of 3 days and application at BBCH 12 – 49.

The applicant has submitted 4 outdoor trials on kale in the context of this application undertaken using a SL formulation. All 4 of the trials were undertaken in northern Europe. The trials were conducted with foliar spray applications at 2 x 0.125 kg a.s./ha, with a 10 day RTI, a 3 day PHI and with the last application at BBCH 44 – 49. As all final applications were carried out in the same principal growth stage as specified in the notified cGAP, and as the RTIs and PHIs match the notified cGAP, the trials are considered acceptable to support the notified GAP on kohlrabi.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 19 onwards), therefore half of the trials should be decline trials. All of the trials were decline trials, therefore this is sufficient to support the proposed MRL.

As set out in the GB Extrapolation Guidance 2024, kohlrabi is a minor crop. As 4 trials on kohlrabi are available which support the notified cGAP, sufficient data are available to support the notified use on kohlrabi.

Sufficient residue trials are available to support the proposed MRL for kohlrabi at the notified GAP.

#### **0251020 Lettuces**

The authorised critical GAP in the EU on lettuce is foliar spray application at a rate of 2 x 0.125 kg a.s./ha with an RTI of 10 days, a PHI of 3 days and application at all growth stages.

The applicant has submitted 22 outdoor trials on lettuce in the context of this application undertaken using a SL formulation. Ten of the trials were undertaken in northern Europe and 12 in southern Europe. The trials were conducted with foliar spray applications at 2 x 0.125 kg a.s./ha, with a 9 – 11 day RTI, a 3/4 day PHI and with the last application at BBCH 46 – 49. Normal commercial harvest of lettuce takes place at approximately BBCH 49, therefore as the last application was undertaken at the same principal growth stage and as the PHIs and RTIs used match the notified cGAP, the trials are considered acceptable to support the notified use.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 16 onwards), therefore half of the trials should be decline trials. All of the trials were decline trials, therefore this is sufficient to support the proposed MRL.

As set out in the GB Extrapolation Guidance 2024, lettuce is a major crop. As 22 trials on lettuce are available which support the notified cGAP, sufficient data are available to support the notified use on lettuce.

Sufficient residue trials are available to support the proposed MRL for lettuce at the notified GAP.

**0251000 Lettuces and salad plants (except lettuces (0251020) and escaroles/broad-leaved endives (0251030))**

**0252000 Spinaches and similar leaves**

**0256000 Herbs and edible flowers**

The authorised critical GAP in the EU on leafy vegetables, fresh herbs and edible flowers is foliar spray application at a rate of 2 x 0.125 kg a.s./ha with an RTI of 10 days, a PHI of 3 days and application at all growth stages.

The applicant has submitted 16 outdoor trials on open leaf lettuce varieties in the context of this application undertaken using a SL formulation. Eight of the trials were undertaken in northern Europe and 8 in southern Europe. The trials were conducted with foliar spray applications at 2 x 0.125 kg a.s./ha, with a 9 – 11 day RTI, a 3/4 day PHI and with the last application at BBCH 46 – 49. Normal commercial harvest of lettuce takes place at approximately BBCH 49, therefore as the last application was undertaken at the same principal growth stage and as the PHIs and RTIs used match the notified cGAP, the trials are considered acceptable to support the notified use.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 16 onwards), therefore half of the trials should be decline trials. All of the trials were decline trials, therefore this is sufficient to support the proposed MRL.

As set out in the GB Extrapolation Guidance 2024, lettuce is a major crop. Trials on open leaf varieties of lettuce can be extrapolated to the whole subgroups (a) lettuces and salad plants, (b) spinaches and similar leaves, (d) watercresses, (f) herbs and edible flowers before and after formation of the edible part. As 16 trials on open leaf varieties of lettuce are available, the requirements of the agreed extrapolation have been met and sufficient data are available to support a GB MRL for the notified use on leafy vegetables, fresh herbs and edible flowers.

Sufficient residue trials are available to support the proposed MRL for other lettuce and other salad plants including brassica species, spinach and similar leaves and herbs and edible flowers at the notified GAP.

### **0401070 Soyabeans**

The authorised critical GAP in the USA and Canada on soyabeans is foliar spray application at a rate of 2 x 0.205 kg a.s./ha with an RTI of 10 days, a PHI of 21 days and application at all growth stages.

The applicant has submitted 20 outdoor trials on soyabean in the context of this application undertaken using an SL formulation. Each trial included separate plots which harvested soyabean seed separately to soyabean hay and forage. The trials were conducted with foliar spray applications at 2 x 0.196 – 0.221 kg a.s./ha, with a 7 – 10 day RTI, a 19 – 22 day PHI (a 5/7 day PHI was used for hay and forage) and with the last application at BBCH 79 – 96 (BBCH 16 – 69 for hay and forage). Three of the seed trials and two of the forage/hay trials had an RTI of 7 days, all remaining trials used RTIs within  $\pm 25\%$  of the cGAP. The residues reported from the trials with a 7 day RTI are similar or lower than the residues from trials with an RTI within  $\pm 25\%$  of the cGAP. As this is the case, and that 7 days is only slightly outside  $\pm 25\%$  of the cGAP, the RTIs used are considered acceptable. Normal commercial harvest of soyabean seed takes place at BBCH 99. As a BBCH is not specified in the cGAP, and as the PHI and RTI used in the trials are considered acceptable to support the notified cGAP, this is considered sufficient to support the notified GAP on soyabeans.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 65 onwards), therefore half of the trials should be decline trials. Four of the 20 trials were decline trials, which is sufficient given there is only a requirement to provide a total of 8 trials and hence only 4 of which need to be decline trials.

As set out in the GB Extrapolation Guidance 2024, soyabean is a major crop. As 20 trials on soyabean are available, sufficient data are available to support a GB MRL for the notified use on soyabean.

Sufficient residue trials are available to support the proposed MRL for soyabean at the notified GAP.

#### **0402010 Olives for oil production**

##### **0161030 Table olives**

The authorised critical GAP in the EU on olives is foliar spray application at a rate of 1 x 0.150 kg a.s./ha with a PHI of 14 days and application at BBCH 55 – 85.

The applicant has submitted 8 outdoor trials on olives (for oil production) in the context of this application undertaken using a SL formulation. All of the trials were undertaken in southern Europe. The trials were conducted with foliar spray application at 1 x 0.15 kg a.s./ha, with a 14 day PHI and with the last application at BBCH 79 – 88. As the application was undertaken at the same or very close to the principal growth stage specified in the notified cGAP, and as the PHIs used match the notified cGAP, the trials are considered acceptable to support the notified use.

The submitted trials are conducted with applications after the formation of the edible part (BBCH 65 onwards), therefore half of the trials should be decline trials. All of the trials were decline trials, therefore this is sufficient to support the proposed MRL.

As set out in the GB Extrapolation Guidance 2024, olives are a major crop in the EU. As 8 trials on olives for oil production are available, which can be extrapolated to table olives before and after the edible part, sufficient data are available to support the notified use on olives.

As olives are a tall crop, residues may be driven by spray concentration due to direct application to the plant and the fact that the spray is often applied to run off. The notified GAP on olives includes a water volume of 500 – 1200 L/ha, resulting in a range of spray concentrations of 0.0125 – 0.03 kg a.s./hL. The spray concentrations used in the trials ranged from 0.0136 – 0.023 kg a.s./hL, with the highest spray concentration being within 25% of the critical spray concentration. Therefore the spray concentrations used cover the range stated in the notified GAP. Therefore, the trials are considered sufficient to support the notified GAP.

Sufficient residue trials are available to support the proposed MRL IT for olives at the authorised GAP.

It should be noted that the JMPR adopted flupyradifurone CXLs for table olives and olives for oil production in 2025 which were adopted as GB MRLs in February 2026 (HSE, 2026).

JMPR data on DFA were considered by HSE in order to set GB MRLs linked to the flupyradifurone CXLs. The notified use on table olives and olives for oil production is covered by the adopted CXLs, for both flupyradifurone and DFA.

### Analytical methods

Analysis for residues of flupyradifurone and DFA in strawberries, cauliflower, broccoli, head cabbage, Brussels sprouts, kale, kohlrabi, lettuce, and olives was using the HPLC-MS/MS method 01212. Analysis for residues of flupyradifurone and DFA in strawberries, potatoes, cauliflower, broccoli, head cabbage, Brussels sprouts, kale, kohlrabi, lettuce, soyabean, and olives was using HPLC-MS/MS method 01304 (also referred to as RV-001-P10-02).

The analytical method 01212 was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR, NL, 2015). The analytical method 01304 (also called Method RV-001-P10-02) was satisfactorily validated during active approval on high water (forage), high protein (dried beans), high acid (orange), high oil (soyabean seed) and high starch (wheat grain) commodities (DAR, NL, 2015).

Extraction efficiency was satisfactorily addressed for the method. Sufficient procedural recoveries were obtained in the trials, therefore the methods are considered suitably validated for strawberries, potatoes, cauliflower, broccoli, head cabbage, Brussels sprouts, kale, kohlrabi, lettuce, soyabeans and olives.

### Storage stability

A summary of the available storage stability data for flupyradifurone and its metabolite DFA from the approval of the active substance (EFSA, 2015) as well as data previously submitted and evaluated (HSE, 2025a).

**Table 3.2-1 Summary of the available storage stability data**

| Commodity group    | Reference  | Commodity  | T (°C) | Stability (months) |     |
|--------------------|------------|------------|--------|--------------------|-----|
|                    |            |            |        | Flupyradifurone    | DFA |
| High water content | EFSA, 2015 | Spinach    | -20    | 18                 | 18  |
|                    |            | Sugar cane | -20    | 18                 | 18  |
|                    |            | Tomato     | -20    | 18                 | 18  |



|                      |            |               |     |    |         |
|----------------------|------------|---------------|-----|----|---------|
|                      | HSE, 2025a | Sugar cane    | -21 | 52 | 52      |
|                      |            | Tomato fruit  | -21 | 52 | 52      |
|                      |            | Spinach       | -21 | 52 | 52      |
| High oil content     | EFSA, 2015 | Soyabean seed | -20 | 18 | 18      |
|                      |            | Coffee bean   | -20 | 18 | 18      |
|                      | HSE, 2025a | Soyabean seed | -21 | 52 | 35      |
|                      |            | Coffee bean   | -21 | 52 | 52      |
| High acid content    | EFSA, 2015 | Orange        | -20 | 18 | 18      |
|                      | HSE, 2025a | Orange        | -21 | 52 | 52      |
| High starch content  | EFSA, 2015 | Wheat grain   | -20 | 18 | 18      |
|                      | HSE, 2025a | Wheat grain   | -21 | 52 | 52      |
| High protein content | EFSA, 2015 | Bean seed     | -20 | 18 | 18      |
|                      | HSE, 2025a | Navy bean     | -21 | 52 | 52      |
| Animal matrices      | EFSA, 2015 | Bovine fat    | -20 | -  | 43 days |
|                      |            | Bovine kidney | -20 | -  | 43 days |
|                      |            | Bovine muscle | -20 | -  | 43 days |
|                      |            | Bovine liver  | -20 | -  | 43 days |

The stability of flupyradifurone during storage has been demonstrated in high water (spinach, sugar cane, tomato), high oil (soyabean seed, coffee bean), high acid (orange), high starch (wheat grain) and high protein (bean seed) for a period of 52 months when stored at  $\leq -21^{\circ}\text{C}$ .

The stability of metabolite DFA has been demonstrated in high water (spinach, sugar cane, tomato), high acid (orange), high starch (wheat grain) and high protein (bean seed) for a period of 52 months and in high oil for a period of 35 months when stored at  $\leq -20^{\circ}\text{C}$ .

The maximum frozen storage periods for flupyradifurone and its metabolite DFA in the residues trials are tabulated below and compared to the respective demonstrated periods of storage stability.

| Residue trial commodity | Maximum frozen storage period in trials for flupyradifurone and DFA (days) | Relevant storage data available on: | Demonstrated frozen storage stability (months) |     |
|-------------------------|----------------------------------------------------------------------------|-------------------------------------|------------------------------------------------|-----|
|                         |                                                                            |                                     | Flupyradifurone                                | DFA |
| Strawberry              | 396 (~13 months)                                                           | Orange                              | 52                                             | 52  |
| Potato                  | 263 (~8.5 months)                                                          | Wheat grain                         | 52                                             | 52  |
| Cauliflower & broccoli  | 446 (~14.5 months)                                                         | Sugar cane, tomato fruit, spinach   | 52                                             | 52  |
| Head cabbage            | 502 (~16.5 months)                                                         |                                     | 52                                             | 52  |
| Brussels sprouts        | 330 (~11 months)                                                           |                                     | 52                                             | 52  |
| Kale                    | 346 (~11.5 months)                                                         |                                     | 52                                             | 52  |
| Kohlrabi                | 376 (~12.5 months)                                                         |                                     | 52                                             | 52  |
| Lettuce                 | 236 (~8 months)                                                            |                                     | 52                                             | 52  |
| Soyabean                | 254 (~8.5 months)                                                          | Soyabean seed                       | 52                                             | 35  |

|        |                    |  |    |    |
|--------|--------------------|--|----|----|
| Olives | 379 (~12.5 months) |  | 52 | 35 |
|--------|--------------------|--|----|----|

Samples from residue trials were stored for a maximum of 396 days for strawberry, 263 days for potato, 446 days for cauliflower and broccoli, 502 days for head cabbage, 330 days for Brussels sprouts, 346 days for kale, 376 days for kohlrabi, 236 days for lettuce, 254 days for soyabean and 379 days for olives.

Therefore, sufficient data are available to support the storage stability of flupyradifurone and the metabolite DFA in strawberries (high acid content), potatoes, root and tuber vegetables (high starch content), flowering and head brassicas, Brussels sprouts, kale, kohlrabi, leafy vegetables and herbs (high water content), soyabean and olives (high oil content).

**Table 3.2 Overview of the available residue trials data**

**RD-RA: Sum of flupyradifurone and DFA, expressed as flupyradifurone**

**RD-Enf 1: Flupyradifurone**

**RD-Enf 2: DFA**

| <b>Commodity</b> | <b>Region/<br/>Indoor<br/>(a)</b>        | <b>Residue levels (mg/kg)<br/>observed in the trials<br/>representative for the<br/>intended GAPs<br/>(b)</b>                                                                                                                      | <b>Recommendations/<br/>comments<br/>(OECD calculations)</b>                                    | <b>MRL<br/>proposals<br/>(mg/kg)</b>                      | <b>HR<br/>(mg/kg)<br/>(c)</b>                                                      | <b>STMR<br/>(mg/kg)<br/>(d)</b>                                                     |
|------------------|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Strawberries     | EU/<br>Protected<br>2 x 125 g<br>a.s./ha | <b>RD-Enf 1):</b> 0.018, 0.046,<br>0.079, 0.094, 0.16, 0.17,<br>0.19, 0.20<br><br><b>RD-Enf 2):</b> 2 x <0.007,<br>0.010, 0.012, 0.014, 2 x<br>0.015, 0.018<br><br><b>RD-RA:</b> 0.038, 0.066, 0.10,<br>0.11, 2 x 0.19, 0.21, 0.22 | RD-Enf 1)<br>MRL <sub>OECD</sub> =0.397/0.4<br><br>RD-Enf 2)<br>MRL <sub>OECD</sub> =0.031/0.03 | <b>RD-Enf 1):</b><br>0.4<br><br><b>RD-Enf 2):</b><br>0.03 | <b>RD-Enf 1):</b> 0.20<br><br><b>RD-Enf 2):</b> 0.018<br><br><b>RD-RA:</b><br>0.22 | <b>RD-Enf 1):</b> 0.127<br><br><b>RD-Enf 2):</b> 0.013<br><br><b>RD-RA:</b><br>0.15 |
|                  | EU/<br>Protected<br>1 x 125 g<br>a.s./ha | <b>RD-Enf 1):</b> 0.047, 0.084,<br>0.088, 2 x 0.16, 0.19, 0.23,<br>0.35<br><br><b>RD-Enf 2):</b> 2 x <0.007,<br>0.008, 0.009, 0.013, 0.014,<br>0.023, 0.030                                                                        | RD-Enf 1)<br>MRL <sub>OECD</sub> =0.551/0.6<br><br>RD-Enf 2)<br>MRL <sub>OECD</sub> =0.048/0.05 | <b>RD-Enf 1):</b><br>0.6<br><br><b>RD-Enf 2):</b><br>0.05 | <b>RD-Enf 1):</b> 0.35<br><br><b>RD-Enf 2):</b> 0.03                               | <b>RD-Enf 1):</b> 0.16<br><br><b>RD-Enf 2):</b> 0.011                               |

| Commodity                                           | Region/<br>Indoor<br>(a)                             | Residue levels (mg/kg)<br>observed in the trials<br>representative for the<br>intended GAPs<br>(b)                                                                                                                                                         | Recommendations/<br>comments<br>(OECD calculations)                                                                                                        | MRL<br>proposals<br>(mg/kg)                                | HR<br>(mg/kg)<br>(c)                                                                      | STMR<br>(mg/kg)<br>(d)                                                                      |
|-----------------------------------------------------|------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|-------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
|                                                     |                                                      | <b>RD-RA:</b> 0.067, 0.10, 0.11, 2<br>x 0.18, 0.21, 0.25, 0.37                                                                                                                                                                                             |                                                                                                                                                            |                                                            | <b>RD-RA:</b><br>0.37                                                                     | <b>RD-RA:</b><br>0.18                                                                       |
| Strawberries                                        | CXL<br>2 x 205 g<br>a.s./ha, 10 day<br>RI, 0 day PHI | <b>RD-Enf 1):</b> 0.23, 0.33, 2 x<br>0.38, 0.43, 0.51, 2 x 0.54,<br>0.58, 0.62<br><br><b>RD-Enf 2):</b> 3 x <0.017,<br>0.018, 0.022, 0.028, 0.037,<br>0.050, 0.053, 0.29<br><br><b>RD-RA:</b> 0.33, 0.38, 2 x 0.43,<br>0.48, 0.57, 2 x 0.59, 0.63,<br>0.90 | RD-Enf 1)<br>MRL <sub>OECD</sub> =1.362/1.5<br><br>RD-Enf 2)<br>MRL <sub>OECD</sub> =0.390/0.4                                                             | <b>RD-Enf 1):</b><br>1.5<br><br><b>RD-Enf 2):</b><br>0.4   | <b>RD-Enf<br/>1):</b> 0.62<br><br><b>RD-Enf<br/>2):</b> 0.29<br><br><b>RD-RA:</b><br>0.94 | <b>RD-Enf<br/>1):</b> 0.47<br><br><b>RD-Enf<br/>2):</b> 0.025<br><br><b>RD-RA:</b><br>0.525 |
| Potatoes →<br>tropical root and<br>tuber vegetables | USA &<br>Canada/<br>Outdoor                          | <b>RD-Enf 1):</b> 4 x <0.01 <sup>†</sup> , 9 x<br><0.01, 0.012 <sup>†</sup> , 2 x 0.020,<br>0.022, 0.024 <sup>†</sup> , 0.037<br><br><b>RD-Enf 2):</b> 5 x <0.017 <sup>†</sup> , 11 x<br><0.017, 0.023 <sup>†</sup> , 0.024, 0.029                         | Trials on potatoes<br>extrapolated to the whole<br>subgroup (b) tropical root and<br>tuber vegetables.<br><br>RD-Enf 1)<br>MRL <sub>OECD</sub> =0.043/0.05 | <b>RD-Enf 1):</b><br>0.05<br><br><b>RD-Enf 2):</b><br>0.04 | <b>RD-Enf<br/>1):</b> 0.037<br><br><b>RD-Enf<br/>2):</b> 0.029                            | <b>RD-Enf<br/>1):</b> 0.01<br><br><b>RD-Enf<br/>2):</b> 0.017                               |

| <b>Commodity</b>                                                             | <b>Region/<br/>Indoor<br/>(a)</b>                    | <b>Residue levels (mg/kg)<br/>observed in the trials<br/>representative for the<br/>intended GAPs<br/>(b)</b>                                                                                                                           | <b>Recommendations/<br/>comments<br/>(OECD calculations)</b>                                            | <b>MRL<br/>proposals<br/>(mg/kg)</b>                       | <b>HR<br/>(mg/kg)<br/>(c)</b>                                                       | <b>STMR<br/>(mg/kg)<br/>(d)</b>                                                     |
|------------------------------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
|                                                                              |                                                      | <b>RD-RA:</b> 3 x <0.06 <sup>†</sup> , 7 x <0.06, 0.062 <sup>†</sup> , 2 x 0.070, 0.072, 0.074 <sup>†</sup> , 0.079 <sup>†</sup> , 0.080, 0.087, 0.096                                                                                  | RD-Enf 2)<br>MRL <sub>OECD</sub> =0.032/0.04                                                            |                                                            | <b>RD-RA:</b><br>0.096                                                              | <b>RD-RA:</b><br>0.06                                                               |
| Potatoes                                                                     | CXL<br>2 x 205 g<br>a.s./ha, 7 day<br>RTI, 7 day PHI | <b>RD-Enf 1):</b> 12 x <0.01, 2 x 0.010, 0.012, 2 x 0.020, 0.022, 2 x 0.037<br><br><b>RD-Enf 2):</b> 17 x <0.017, 2 x 0.023, 0.029<br><br><b>RD-RA:</b> 9 x <0.01, 0.060, 0.062, 2 x 0.070, 0.071, 0.072, 0.080, 0.088, 0.096, 2 x 0.12 | RD-Enf 1)<br>MRL <sub>OECD</sub> =0.049/0.05<br><br>RD-Enf 2)<br>MRL <sub>OECD</sub> =0.031/0.03        | <b>RD-Enf 1):</b><br>0.05<br><br><b>RD-Enf 2):</b><br>0.03 | <b>RD-Enf 1):</b> 0.037<br><br><b>RD-Enf 2):</b> 0.029<br><br><b>RD-RA:</b><br>0.14 | <b>RD-Enf 1):</b> 0.01<br><br><b>RD-Enf 2):</b> 0.017<br><br><b>RD-RA:</b><br>0.061 |
| Cauliflower and<br>broccoli →<br>whole subgroup<br>(a) flowering<br>brassica | Northern<br>Europe/<br>Outdoor                       | <b>RD-Enf 1):</b><br>Cauliflower: 0.04, 0.071, 0.15, 0.19<br>Broccoli: 0.11, 0.13, 0.18, 0.22                                                                                                                                           | Trials on cauliflower and<br>broccoli extrapolated to the<br>whole subgroup (a) flowering<br>brassicas. | <b>RD-Enf 1):</b><br>0.4<br><br><b>RD-Enf 2):</b><br>0.5   | <b>RD-Enf 1):</b> 0.22<br><br><b>RD-Enf 2):</b> 0.27                                | <b>RD-Enf 1):</b> 0.14<br><br><b>RD-Enf 2):</b> 0.04                                |

| Commodity | Region/<br>Indoor<br>(a)    | Residue levels (mg/kg)<br>observed in the trials<br>representative for the<br>intended GAPs<br>(b)                                                                                                     | Recommendations/<br>comments<br>(OECD calculations)                                                                                                                                                                                                                                 | MRL<br>proposals<br>(mg/kg)                              | HR<br>(mg/kg)<br>(c)                                                            | STMR<br>(mg/kg)<br>(d)                                                            |
|-----------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
|           |                             | <b>RD-Enf 2):</b><br>Cauliflower: 0.015, 0.021, 0.030, 0.037<br>Broccoli: 0.043, 0.057, 0.11, 0.27<br><br><b>RD-RA:</b><br>Cauliflower: 0.102, 0.12, 0.173, 0.28,<br>Broccoli: 0.26, 0.30, 0.47, 0.824 | Northern and southern Europe data similar (U-test, 5%) but result in MRL proposals outside neighbouring classes. The flupyradifurone MRL based on the southern Europe data and the DFA MRL based on the northern Europe data are used in line with the exporting jurisdiction (EU). |                                                          | <b>RD-RA:</b><br>0.824                                                          | <b>RD-RA:</b><br>0.27                                                             |
|           | Southern Europe/<br>Outdoor | <b>RD-Enf 1):</b><br>Cauliflower: 0.015, 0.018, 0.019, 0.052<br>Broccoli: 0.19, 0.23, 0.26, 0.27<br><br><b>RD-Enf 2):</b><br>Cauliflower: 0.018, 2 x 0.024, 0.032                                      |                                                                                                                                                                                                                                                                                     | <b>RD-Enf 1):</b><br>0.6<br><br><b>RD-Enf 2):</b><br>0.2 | <b>RD-Enf 1):</b> 0.27<br><br><b>RD-Enf 2):</b> 0.093<br><br><b>RD-RA:</b> 0.47 | <b>RD-Enf 1):</b> 0.121<br><br><b>RD-Enf 2):</b> 0.032<br><br><b>RD-RA:</b> 0.172 |

| <b>Commodity</b> | <b>Region/<br/>Indoor<br/>(a)</b>                   | <b>Residue levels (mg/kg)<br/>observed in the trials<br/>representative for the<br/>intended GAPs<br/>(b)</b>                                                                  | <b>Recommendations/<br/>comments<br/>(OECD calculations)</b>                                 | <b>MRL<br/>proposals<br/>(mg/kg)</b>                     | <b>HR<br/>(mg/kg)<br/>(c)</b>                                                    | <b>STMR<br/>(mg/kg)<br/>(d)</b>                                                     |
|------------------|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
|                  |                                                     | Broccoli: 0.031, 0.090, 2 x 0.093<br><br><b>RD-RA:</b><br>Cauliflower: 0.063, 0.083, 0.09, 0.11<br>Broccoli: 0.234, 0.36, 0.38, 0.47                                           |                                                                                              |                                                          |                                                                                  |                                                                                     |
| Cauliflower      | CXL<br>2 x 205 g<br>a.s./ha, 7day<br>RTI, 1 day PHI | <b>RD-Enf 1):</b> 0.022, 0.032, 0.087, 0.11, 2.1, 2.4<br><br><b>RD-Enf 2):</b> <0.017, 0.024, 0.027, 0.031, 0.062, 0.108<br><br><b>RD-RA:</b> 0.11, 0.20, 0.26, 0.46, 2.2, 2.5 | RD-Enf 1)<br>MRL <sub>OECD</sub> =5.328/6<br><br>RD-Enf 2)<br>MRL <sub>OECD</sub> =0.183/0.2 | <b>RD-Enf 1):</b><br>6.0<br><br><b>RD-Enf 2):</b><br>0.2 | <b>RD-Enf 1):</b> 2.4<br><br><b>RD-Enf 2):</b> 0.108<br><br><b>RD-RA:</b><br>2.6 | <b>RD-Enf 1):</b> 0.099<br><br><b>RD-Enf 2):</b> 0.029<br><br><b>RD-RA:</b><br>0.36 |
| Head cabbage     | Northern<br>Europe/<br>Outdoor                      | <b>RD-Enf 1):</b> <0.01, 0.011, 0.012, 3 x 0.020, 0.054, 0.070                                                                                                                 | Northern and southern Europe data similar (U-test, 5%) but result in MRL proposals outside   | <b>RD-Enf 1):</b><br>0.15                                | <b>RD-Enf 1):</b> 0.07                                                           | <b>RD-Enf 1):</b> 0.02                                                              |



| <b>Commodity</b> | <b>Region/<br/>Indoor<br/>(a)</b>                   | <b>Residue levels (mg/kg)<br/>observed in the trials<br/>representative for the<br/>intended GAPs<br/>(b)</b>                                                       | <b>Recommendations/<br/>comments<br/>(OECD calculations)</b>                                                            | <b>MRL<br/>proposals<br/>(mg/kg)</b>                     | <b>HR<br/>(mg/kg)<br/>(c)</b>                                                      | <b>STMR<br/>(mg/kg)<br/>(d)</b>                                                      |
|------------------|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
|                  |                                                     | <b>RD-Enf 2):</b> <0.007, 2 x<br>0.020, 0.027, 0.030, 0.050,<br>0.087, 0.093<br><br><b>RD-RA:</b> 2 x 0.070, 0.090,<br>0.10, 0.107, 0.16, 0.27, 0.29                | neighbouring classes. The MRLs based on the southern Europe data are used in line with the exporting jurisdiction (EU). | <b>RD-Enf 2):</b><br>0.2                                 | <b>RD-Enf 2):</b> 0.093<br><br><b>RD-RA:</b><br>0.29                               | <b>RD-Enf 2):</b> 0.029<br><br><b>RD-RA:</b><br>0.104                                |
|                  | Southern Europe/<br>Outdoor                         | <b>RD-Enf 1):</b> 0.030, 0.049,<br>0.059, 0.13<br><br><b>RD-Enf 2):</b> 0.032, 0.040,<br>0.053, 0.087<br><br><b>RD-RA:</b> 0.107, 0.143, 2 x<br>0.27                |                                                                                                                         | <b>RD-Enf 1):</b><br>0.3<br><br><b>RD-Enf 2):</b><br>0.2 | <b>RD-Enf 1):</b> 0.13<br><br><b>RD-Enf 2):</b> 0.087<br><br><b>RD-RA:</b><br>0.27 | <b>RD-Enf 1):</b> 0.054<br><br><b>RD-Enf 2):</b> 0.047<br><br><b>RD-RA:</b><br>0.207 |
| Head cabbage     | CXL<br>2 x 205 g<br>a.s./ha, 7day<br>RTI, 1 day PHI | <b>RD-Enf 1):</b> 0.11, 0.12, 0.32,<br>0.33, 0.38, 0.45, 0.69, 0.82,<br>0.83<br><br><b>RD-Enf 2):</b> 0.027, 2 x 0.037,<br>0.043, 0.083, 0.097, 0.12,<br>0.13, 0.18 | <b>RD-Enf 1)</b><br>MRL <sub>OECD</sub> =1.545/1.5<br><br><b>RD-Enf 2)</b><br>MRL <sub>OECD</sub> =0.293/0.3            | <b>RD-Enf 1):</b><br>1.5<br><br><b>RD-Enf 2):</b><br>0.3 | <b>RD-Enf 1):</b> 0.83<br><br><b>RD-Enf 2):</b> 0.177                              | <b>RD-Enf 1):</b> 0.38<br><br><b>RD-Enf 2):</b> 0.083                                |

| <b>Commodity</b>                       | <b>Region/<br/>Indoor<br/>(a)</b> | <b>Residue levels (mg/kg)<br/>observed in the trials<br/>representative for the<br/>intended GAPs<br/>(b)</b>                                                                                                                        | <b>Recommendations/<br/>comments<br/>(OECD calculations)</b>          | <b>MRL<br/>proposals<br/>(mg/kg)</b>                      | <b>HR<br/>(mg/kg)<br/>(c)</b>                                                      | <b>STMR<br/>(mg/kg)<br/>(d)</b>                                                     |
|----------------------------------------|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
|                                        |                                   | <b>RD-RA:</b> 0.20, 0.24, 0.44,<br>0.60, 0.67, 0.79, 0.93, 1.0,<br>1.1                                                                                                                                                               |                                                                       |                                                           | <b>RD-RA:</b><br>1.3                                                               | <b>RD-RA:</b><br>0.67                                                               |
| Brussels sprouts                       | Europe/<br>Outdoor                | <b>RD-Enf 1):</b> 0.010, 0.015,<br>0.020, 0.022, 0.032, 2 x<br>0.040, 0.055<br><br><b>RD-Enf 2):</b> 0.020, 2 x 0.027,<br>0.037, 0.060, 0.080, 0.083,<br>0.10<br><br><b>RD-RA:</b> 2 x 0.090, 0.091,<br>0.13, 0.19, 0.25, 0.28, 0.31 | RD-Enf 1)<br>MRLOECD=0.090/0.09<br><br>RD-Enf 2)<br>MRLOECD=0.177/0.2 | <b>RD-Enf 1):</b><br>0.09<br><br><b>RD-Enf 2):</b><br>0.2 | <b>RD-Enf 1):</b> 0.055<br><br><b>RD-Enf 2):</b> 0.10<br><br><b>RD-RA:</b><br>0.31 | <b>RD-Enf 1):</b> 0.027<br><br><b>RD-Enf 2):</b> 0.049<br><br><b>RD-RA:</b><br>0.16 |
| Kale → Chinese<br>cabbages/pe-<br>tsai | Europe/<br>Outdoor                | <b>RD-Enf 1):</b> 0.09, 0.22, 0.76,<br>0.87, 1.1, 1.9<br><br><b>RD-Enf 2):</b> 0.057, 0.11,<br>0.137, 0.150, 0.20, 0.30                                                                                                              | RD-Enf 1)<br>MRLOECD=3.442/4.0<br><br>RD-Enf 2)<br>MRLOECD=0.493/0.5  | <b>RD-Enf 1):</b><br>4<br><br><b>RD-Enf 2):</b><br>0.5    | <b>RD-Enf 1):</b> 1.9<br><br><b>RD-Enf 2):</b> 0.30                                | <b>RD-Enf 1):</b> 0.815<br><br><b>RD-Enf 2):</b> 0.144                              |

| Commodity | Region/<br>Indoor<br>(a)       | Residue levels (mg/kg)<br>observed in the trials<br>representative for the<br>intended GAPs<br>(b)                                                                                                                                                                 | Recommendations/<br>comments<br>(OECD calculations)                                                                                                                                                                                                                                                               | MRL<br>proposals<br>(mg/kg)                               | HR<br>(mg/kg)<br>(c)                                                               | STMR<br>(mg/kg)<br>(d)                                                             |
|-----------|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
|           |                                | <b>RD-RA:</b> 0.20, 0.54, 1.15,<br>1.35, 1.50, 2.24                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                   |                                                           | <b>RD-RA:</b><br>2.24                                                              | <b>RD-RA:</b><br>1.25                                                              |
| Kohlrabi  | Europe/<br>Outdoor             | <b>RD-Enf 1):</b> 0.020, 0.026,<br>0.030, 0.041<br><br><b>RD-Enf 2):</b> 0.043, 0.050,<br>0.070, 0.080<br><br><b>RD-RA:</b> 0.15, 0.16, 0.22,<br>0.25                                                                                                              | RD-Enf 1)<br>MRL <sub>OECD</sub> =3.442/4.0<br><br>RD-Enf 2)<br>MRL <sub>OECD</sub> =0.493/0.5                                                                                                                                                                                                                    | <b>RD-Enf 1):</b><br>0.09<br><br><b>RD-Enf 2):</b><br>0.2 | <b>RD-Enf 1):</b> 0.041<br><br><b>RD-Enf 2):</b> 0.08<br><br><b>RD-RA:</b><br>0.25 | <b>RD-Enf 1):</b> 0.028<br><br><b>RD-Enf 2):</b> 0.06<br><br><b>RD-RA:</b><br>0.19 |
| Lettuce   | Northern<br>Europe/<br>Outdoor | <b>RD-Enf 1):</b> 0.11, 0.37, 0.43,<br>0.58, 0.66, 0.68, 0.83, 1.0,<br>1.1, 1.5, 2.9<br><br><b>RD-Enf 2):</b> 5 x <0.007, 2 x<br>0.009, 2 x 0.010, 0.033,<br>0.067<br><br><b>RD-RA:</b> 0.13, 0.39, 0.458,<br>0.60, 0.68, 0.70, 0.85, 1.02,<br>1.137, 1.523, 2.996 | Northern and southern<br>Europe data similar (U-test,<br>5%) but result in MRL<br>proposals outside<br>neighbouring classes. The<br>flupyradifurone MRL based on<br>the southern Europe data and<br>the DFA MRL based on the<br>northern Europe data are<br>used in line with the exporting<br>jurisdiction (EU). | <b>RD-Enf 1):</b><br>4.0<br><br><b>RD-Enf 2):</b><br>0.09 | <b>RD-Enf 1):</b> 2.9<br><br><b>RD-Enf 2):</b> 0.067<br><br><b>RD-RA:</b><br>2.996 | <b>RD-Enf 1):</b> 0.68<br><br><b>RD-Enf 2):</b> 0.009<br><br><b>RD-RA:</b><br>0.70 |

| <b>Commodity</b>                                                                                                                            | <b>Region/<br/>Indoor<br/>(a)</b> | <b>Residue levels (mg/kg)<br/>observed in the trials<br/>representative for the<br/>intended GAPs<br/>(b)</b>                                                                                                                                                                         | <b>Recommendations/<br/>comments<br/>(OECD calculations)</b>                                                                                                                                                                             | <b>MRL<br/>proposals<br/>(mg/kg)</b>                      | <b>HR<br/>(mg/kg)<br/>(c)</b>                                                            | <b>STMR<br/>(mg/kg)<br/>(d)</b>                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
|                                                                                                                                             | Southern<br>Europe/<br>Outdoor    | <b>RD-Enf 1):</b> 0.35, 0.40, 0.48,<br>0.60, 0.72, 1.1, 1.3, 1.5, 2.1,<br>2.7, 3.1<br><br><b>RD-Enf 2):</b> 2 x 0.007, 0.010,<br>2 x 0.013, 0.016, 2 x 0.017,<br>0.025, 0.043, 0.050<br><br><b>RD-RA:</b> 0.38, 0.42, 0.53,<br>0.641, 0.755, 1.12, 1.325,<br>1.577, 2.15, 2.73, 3.813 |                                                                                                                                                                                                                                          | <b>RD-Enf 1):</b><br>6.0<br><br><b>RD-Enf 2):</b><br>0.08 | <b>RD-Enf 1):</b><br>3.1<br><br><b>RD-Enf 2):</b><br>0.05<br><br><b>RD-RA:</b><br>3.813  | <b>RD-Enf 1):</b><br>1.1<br><br><b>RD-Enf 2):</b><br>0.016<br><br><b>RD-RA:</b><br>1.12    |
| Lettuce (open leaf varieties only) → whole subgroups (a) lettuce and salad plants (0251000), (b) spinaches and similar leaves (0252000) and | Northern<br>Europe/<br>Outdoor    | <b>RD-Enf 1):</b> 0.11, 0.43, 0.66,<br>0.83, 1.0, 1.1, 1.5, 2.9<br><br><b>RD-Enf 2):</b> 3 x <0.007, 2 x<br>0.009, 0.010, 0.033, 0.067<br><br><b>RD-RA:</b> 0.13, 0.458, 0.68,<br>0.85, 1.02, 1.137, 1.523,<br>2.996                                                                  | The U-test (5%) shows that the northern and southern Europe datasets are similar and the proposed MRLs for both flupyradifurone and DFA are either identical or in neighbouring MRL classes. Therefore, the datasets have been combined. | <b>RD-Enf 1):</b><br>5.0<br><br><b>RD-Enf 2):</b><br>0.1  | <b>RD-Enf 1):</b><br>2.9<br><br><b>RD-Enf 2):</b><br>0.067<br><br><b>RD-RA:</b><br>2.996 | <b>RD-Enf 1):</b><br>0.915<br><br><b>RD-Enf 2):</b><br>0.009<br><br><b>RD-RA:</b><br>0.935 |

| <b>Commodity</b>                             | <b>Region/<br/>Indoor<br/>(a)</b> | <b>Residue levels (mg/kg)<br/>observed in the trials<br/>representative for the<br/>intended GAPs<br/>(b)</b>                                                                                                                    | <b>Recommendations/<br/>comments<br/>(OECD calculations)</b>                                                                                                       | <b>MRL<br/>proposals<br/>(mg/kg)</b>                      | <b>HR<br/>(mg/kg)<br/>(c)</b>                                                             | <b>STMR<br/>(mg/kg)<br/>(d)</b>                                                            |
|----------------------------------------------|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|-------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| (f) herbs and<br>edible flowers<br>(0256000) |                                   |                                                                                                                                                                                                                                  | Combined:<br>RD-Enf 1)<br>MRL <sub>OECD</sub> =4.644/5.0<br><br>RD-Enf 2)<br>MRL <sub>OECD</sub> =0.104/0.1<br><br>RD-RA HR: 3.813 mg/kg<br>RD-RA STMR: 1.07 mg/kg |                                                           |                                                                                           |                                                                                            |
|                                              | Southern<br>Europe/<br>Outdoor    | <b>RD-Enf 1):</b> 0.35, 0.60, 0.72,<br>1.1, 1.3, 1.5, 2.1, 3.1<br><br><b>RD-Enf 2):</b> 0.007, 2 x 0.013,<br>0.016, 0.017, 0.025, 0.043,<br>0.050<br><br><b>RD-RA:</b> 0.38, 0.641, 0.755,<br>1.12, 1.325, 1.577, 2.15,<br>3.813 |                                                                                                                                                                    | <b>RD-Enf 1):</b><br>5.0<br><br><b>RD-Enf 2):</b><br>0.09 | <b>RD-Enf<br/>1):</b> 3.1<br><br><b>RD-Enf<br/>2):</b> 0.05<br><br><b>RD-RA:</b><br>3.813 | <b>RD-Enf<br/>1):</b> 1.2<br><br><b>RD-Enf<br/>2):</b> 0.017<br><br><b>RD-RA:</b><br>1.223 |
| Head lettuce                                 | CXL                               | <b>RD-Enf 1):</b> 0.31, 0.69, 0.76,<br>1.2, 1.3, 1.6, 2.0, 2.3                                                                                                                                                                   | RD-Enf 1)<br>MRL <sub>OECD</sub> =3.986/4                                                                                                                          | <b>RD-Enf 1):</b><br>4.0                                  | <b>RD-Enf<br/>1):</b> 2.3                                                                 | <b>RD-Enf<br/>1):</b> 1.25                                                                 |

| Commodity          | Region/<br>Indoor<br>(a)                      | Residue levels (mg/kg)<br>observed in the trials<br>representative for the<br>intended GAPs<br>(b)                                                                                                                                                                                                                                                                             | Recommendations/<br>comments<br>(OECD calculations)                  | MRL<br>proposals<br>(mg/kg)                              | HR<br>(mg/kg)<br>(c)                                                                       | STMR<br>(mg/kg)<br>(d)                                                                     |
|--------------------|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
|                    | 2 x 205 g<br>a.s./ha, 7 day<br>RTI, 1 day PHI | <b>RD-Enf 2):</b> 3 x <0.017,<br>0.017, 0.031, 0.034, 0.043,<br>0.063<br><br><b>RD-RA:</b> 0.38, 0.77, 0.83,<br>1.2, 1.4, 1.7, 2.1, 2.4                                                                                                                                                                                                                                        | RD-Enf 2)<br>MRLOECD=0.097/0.1                                       | <b>RD-Enf 2):</b><br>0.1                                 | <b>RD-Enf<br/>2):</b> 0.063<br><br><b>RD-RA:</b><br>2.4                                    | <b>RD-Enf<br/>2):</b> 0.024<br><br><b>RD-RA:</b><br>1.3                                    |
| Soyabean<br>(seed) | USA/<br>Outdoor                               | <b>RD-Enf 1):</b> 4 x <0.01, 0.01, 2<br>x 0.015, 0.02, 0.035, 0.055,<br>2 x 0.07, 0.085, 0.155,<br>0.215, 0.255, 0.275, 0.355,<br>0.61, 1.02<br><br><b>RD-Enf 2):</b> 8 x <0.017,<br>0.023, 0.029, 0.03, 2 x<br>0.035, 0.063, 0.087, 0.115,<br>0.124, 0.168, 0.194, 0.539<br><br><b>RD-RA:</b> 4 x <0.06, 0.06, 2 x<br>0.065, 0.07, 0.14, 0.145,<br>0.155, 0.275, 0.32, 0.325, | RD-Enf 1)<br>MRLOECD=1.182/1.5<br><br>RD-Enf 2)<br>MRLOECD=0.564/0.6 | <b>RD-Enf 1):</b><br>1.5<br><br><b>RD-Enf 2):</b><br>0.6 | <b>RD-Enf<br/>1):</b> 1.02<br><br><b>RD-Enf<br/>2):</b> 0.539<br><br><b>RD-RA:</b><br>2.64 | <b>RD-Enf<br/>1):</b> 0.063<br><br><b>RD-Enf<br/>2):</b> 0.03<br><br><b>RD-RA:</b><br>0.15 |

| Commodity      | Region/<br>Indoor<br>(a)                                  | Residue levels (mg/kg)<br>observed in the trials<br>representative for the<br>intended GAPs<br>(b)                                                                                                                                                                                                                                                                                                                      | Recommendations/<br>comments<br>(OECD calculations)                                            | MRL<br>proposals<br>(mg/kg)                              | HR<br>(mg/kg)<br>(c)                                                            | STMR<br>(mg/kg)<br>(d)                                                              |
|----------------|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|----------------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
|                |                                                           | 0.44, 0.535, 0.66, 0.935,<br>0.955, 2.64                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                |                                                          |                                                                                 |                                                                                     |
| Soyabean (dry) | CXL<br>2 x 205 g<br>a.s./ha, 10 day<br>RTI, 21 day<br>PHI | <b>RD-Enf 1):</b> 4 x <0.01, 0.012,<br>2 x 0.015, 0.019, 0.034,<br>0.053, 0.068, 0.069, 0.082,<br>0.15, 0.22, 0.25, 0.28, 0.36,<br>0.61, 1.0<br><br><b>RD-Enf 2):</b> 8 x <0.017,<br>0.023, 0.029, 0.030, 2 x<br>0.035, 0.063, 0.087, 0.115,<br>0.123, 0.168, 0.193, 0.533<br><br><b>RD-RA:</b> <0.06, 0.082, 0.085,<br>0.090, 0.11, 0.13, 0.25, 0.26,<br>0.66, 0.70, 1.2, 1.5, 1.7, 2 x<br>1.8, 2.0, 3.7, 3.9, 4.1, 11 | RD-Enf 1)<br>MR <sub>LOECD</sub> =1.168/1.5<br><br>RD-Enf 2)<br>MR <sub>LOECD</sub> =0.558/0.6 | <b>RD-Enf 1):</b><br>1.5<br><br><b>RD-Enf 2):</b><br>0.6 | <b>RD-Enf 1):</b> 1.0<br><br><b>RD-Enf 2):</b> 0.533<br><br><b>RD-RA:</b><br>11 | <b>RD-Enf 1):</b> 0.061<br><br><b>RD-Enf 2):</b> 0.030<br><br><b>RD-RA:</b><br>0.95 |
| Soyabean (hay) | USA/<br>Outdoor                                           | <b>RD-Enf 1):</b> 1.47, 2.56, 3.91,<br>4.19, 6.22, 6.44, 6.56, 6.59,<br>6.75, 6.90, 8.05, 8.31, 8.495,                                                                                                                                                                                                                                                                                                                  | RD-Enf 1)<br>MR <sub>LOECD</sub> =24.298/30<br><br>RD-Enf 2)                                   | <b>RD-Enf 1):</b><br>-                                   | <b>RD-Enf 1):</b> 17.36                                                         | <b>RD-Enf 1):</b> 7.475                                                             |

| Commodity      | Region/<br>Indoor<br>(a) | Residue levels (mg/kg)<br>observed in the trials<br>representative for the<br>intended GAPs<br>(b)                                                                                                                                                                                                                                                                        | Recommendations/<br>comments<br>(OECD calculations)                                                 | MRL<br>proposals<br>(mg/kg)                                      | HR<br>(mg/kg)<br>(c)                                     | STMR<br>(mg/kg)<br>(d)                                    |
|----------------|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------|
|                |                          | <p>8.54, 9.35, 11.2, 11.65, 12.6, 14.84, 17.36</p> <p><b>RD-Enf 2):</b> 0.344, 0.419, 0.485, 0.54, 0.642, 0.724, 0.932, 1.007, 1.132, 1.30, 1.365, 1.377, 1.43, 1.44, 1.487, 1.722, 1.88, 2.103, 2.22, 2.73</p> <p><b>RD-RA:</b> 3.39, 6.66, 8.39, 9.36, 9.54, 9.76, 10.09, 10.38, 10.45, 10.57, 10.88, 11.36, 11.44, 12.75, 12.86, 13.86, 15.57, 17.86, 19.84, 21.49</p> | MRL <sub>OECD</sub> =3.868/4.0                                                                      | <b>RD-Enf 2):</b><br>-                                           | <b>RD-Enf 2):</b> 2.73<br><br><b>RD-RA:</b> 21.49        | <b>RD-Enf 2):</b> 1.333<br><br><b>RD-RA:</b> 10.725       |
| Soyabean (hay) | CXL                      | <b>RD-Enf 1):</b> 2.1, 4.4, 4.6, 6.2, 7.2, 8.2, 8.6, 8.8, 9.3, 10, 12, 4 x 15, 16, 18, 19, 20, 29                                                                                                                                                                                                                                                                         | <p>RD-Enf 1)<br/>MRL<sub>OECD</sub>=38.193/40</p> <p>RD-Enf 2)<br/>MRL<sub>OECD</sub>=5.412/6.0</p> | <p><b>RD-Enf 1):</b><br/>40</p> <p><b>RD-Enf 2):</b><br/>6.0</p> | <p><b>RD-Enf 1):</b> 29</p> <p><b>RD-Enf 2):</b> 3.3</p> | <p><b>RD-Enf 1):</b> 11</p> <p><b>RD-Enf 2):</b> 1.75</p> |



| Commodity            | Region/<br>Indoor<br>(a) | Residue levels (mg/kg)<br>observed in the trials<br>representative for the<br>intended GAPs<br>(b)                                                                                                                                                                                               | Recommendations/<br>comments<br>(OECD calculations)                                           | MRL<br>proposals<br>(mg/kg)                          | HR<br>(mg/kg)<br>(c)                                                              | STMR<br>(mg/kg)<br>(d)                                                              |
|----------------------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
|                      |                          | <b>RD-Enf 2):</b> 0.43, 0.65, 2 x 0.90, 2 x 1.1, 2 x 1.2, 2 x 1.7, 1.8, 2.2, 2.3, 3 x 2.4, 2.5, 2.6, 2 x 3.3<br><br><b>RD-RA:</b> 4.8, 11, 6 x 13, 14, 15, 16, 18, 21, 2 x 22, 2 x 23, 24, 26, 36                                                                                                |                                                                                               |                                                      | <b>RD-RA:</b><br>15.5                                                             | <b>RD-RA:</b><br>41                                                                 |
| Soyabean<br>(forage) | USA/<br>Outdoor          | <b>RD-Enf 1):</b> 0.94, 1.01, 1.11, 1.95, 2.22, 2.52, 2.78, 2.84, 2.89, 3.02, 3.56, 3.75, 3.90, 4.07, 4.08, 4.26, 4.48, 4.98, 5.30, 6.77<br><br><b>RD-Enf 2):</b> 0.085, 0.18, 0.265, 0.29, 0.292, 0.31, 0.345, 0.38, 0.417, 0.45, 0.484, 2 x 0.495, 0.502, 2 x 0.517, 0.529, 0.553, 0.572, 0.80 | RD-Enf 1)<br>MRL <sub>OECD</sub> =9.965/10<br><br>RD-Enf 2)<br>MRL <sub>OECD</sub> =1.272/1.5 | <b>RD-Enf 1):</b><br>-<br><br><b>RD-Enf 2):</b><br>- | <b>RD-Enf 1):</b> 6.77<br><br><b>RD-Enf 2):</b> 0.80<br><br><b>RD-RA:</b><br>8.25 | <b>RD-Enf 1):</b> 3.29<br><br><b>RD-Enf 2):</b> 0.467<br><br><b>RD-RA:</b><br>4.715 |

| Commodity                                      | Region/<br>Indoor<br>(a)       | Residue levels (mg/kg)<br>observed in the trials<br>representative for the<br>intended GAPs<br>(b)                                                                                                                                                                                                              | Recommendations/<br>comments<br>(OECD calculations)                                            | MRL<br>proposals<br>(mg/kg)                          | HR<br>(mg/kg)<br>(c)                                                      | STMR<br>(mg/kg)<br>(d)                                                     |
|------------------------------------------------|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|------------------------------------------------------|---------------------------------------------------------------------------|----------------------------------------------------------------------------|
|                                                |                                | <b>RD-RA:</b> 1.73, 2.15, 2.46, 3.27, 3.61, 3.82, 4.07, 4.37, 4.39, 4.53, 4.90, 5.02, 5.10, 5.28, 5.33, 5.35, 5.56, 5.65, 5.89, 8.25                                                                                                                                                                            |                                                                                                |                                                      |                                                                           |                                                                            |
| Soyabean<br>(forage)                           | CXL                            | <b>RD-Enf 1):</b> 4.2, 6.1, 6.2, 8.1, 11, 12, 2 x 14, 115, 2 x 16, 2 x 18, 2 x 20, 21, 26, 2 x 29, 34<br><br><b>RD-Enf 2):</b> 0.47, 0.86, 1.2, 2 x 1.6, 2 x 1.7, 3 x 1.8, 2 x 2.3, 3 x 2.5, 2 x 2.6, 3.0, 2 x 3.2<br><br><b>RD-RA:</b> 8.8, 11, 14, 15, 16, 19, 2 x 21, 22, 3 x 23, 3 x 24, 29, 31, 35, 36, 41 | RD-Enf 1)<br>MRL <sub>OECD</sub> =50.640/50<br><br>RD-Enf 2)<br>MRL <sub>OECD</sub> =6.185/7.0 | <b>RD-Enf 1):</b><br>-<br><br><b>RD-Enf 2):</b><br>- | <b>RD-Enf 1):</b> 34<br><br><b>RD-Enf 2):</b> 3.2<br><br><b>RD-RA:</b> 46 | <b>RD-Enf 1):</b> 16<br><br><b>RD-Enf 2):</b> 2.05<br><br><b>RD-RA:</b> 23 |
| Olives for oil<br>production →<br>table olives | Southern<br>Europe/<br>Outdoor | <b>RD-Enf 1):</b> 0.19, 0.25, 0.30, 0.40, 0.49, 0.57, 0.89, 3.2                                                                                                                                                                                                                                                 | RD-Enf 1)<br>MRL <sub>OECD</sub> =4.786/5.0                                                    | <b>RD-Enf 1):</b><br>5.0                             | <b>RD-Enf 1):</b> 3.2                                                     | <b>RD-Enf 1):</b> 0.445                                                    |

| Commodity | Region/<br>Indoor<br>(a) | Residue levels (mg/kg)<br>observed in the trials<br>representative for the<br>intended GAPs<br>(b)                                                     | Recommendations/<br>comments<br>(OECD calculations) | MRL<br>proposals<br>(mg/kg) | HR<br>(mg/kg)<br>(c)                                 | STMR<br>(mg/kg)<br>(d)                                |
|-----------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|-----------------------------|------------------------------------------------------|-------------------------------------------------------|
|           |                          | <b>RD-Enf 2):</b> 0.008, 0.016, 2 x<br>0.019, 2 x 0.025, 0.033,<br>0.057<br><br><b>RD-RA:</b> 0.21, 0.28, 0.34,<br>0.425, 0.556, 0.629, 0.914,<br>3.31 | RD-Enf 2)<br>MRL <sub>OECD</sub> =0.084/0.09        | <b>RD-Enf 2):</b><br>0.09   | <b>RD-Enf 2):</b> 0.057<br><br><b>RD-RA:</b><br>3.31 | <b>RD-Enf 2):</b> 0.022<br><br><b>RD-RA:</b><br>0.491 |

(a) GB or the country for an import tolerance and whether the GAP is for an outdoor use or an indoor/protected/glasshouse use.

(b) Residue levels in trials conducted according to GAPs reported in ascending order. When residue definitions for enforcement and risk assessment differ, **Enf/RA** differentiate data expressed according to the residue definition for **Enforcement** and **Risk Assessment**.

(c) **HR**: Highest residue, according to the residue for risk assessment, (within brackets when expressed according to the residue definition for enforcement: HR<sub>Enf</sub>)

(d) **STMR**: Supervised Trials Median Residue according to the residue definition risk assessment (within brackets when expressed according to the residue definition for enforcement: STMR<sub>Enf</sub>)

† Residue calculated from the mean of two or more replicate trials.

### Further consideration of the MRLs, including the CXLs

The final MRLs recommended for adoption may be based on the IT request or the CXL. In addition, as outlined in section 3.5, residues in rotational crops need to be taken into account in the MRL setting process. Further information on the final MRLs recommended for adoption is outlined in section 3.6.

## 3.3 Conversion factors for risk assessment for products of plant origin

The residue definitions for enforcement (RD-Enf) and risk assessment (RD-RA) are different, however a conversion factor is not required as the RD-RA is the sum of the two separate RD-Enf.

## 3.4 Effect of industrial processing and/or household preparation

### 3.4.1 Nature of the residues in processed commodities

Hydrolysis of flupyradifurone under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was assessed for the approval of the active substance (EFSA, 2015).

A summary of the available hydrolysis data is presented in Table 3.4.1-1.

**Table 3.4.1-1 Overview of the available hydrolysis studies on flupyradifurone**

| Conditions                                                | Flupyradifurone |
|-----------------------------------------------------------|-----------------|
| <b>Pasteurisation</b> (20 minutes, 90°C, pH 4)            | 101.7%          |
| <b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5) | 104.9%          |
| <b>Sterilisation</b> (20 minutes, 120°C, pH 6)            | 97.3%           |

The hydrolysis data demonstrates that flupyradifurone is stable across the standard conditions, therefore specific residue definitions for processed commodities are not required.

Note that no data is available on the stability of major metabolite DFA under processing conditions (EFSA, 2015). However, as concluded during active approval, the structural similarity between DFA and trifluoroacetic acid (TFA), which is very stable under hydrolysis

conditions, suggests that DFA is unlikely to degrade under hydrolysis conditions (DAR, NL, 2015).

### **3.4.2 Magnitude of the residues in processed commodities**

The relevant processed fractions for the notified crops are listed in Table 3.4.2-1. Note that the HR values used in the table below are based on the notified uses, including both primary and rotational residues. Consideration of processing requirements have not been made for the CXLs as these have been adopted as international food standards.

**Table 3.4.2-1 Overview of the requirements for processing studies**

| Commodity                  | Relevant processed fractions                                                                                                                                                                                                                                          | HR (mg/kg)      |                       |                                                              |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------------|--------------------------------------------------------------|
|                            |                                                                                                                                                                                                                                                                       | Flupyradifurone | DFA, expressed as DFA | Sum of flupyradifurone and DFA, expressed as flupyradifurone |
| <b>Strawberries</b>        | Canned (cat. 2), juice (cat. 1), jam/jelly (cat. 2)                                                                                                                                                                                                                   | 0.35            | 0.03                  | 0.37                                                         |
| <b>Olives</b>              | Oil (cat. 1)                                                                                                                                                                                                                                                          | 3.2             | 0.057                 | 3.31                                                         |
| <b>Potatoes</b>            | Peeled (cat. 2), wet peel (cat. 2), boiled (cat. 2), microwaved (cat. 2), baked (cat. 2), fried (cat. 2), crisps (cat. 2), chips (cat. 2), granules/flakes (cat. 2), process waste (cat. 2), ensiled (cat. 1), starch (cat. 1), dried pulp (cat. 2), protein (cat. 1) | 0.037           | 0.029                 | 0.096                                                        |
| <b>Flowering brassicas</b> | Inner and outer leaves (cat. 2), cooked (cat. 2)                                                                                                                                                                                                                      | 0.27            | 0.27                  | 0.824                                                        |
| <b>Brussels sprouts</b>    | Inner and outer leaves (cat. 2), cooked (cat. 2)                                                                                                                                                                                                                      | 0.055           | 0.10                  | 0.31                                                         |
| <b>Head cabbages</b>       | Inner and outer leaves (cat. 2), cooked (cat. 2), sauerkraut (cat. 2), sauerkraut juice (cat. 2)                                                                                                                                                                      | 0.13            | 0.093                 | 0.29                                                         |
| <b>Kales</b>               | Inner and outer leaves (cat. 2), cooked (cat. 2)                                                                                                                                                                                                                      | 1.9             | 0.30                  | 2.24                                                         |

|                                   |                                                                                 |       |       |       |
|-----------------------------------|---------------------------------------------------------------------------------|-------|-------|-------|
| <b>Chinese cabbage</b>            | Inner and outer leaves (cat. 2), cooked (cat. 2)                                | 1.9   | 0.30  | 2.24  |
| <b>Kohlrabies</b>                 | Inner and outer leaves (cat. 2), cooked (cat. 2)                                | 0.041 | 0.08  | 0.25  |
| <b>Spinach and similar leaves</b> | Cooked (cat. 2)                                                                 | 3.1   | 0.067 | 3.813 |
| <b>Herbs and edible flowers</b>   | Dried (cat. 2)                                                                  | 3.1   | 0.067 | 3.813 |
| <b>Soyabeans</b>                  | Flour (cat. 1), milk (cat. 2), tofu (cat. 2), soy sauce (cat. 2), miso (cat. 2) | 1.02  | 0.539 | 2.64  |

### **Strawberries**

Data is available on grape juice and jelly from the active approval which can be extrapolated to strawberry (EFSA, 2015). However, no data is available for canned and jam. These are category 2 processes and not essential for risk assessment. Overall, sufficient processing data is available for the notified use on strawberries.

### **Olives**

A newly submitted study has been evaluated as part of this application which provides data on olive oil. Therefore, sufficient processing data is available for the notified use on olives.

### **Potatoes**

The adoption of the CXL is recommended for potatoes. Sufficient JMPR processing data is available for the processing of potatoes.

### **Flowering brassicas**

No data is available, however the processing procedures for flowering brassicas are category 2 and therefore not essential for risk assessment.

### **Brussels sprouts**

No data is available, however the processing procedures for Brussels sprouts are category 2 and therefore not essential for risk assessment.

### **Head cabbage**

No data is available, however the processing procedures for head cabbage are category 2 and therefore not essential for risk assessment.

### **Kales**

No data is available, however the processing procedures for kales are category 2 and therefore not essential for risk assessment.

### **Chinese cabbage**

No data is available, however the processing procedures for Chinese cabbages are category 2 and therefore not essential for risk assessment.

### **Kohlrabies**

No data is available, however the processing procedures for kohlrabies are category 2 and therefore not essential for risk assessment.

### **Spinach and similar leaves**



No data is available, however the processing procedure for spinach and similar leaves are category 2 and therefore not essential for risk assessment.

### Herbs and edible flowers

No data is available, however the processing procedure for herbs and edible flowers are category 2 and therefore not essential for risk assessment.

### Soyabeans

A newly submitted study has been evaluated as part of this application which provides data on soyabean flour and milk. No data is available for tofu, soy sauce and miso, however these are category 2 processes and are not essential for risk assessment. Therefore, sufficient processing data is available for the notified use on soyabeans.

Processing studies for flupyradifurone were conducted during approval (EFSA, 2015) on lettuce, hops, apples, grapes, tomatoes and cucumbers. Processing studies for flupyradifurone on orange, barley and wheat have been assessed previously in a previous ER/RO (HSE, 2025b). New processing studies for flupyradifurone on olives and soyabeans have been assessed under this application and the relevant processing factors are included in Table 3.4.2-2.

**Table 3.4.2-2 Overview of the available new processing studies**

| Crop (RAC)                | Processed product        | Number of trials | Processing factor (Pf) |                          | CF  |
|---------------------------|--------------------------|------------------|------------------------|--------------------------|-----|
|                           |                          |                  | Individual values      | Median Pf <sup>(a)</sup> |     |
| RD-Enf 1) Flupyradifurone |                          |                  |                        |                          |     |
| Soyabean                  | Aspirated grain fraction | 2                | 15.88, 11.69           | 13.79                    | n/a |
|                           | Meal                     | 2                | 0.85, 1.25             | 1.05                     |     |
|                           | Hulls                    | 2                | 0.78, 1.17             | 0.98                     |     |
|                           | Refined oil              | 2                | <0.01, <0.02           | <0.02                    |     |
|                           | Milk                     | 2                | 0.04, 0.09             | 0.07 <sup>(b)</sup>      |     |
|                           | Defatted flour           | 2                | 1.05, 1.19             | 1.12                     |     |

|                                                                                                   |                               |   |              |                      |     |
|---------------------------------------------------------------------------------------------------|-------------------------------|---|--------------|----------------------|-----|
| Olive                                                                                             | Crude oil                     | 2 | 0.12, 0.13   | 0.13                 | n/a |
|                                                                                                   | Refined oil                   | 2 | <0.03, <0.06 | <0.05 <sup>(b)</sup> |     |
|                                                                                                   | Refined solvent extracted oil | 2 | <0.03, <0.06 | <0.05 <sup>(b)</sup> |     |
| RD-Enf 2)      DFA, expressed as DFA                                                              |                               |   |              |                      |     |
| Soyabean                                                                                          | Aspirated grain fraction      | 2 | 8.18, 4.81   | 6.50                 | n/a |
|                                                                                                   | Meal                          | 2 | 1.19, 1.44   | 1.32                 |     |
|                                                                                                   | Hulls                         | 2 | 1.04, 0.78   | 0.91                 |     |
|                                                                                                   | Refined oil                   | 2 | <0.96, <0.16 | <0.56 <sup>(b)</sup> |     |
|                                                                                                   | Milk                          | 2 | <0.96, <0.16 | <0.56 <sup>(b)</sup> |     |
|                                                                                                   | Defatted flour                | 2 | 1.44, 1.27   | 1.36                 |     |
| Olive                                                                                             | Crude oil                     | 2 | 0.57         | 0.57 <sup>(b)</sup>  | n/a |
|                                                                                                   | Refined oil                   | 2 | 0.57         | 0.57 <sup>(b)</sup>  |     |
|                                                                                                   | Refined solvent extracted oil | 2 | 0.57         | 0.57 <sup>(b)</sup>  |     |
| RD-RA:      Sum of flupyra-      difurone      and DFA,      expressed      as<br>flupyradifurone |                               |   |              |                      |     |
| Soyabean                                                                                          | Aspirated grain fraction      | 2 | 15.34, 8.77  | 12.06                | n/a |
|                                                                                                   | Meal                          | 2 | 0.88, 1.34   | 1.11                 |     |
|                                                                                                   | Hulls                         | 2 | 0.80, 1.01   | 0.91                 |     |
|                                                                                                   | Refined oil                   | 2 | <0.08, <0.08 | <0.08                |     |

|              |                               |   |              |                      |     |
|--------------|-------------------------------|---|--------------|----------------------|-----|
|              | Milk                          | 2 | 0.11, 0.12   | 0.12                 |     |
|              | Defatted flour                | 2 | 1.07, 1.23   | 1.15                 |     |
| <b>Olive</b> | Crude oil                     | 2 | 0.15, 0.22   | 0.19                 | n/a |
|              | Refined oil                   | 2 | <0.07, <0.15 | <0.11 <sup>(b)</sup> |     |
|              | Refined solvent extracted oil | 2 | <0.07, <0.15 | <0.11 <sup>(b)</sup> |     |

(a) The mean has been used to derive the Pfs as only two trials are available

(b) Tentative Pfs as derived from two trials with ≥50% difference between individual Pfs. In this case, a third study is not necessary as the Pfs are not required to refine the risk assessment and they only represent a concentration effect.

The available processing data is sufficient to support the proposed MRLs.

## 3.5 Rotational crops

The notified uses include crops which may be grown in rotation. The maximum DT90 for flupyradifurone is > 1000 days (EFSA, 2015) and DFA is persistent in soil. Therefore, residues may arise in rotational crops. However, for import tolerance based MRLs, residues in rotational crops are not typically considered. However, specific MRLs are established in the GB MRL Statutory Register for DFA that may arise in both primary and rotational crops from the use of flupyradifurone. Therefore, residues in rotational crops needs to be considered further.

It is further noted that flupyradifurone may accumulate in soil from year on year use. As the active substance was evaluated in accordance with the data requirements outlined in Assimilated Regulation No 544/2011, the effect of accumulation is not considered as part of this Evaluation Report/Reasoned Opinion. In addition, there are specific MRL supplementary information requirements to address this issue, as outlined as footnotes in the GB MRL Statutory Register. Data to address these requirements will be considered separately.

### 3.5.1 Nature of residues (Confined metabolism study on rotational crops)

Metabolism in rotational crops was investigated following bare soil treatment in turnips (root and tuber vegetables), Swiss chard (leafy vegetables) and wheat (cereals) for the approval of the active substance (EFSA, 2015).

A summary of the available rotational crop metabolism data is presented below (EFSA, 2015):

*“A similar metabolic profile was observed in the confined rotational studies conducted with a <sup>14</sup>Cpyridinyl and <sup>14</sup>C-furanone labelling, where flupyradifurone and its metabolites flupyradifuronehydroxy, 6-CNA and their conjugates were seen to be the major components of the radioactive residues. These radiolabelled studies are however incomplete as they did not include a labelling on the difluoroethyl amino group. Information provided by rotational crop field studies, indicates that DFA is the major component of the residues in rotational crops. The presence of DFA is mostly the result of a preferential uptake from soil, where this metabolite was identified as a major metabolite.”*

**Table 3.5.1-1 Summary of the available rotational crop metabolism studies**

| Crop groups        | Crop(s)     | PBI (days)    | Comments                                                            |
|--------------------|-------------|---------------|---------------------------------------------------------------------|
| Root/tuber crops   | Turnip      | 29, 135 & 296 | Trials conducted with an application at 436 g a.s./ha on bare soil. |
| Leafy crops        | Swiss chard |               |                                                                     |
| Cereal/grass crops | Wheat       |               |                                                                     |

Metabolism in rotational crops was found to be via a similar pathway to primary crops, therefore specific residue definitions for rotational crop are not required.

The application rate in the rotational crop metabolism study (0.436 kg a.s./ha) is similar to that in the notified GAPs (at least 1.06N), the results of these studies are therefore considered applicable to support the setting of MRLs.

### 3.5.2 Magnitude of residues (Rotational crop field trials)

During approval of the active substance (EFSA 2015), residues in rotational crops were investigated following bare soil treatment or following the harvest of lettuce treated as a primary crop (EFSA, 2015). Rotational crops of turnip, carrot, potato, onion (root and tuber vegetables), lettuce, leek (leafy vegetables), barley (cereals), cucumber (fruit and fruiting vegetables), beans, peas and winter rape (pulses and oilseeds) were used. Crops were planted at a range of 25 – 329 days after treatment with flupyradifurone to bare soil or to the primary lettuce crop at 200 – 250 g a.s./ha.

Newly submitted rotational crop field trials have been carried out on commodities relevant to the notified uses. The studies have been assessed as part of this evaluation and are summarised in the table below. Rotational crops of potato, cauliflower, broccoli, cabbage, oilseed rape and strawberry were used. Crops were planted at a range of 21 – 363 days after treatment with flupyradifurone to bare soil at 175 – 300 g a.s./ha (approximately 0.9 – 1.6N based on the EU cGAP and 0.4 – 0.7N based on the USA cGAP).

If new data is available on the same crop as considered in the existing data (e.g. potato), the highest residue is used for further considerations as a worst case.

The rotational crop trials data available is summarised in Table 3.5.2-1.

**Table 3.5.2-1 Summary of the field rotational crop studies**

| Crop group                 | Crop               | Application |           |                              | Residue levels (mg/kg) |                        |
|----------------------------|--------------------|-------------|-----------|------------------------------|------------------------|------------------------|
|                            |                    | PBI (days)  | g a.s./ha | On bare soil or primary crop | Flup.                  | DFA, expressed as DFA  |
| Existing data (EFSA, 2015) |                    |             |           |                              |                        |                        |
| Root crops                 | Carrot/turnip root | 25 to 30    | 200       | Bare soil                    | 4 x <0.01              | 0.01, 0.02, 0.02, 0.03 |
|                            |                    | 65 to 145   | 200       | Lettuce                      | 4 x <0.01              | <0.01, 3 x 0.01        |
|                            |                    | 266 to 329  |           |                              | 4 x <0.01              | <0.01, 3 x 0.01        |
|                            | Potato             | 30          | 2 x 125   | Bare soil                    | 4 x <0.01              | 0.01, 0.01, 0.06, 0.08 |
|                            | Onion              | 30          | 2 x 125   | Bare soil                    | 4 x <0.01              | 0.01, 0.02, 0.02, 0.05 |

|                               |                   |            |         |           |                         |                         |
|-------------------------------|-------------------|------------|---------|-----------|-------------------------|-------------------------|
| Leafy crops                   | Lettuce           | 25 to 30   | 200     | Bare soil | 2 x <0.01, 0.01, 0.03   | <0.01, 0.01, 0.02, 0.04 |
|                               |                   | 65 to 145  | 200     | Lettuce   | 3 x <0.01, 0.01         | 3 x <0.01, 0.03         |
|                               |                   | 266 to 329 |         |           | 4 x <0.01               | 3 x <0.01, 0.02         |
| Stem vegetables               | Leek              | 30         | 2 x 125 | Bare soil | 4 x <0.01               | 0.01, 0.01, 0.03, 0.08  |
| Cereals                       | Barley grain      | 25 to 30   | 200     | Bare soil | 3 x <0.01               | 0.03, 0.11, 0.21        |
|                               |                   | 65 to 145  | 200     | Lettuce   | 4 x <0.01               | 0.01, 0.03, 0.03, 0.09  |
|                               |                   | 266 to 329 |         |           | 4 x <0.01               | 0.02, 0.03, 0.03, 0.12  |
|                               | Barley straw      | 25 to 30   | 200     | Bare soil | <0.01, 0.01, 0.02, 0.04 | <0.02, 0.02, 0.04, 0.11 |
|                               |                   | 65 to 145  | 200     | Lettuce   | 3 x <0.01, 0.02         | 3 x <0.02, 0.03         |
|                               |                   | 266 to 329 |         |           | 4 x <0.01               | 3 x <0.02, 0.06         |
| Fruit and fruiting vegetables | Cucumber          | 30         | 2 x 125 | Bare soil | 4 x <0.01               | 0.02, 0.09, 0.11, 0.14  |
| Pulse and oilseeds            | Beans (with pods) | 30         | 2 x 125 | Bare soil | 4 x <0.01               | 0.09, 0.13, 0.19, 0.37  |
|                               | Peas (dry)        | 30         | 2 x 125 | Bare soil | 4 x <0.01               | 0.22, 0.33, 0.70, 0.77  |
|                               | Winter rape       | 30         | 2 x 125 | Bare soil | 4 x <0.01               | 0.02, 0.02, 0.03, 0.05  |
| <b>New data</b>               |                   |            |         |           |                         |                         |

|                               |                          |            |     |           |           |                                                                |
|-------------------------------|--------------------------|------------|-----|-----------|-----------|----------------------------------------------------------------|
| Root and tuber vegetables     | Potato                   | 148 to 181 | 300 | Bare soil | 4 x <0.01 | 0.012, 0.023<br>0.043, 0.087                                   |
|                               |                          | 292 to 349 |     |           | 4 x <0.01 | <0.007,<br>0.012, 0.018,<br>0.019                              |
| Flowering brassicas           | Cauliflower/<br>broccoli | 21 to 30   | 300 | Bare soil | 4 x <0.01 | 0.025, 0.043,<br>0.057, 0.067                                  |
|                               |                          | 129 to 161 |     |           | 4 x <0.01 | 0.015, 0.037,<br>0.050, 0.060                                  |
|                               |                          | 295 to 343 |     |           | 4 x <0.01 | 0.008, 0.019,<br>0.023, 0.040                                  |
| Head brassicas                | Cabbage                  | 26 to 29   | 300 | Bare soil | 4 x <0.01 | 0.0229,<br>0.0317,<br>0.0433,<br>0.0467                        |
| Oilseeds                      | Rape seed                | 137 to 179 | 175 | Bare soil | 8 x <0.01 | 2 x <0.007,<br>0.007, 0.009,<br>0.014, 0.015,<br>0.0194, 0.022 |
|                               |                          | 273 to 335 |     |           | 3 x <0.01 | 0.007, 0.008,<br>0.013                                         |
|                               | Rape green material      | 137 to 179 | 175 | Bare soil | 9 x <0.01 | 4 x <0.007,<br>0.010, 0.015,<br>0.0167,<br>0.057, 0.083        |
|                               |                          | 273 to 335 |     |           | 4 x <0.01 | 0.007, 0.008,<br>0.043, 0.047                                  |
|                               | Rape straw               | 137 to 179 | 175 | Bare soil | 5 x <0.01 | 4 x <0.007,<br>0.0106                                          |
|                               |                          |            |     |           |           |                                                                |
| Fruit and fruiting vegetables | Strawberry               | 22 to 29   | 300 | Bare soil | 4 x <0.01 | 0.009, 0.070,<br>0.10, 0.12                                    |
|                               |                          | 133 to 158 |     |           | 4 x <0.01 | 0.012, 0.047,<br>0.070, 0.12                                   |
|                               |                          | 301 to 363 |     |           | 4 x <0.01 | <0.007,<br>0.017, 0.024,<br>0.077                              |

## **Initial consideration of residues in rotational crops**

The rotational residue trials demonstrated residues of flupyradifurone are expected to be >0.01 mg/kg in lettuce at PBIs up to 145 days, while residues of DFA are expected to be >0.01 mg/kg in all crops at all PBIs. On this basis, consideration of potential residues in rotational crops following application of flupyradifurone are required.

## **Application rates and crop interception**

The rotational crop data available needs to be scaled to the application rates notified for this assessment. In addition, the timings of the application can be taken into account, as the soil may be partially covered by the crop and not all the active will reach the bare soil and be available for uptake by the following/rotational crops (i.e. crop interception).

For the consideration of rotational residues present in crops imported from the USA/Canada (potatoes, tropical root and tuber vegetables and soyabean (dry)), rotational residues were scaled to the notified critical USA/Canadian GAP (1 x 410 g a.s./ha). No crop interception was applied due to the timing of application at early growth stages. Residues of <LOQ were not scaled. This results in potential rotational residues of flupyradifurone in crops of potatoes, tropical root and tuber vegetables and soyabean (dry) of <0.01 mg/kg. The potential rotational residues of DFA, expressed as DFA are 0.119 mg/kg in potatoes and tropical root and tuber vegetables and 1.26 mg/kg in soyabean (dry).

For the consideration of rotational residues present in crops imported from the EU (strawberries, flowering brassicas, head brassicas, Brussels sprouts, kale, Chinese cabbage, kohlrabi, leafy vegetables, fresh herbs and edible flowers and olives), rotational residues are scaled to the notified critical EU GAP (2 x 125 g a.s./ha) with a 25% crop interception (resulting in a total rate of 187.5 g a.s./ha). Residues of <LOQ were not scaled.

It should be noted that olives are considered a permanent crop. Therefore, as the effect of accumulation is not considered as part of this Evaluation Report/Reasoned Opinion, no further consideration of rotational residues arising in olives is required.

For all other crops, the expected rotational residues of flupyradifurone in crops of strawberries, potatoes, tropical root and tuber vegetables, flowering brassicas, head brassicas, Brussels sprouts, kale, Chinese cabbage, kohlrabi and soyabean are up to <0.01 mg/kg. The expected rotational residues of flupyradifurone in leafy vegetables, fresh herbs and edible flowers, including lettuce, is 0.028 mg/kg. The expected rotational residues of DFA, expressed as DFA are 0.075 mg/kg in strawberries, 0.119 mg/kg in potatoes and tropical root and tuber vegetables, 0.056 mg/kg in flowering brassicas, kale, Chinese cabbage and kohlrabi, 0.039 mg/kg in head brassicas and Brussels sprouts and 0.05 mg/kg in leafy vegetables, fresh herbs and edible flowers, and 0.082 mg/kg in soyabeans.



The rotational crop residue levels expected in crops are summarised in Tables 3.5.2-2, -3 and -4. For each notified use the table outlines the HR from the rotational crop study.

**Table 3.5.2-2 Summary of the rotational residues of flupyradifurone expected to arise in the notified use of flupyradifurone**

Flupyradifurone (RD-Enf 1 & part of RD-RA)

| Notified crop (cGAP)                                                     | Crop used in study    | Rotational HR from study (mg/kg) | Rotational HR from study scaled to notified cGAP (mg/kg) | Primary HR (mg/kg)                              | Rotational HR >25% of primary HR? (Y/N) | Relevant endpoint |
|--------------------------------------------------------------------------|-----------------------|----------------------------------|----------------------------------------------------------|-------------------------------------------------|-----------------------------------------|-------------------|
| Strawberry<br>(EU: 2 x 125 g a.s./ha;<br>25% crop interception)          | Strawberry            | <0.01                            | <0.01                                                    | Not required as rotational residue <0.01 mg/kg. | n/a                                     | n/a               |
| Potatoes, tropical root and tuber vegetables<br>(USA: 1 x 410 g a.s./ha) | Potato                | <0.01                            | <0.01                                                    | Not required as rotational residue <0.01 mg/kg. | n/a                                     | n/a               |
| Flowering brassicas<br>(EU: 2 x 125 g a.s./ha;<br>25% crop interception) | Cauliflower/ broccoli | <0.01                            | <0.01                                                    | Not required, rotational residue <0.01 mg/kg    | n/a                                     | n/a               |
| Head cabbage<br>(EU: 2 x 125 g a.s./ha;<br>25% crop interception)        | Cabbage               | <0.01                            | <0.01                                                    | Not required, rotational residue <0.01 mg/kg    | n/a                                     | n/a               |
| Brussels sprouts<br>(EU: 2 x 125 g a.s./ha;                              | Cabbage               | <0.01                            | <0.01                                                    | Not required, rotational residue <0.01 mg/kg    | n/a                                     | n/a               |

| <b>Notified crop (cGAP)</b>                                                                     | <b>Crop used in study</b> | <b>Rotational HR from study (mg/kg)</b> | <b>Rotational HR from study scaled to notified cGAP (mg/kg)</b> | <b>Primary HR (mg/kg)</b>                    | <b>Rotational HR &gt;25% of primary HR? (Y/N)</b> | <b>Relevant endpoint</b>                     |
|-------------------------------------------------------------------------------------------------|---------------------------|-----------------------------------------|-----------------------------------------------------------------|----------------------------------------------|---------------------------------------------------|----------------------------------------------|
| 25% crop interception)                                                                          |                           |                                         |                                                                 |                                              |                                                   |                                              |
| Kale & Chinese cabbage (EU: 2 x 125 g a.s./ha; 25% crop interception)                           | Cauliflower/ broccoli     | <0.01                                   | <0.01                                                           | Not required, rotational residue <0.01 mg/kg | n/a                                               | n/a                                          |
| Kohlrabi (EU: 2 x 125 g a.s./ha; 25% crop interception)                                         | Cauliflower/ broccoli     | <0.01                                   | <0.01                                                           | Not required, rotational residue <0.01 mg/kg | n/a                                               | n/a                                          |
| Lettuce (EU: 2 x 125 g a.s./ha; 25% crop interception)                                          | Lettuce                   | 0.03                                    | 0.028                                                           | 3.1                                          | N                                                 | Not used as rotational HR <25% of primary HR |
| Leafy vegetables, fresh herbs and edible flowers (EU: 2 x 125 g a.s./ha; 25% crop interception) | Lettuce                   | 0.03                                    | 0.028                                                           | 3.1                                          | N                                                 |                                              |
| Soyabean                                                                                        | Oilseed rape seed         | <0.01                                   | <0.01                                                           | Not required, rotational                     | n/a                                               | n/a                                          |

| <b>Notified crop<br/>(cGAP)</b> | <b>Crop<br/>used in<br/>study</b> | <b>Rotational HR<br/>from<br/>study<br/>(mg/kg<br/>)</b> | <b>Rotational HR<br/>from<br/>study<br/>scaled<br/>to<br/>notified<br/>cGAP<br/>(mg/kg)</b> | <b>Primary HR<br/>(mg/kg)</b> | <b>Rotational HR<br/>&gt;25% of<br/>primary<br/>HR?<br/>(Y/N)</b> | <b>Relevant<br/>endpoint</b> |
|---------------------------------|-----------------------------------|----------------------------------------------------------|---------------------------------------------------------------------------------------------|-------------------------------|-------------------------------------------------------------------|------------------------------|
| (USA: 1 x 410<br>g a.s./ha)     |                                   |                                                          |                                                                                             | residue<br><0.01 mg/kg        |                                                                   |                              |

**Table 3.5.2-3 Summary of the rotational residues of DFA, expressed as DFA expected to arise in the notified use of flupyradifurone**

DFA, expressed as DFA (RD-Enf 2)

| Notified crop (cGAP)                                                     | Crop used in study    | Rotational HR from study (mg/kg) | Rotational HR from study scaled to notified cGAP (mg/kg) | Primary HR (mg/kg) | Rotational HR >25% of primary HR? (Y/N) | Relevant endpoint                            |
|--------------------------------------------------------------------------|-----------------------|----------------------------------|----------------------------------------------------------|--------------------|-----------------------------------------|----------------------------------------------|
| Strawberry<br>(EU: 2 x 125 g a.s./ha;<br>25% crop interception)          | Strawberry            | 0.12                             | 0.075                                                    | 0.018              | Y                                       | MRL                                          |
| Potatoes, tropical root and tuber vegetables<br>(USA: 1 x 410 g a.s./ha) | Potato                | 0.087                            | 0.119                                                    | 0.029              | Y                                       | STMR/HR for dietary burden, MRL              |
| Flowering brassicas<br>(EU: 2 x 125 g a.s./ha;<br>25% crop interception) | Cauliflower/ broccoli | 0.067                            | 0.056                                                    | 0.27               | N                                       | Not used as rotational HR <25% of primary HR |
| Head cabbage<br>(EU: 2 x 125 g a.s./ha;<br>25% crop interception)        | Cabbage               | 0.0467                           | 0.039                                                    | 0.093              | Y                                       | STMR/HR for dietary burden, MRL              |
| Brussels sprouts<br>(EU: 2 x 125 g a.s./ha;                              | Cabbage               | 0.0467                           | 0.039                                                    | 0.10               | Y                                       | MRL                                          |

|                                                                                                 |                       |       |       |       |   |                                              |
|-------------------------------------------------------------------------------------------------|-----------------------|-------|-------|-------|---|----------------------------------------------|
| 25% crop interception)                                                                          |                       |       |       |       |   |                                              |
| Kale & Chinese cabbage<br>(EU: 2 x 125 g a.s./ha; 25% crop interception)                        | Cauliflower/ broccoli | 0.067 | 0.056 | 0.30  | N | Not used as rotational HR <25% of primary HR |
| Kohlrabi<br>(EU: 2 x 125 g a.s./ha; 25% crop interception)                                      | Cauliflower/ broccoli | 0.067 | 0.056 | 0.08  | Y | MRL                                          |
| Lettuce<br>(EU: 2 x 125 g a.s./ha; 25% crop interception)                                       | Lettuce               | 0.04  | 0.05  | 0.067 | Y | MRL                                          |
| Leafy vegetables, fresh herbs and edible flowers (EU: 2 x 125 g a.s./ha; 25% crop interception) | Lettuce               | 0.04  | 0.05  | 0.067 | Y | MRL                                          |
| Soyabean<br>(USA: 1 x 410 g a.s./ha)                                                            | Oilseed rape seed     | 0.05  | 0.082 | 0.539 | N | Not used as rotational HR <25% of primary HR |

**Table 3.5.2-4 Summary of the rotational residues of the sum of flupyradifurone and DFA, expressed as flupyradifurone expected to arise in the notified use of flupyradifurone**

Sum of flupyradifurone and DFA, expressed as flupyradifurone

| Notified crop (cGAP)                                                  | Crop used in study    | Rotational HR from study (mg/kg) | Rotational HR from study scaled to notified cGAP (mg/kg) | Primary HR (mg/kg) | Rotational HR >25% of primary HR? (Y/N) | Relevant endpoint                            |
|-----------------------------------------------------------------------|-----------------------|----------------------------------|----------------------------------------------------------|--------------------|-----------------------------------------|----------------------------------------------|
| Strawberry (EU: 2 x 125 g a.s./ha; 25% crop interception)             | Strawberry            | 0.37                             | 0.23                                                     | 0.22               | Y                                       | STMR/HR for CRA <sup>(a)</sup>               |
| Potatoes, tropical root and tuber vegetables (USA: 1 x 410 g a.s./ha) | Potato                | 0.261                            | 0.357                                                    | 0.096              | Y                                       | STMR/HR for CRA <sup>(a)</sup>               |
| Flowering brassicas (EU: 2 x 125 g a.s./ha; 25% crop interception)    | Cauliflower/ broccoli | 0.201                            | 0.168                                                    | 0.824              | N                                       | Not used as rotational HR <25% of primary HR |
| Head cabbage (EU: 2 x 125 g a.s./ha; 25% crop interception)           | Cabbage               | 0.140                            | 0.117                                                    | 0.29               | Y                                       | STMR/HR for CRA <sup>(a)</sup>               |
| Brussels sprouts                                                      | Cabbage               | 0.140                            | 0.117                                                    | 0.31               | Y                                       | STMR/HR for CRA <sup>(a)</sup>               |

|                                                                                                 |                       |       |       |       |   |                                              |
|-------------------------------------------------------------------------------------------------|-----------------------|-------|-------|-------|---|----------------------------------------------|
| (EU: 2 x 125 g a.s./ha; 25% crop interception)                                                  |                       |       |       |       |   |                                              |
| Kale & Chinese cabbage<br>(EU: 2 x 125 g a.s./ha; 25% crop interception)                        | Cauliflower/ broccoli | 0.201 | 0.168 | 2.24  | N | Not used as rotational HR <25% of primary HR |
| Kohlrabi<br>(EU: 2 x 125 g a.s./ha; 25% crop interception)                                      | Cauliflower/ broccoli | 0.201 | 0.168 | 0.25  | Y | STMR/HR for CRA <sup>(a)</sup>               |
| Lettuce<br>(EU: 2 x 125 g a.s./ha; 25% crop interception)                                       | Lettuce               | 0.15  | 0.188 | 3.813 | N | Not used as rotational HR <25% of primary HR |
| Leafy vegetables, fresh herbs and edible flowers (EU: 2 x 125 g a.s./ha; 25% crop interception) | Lettuce               | 0.15  | 0.188 | 3.813 | N |                                              |
| Soyabean<br>(USA: 1 x 410 g a.s./ha)                                                            | Oilseed rape seed     | 0.15  | 0.246 | 2.64  | N |                                              |

<sup>(a)</sup> CRA = consumer risk assessment



## Flupyradifurone for the notified uses and CXLs

It is noted that rotational residues of flupyradifurone are expected to be negligible compared with the residues resulting from primary treated crops for all notified uses. As such, no consideration of rotational residues is required for the proposed flupyradifurone MRLs based on the notified uses of flupyradifurone.

Rotational residues of flupyradifurone are not expected to be relevant to the CXLs for strawberries, potatoes, cauliflowers, head cabbages, head lettuces and soyabeans. The GAP on which the CXLs are based is 2 x 205 g a.s./ha, 0 – 21 day PHI; based on these GAPs, crop interception of at least 70 % is expected – the resulting soil exposure is 123 g a.s./ha. This is lower than the rates considered in the rotational crop field trials, for which no residues > LOQ were observed in the crops concerned.

## DFA for the notified uses

As presented in the above table, rotational residues are required to derive DFA MRLs for the notified uses on strawberries, potatoes, tropical root and tuber vegetables, head brassicas, Brussels sprouts, kohlrabi, lettuces and salad plants (except escaroles), spinaches and similar leaves, and fresh herbs and edible flowers. Table 3.5.2-3 gives further details.

**Table 3.5.2-3 DFA MRL proposals following addition of rotational residues – notified uses**

| Notified crop                                 | Primary residues (DFA, expressed as DFA) (mg/kg)  | Scaled rotational HR (mg/kg) | Adjusted dataset <sup>(a)</sup> (primary and rotational residues) (mg/kg) | MRL proposal based on primary + rotational residues (mg/kg) | Current GB MRL (2025/026) (mg/kg) |
|-----------------------------------------------|---------------------------------------------------|------------------------------|---------------------------------------------------------------------------|-------------------------------------------------------------|-----------------------------------|
| DFA,                                          | expressed as                                      | DFA                          | RD-Enf. 2)                                                                |                                                             |                                   |
| Strawberries                                  | 2 x <0.007, 0.010, 0.012, 0.014, 2 x 0.015, 0.018 | 0.075                        | 2 x 0.082, 0.085, 0.087, 0.089, 2 x 0.090, 0.093                          | 0.3                                                         | 0.03                              |
| Potatoes & tropical root and tuber vegetables | 16 x <0.017, 0.023, 0.024, 0.029                  | 0.119                        | 16 x 0.136, 0.142, 0.143, 0.148                                           | 0.5                                                         | 0.09                              |

| <b>Notified crop</b>                                                                                                  | <b>Primary residues (DFA, expressed as DFA) (mg/kg)</b>                                         | <b>Scaled rotational HR (mg/kg)</b> | <b>Adjusted dataset<sup>(a)</sup> (primary and rotational residues) (mg/kg)</b>        | <b>MRL proposal based on primary + rotational residues (mg/kg)</b> | <b>Current GB MRL (2025/026) (mg/kg)</b> |
|-----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------|----------------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------------------------------|
| Head cabbage                                                                                                          | 0.032, 0.040, 0.053, 0.087                                                                      | 0.039                               | 0.071, 0.079, 0.092, 0.126                                                             | 0.3                                                                | 0.02*                                    |
| Brussels sprouts                                                                                                      | 0.020, 2 x 0.027, 0.037, 0.060, 0.080, 0.083, 0.10                                              | 0.039                               | 0.059, 2 x 0.066, 0.076, 0.099, 0.119, 0.122, 0.139                                    | 0.3                                                                | 0.02*                                    |
| Kohlrabi                                                                                                              | 0.043, 0.050, 0.070, 0.080                                                                      | 0.056                               | 0.099, 0.106, 0.126, 0.136                                                             | 0.4                                                                | 0.02*                                    |
| Lettuce                                                                                                               | 5 x <0.007, 2 x 0.009, 2 x 0.010, 0.033, 0.067                                                  | 0.05                                | 5 x 0.057, 2 x 0.059, 2 x 0.060, 0.083, 0.117                                          | 0.2                                                                | 0.09                                     |
| Lettuces and salad plants (except lettuces and escaroles), spinaches and similar leaves, and herbs and edible flowers | 3 x <0.007, 0.007, 2 x 0.009, 0.010, 2 x 0.013, 0.016, 0.017, 0.025, 0.033, 0.043, 0.050, 0.067 | 0.05                                | 4 x 0.057, 2 x 0.059, 0.060, 2 x 0.063, 0.066, 0.067, 0.075, 0.083, 0.093, 0.10, 0.117 | 0.3                                                                | 0.04                                     |

<sup>(a)</sup> In accordance with the OECD guidance (2018), the adjusted dataset has been calculated by addition of the rotational HR to each data point from the primary residue values.

#### DFA for the CXLs

HSE has recommended a number of CXLs for flupyradifurone are adopted as GB MRLs (see Table 0.4). Separate GB MRLs are also set for DFA that may arise in primary and rotational crops, following application of flupyradifurone. As imported crops must fully comply with GB MRLs, then the CXLs for flupyradifurone can only be adopted if an associated GB MRL is adopted for DFA.

The JMPR evaluation, along with the residues data for flupyradifurone, included residues data for DFA. HSE has used this data for DFA to estimate the MRLs required for DFA associated with the CXLs for flupyradifurone. The MRLs estimated for DFA are based on:

- The residue levels of DFA occurring in the primary crop
- The residue levels of DFA that may arise in rotational crops

A summary of the data used to estimate the MRLs for DFA associated with the CXLs is outlined in Table 3.5.2-4. This table shows the residue levels of DFA in the primary crop, the HR of DFA found in rotational crops, the residue levels that may arise as a result of primary and rotational exposure and the MRL estimated.

**Table 3.5.2-4 Summary of the JMPR data for DFA in primary and rotational crops (data relate to the CXLs established for flupyradifurone)**

RD-Enf 2: DFA, expressed as DFA

| <b>Crop</b>  | <b>JMPR Primary residues (DFA, expressed as DFA) (mg/kg)</b> | <b>JMPR Rotational HR (mg/kg)</b> | <b>Rotational HR &gt;25% of primary HR? (Y/N)</b> | <b>JMPR adjusted dataset (primary and rotational) (mg/kg)</b> | <b>Proposed MRL for DFA<sup>†</sup> (mg/kg)</b> |
|--------------|--------------------------------------------------------------|-----------------------------------|---------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------|
| Strawberries | 3 x <0.017, 0.018, 0.022, 0.028, 0.037, 0.050, 0.053, 0.29   | 0.601                             | Y                                                 | 3 x 0.618, 0.619, 0.623, 0.629, 0.638, 0.651, 0.654, 0.891    | 2                                               |
| Potatoes     | 17 x <0.017, 2 x 0.023, 0.029                                | 0.137                             | Y                                                 | 17 x 0.154, 2 x 0.160, 0.166                                  | 0.5                                             |
| Cauliflower  | <0.017, 0.024, 0.027, 0.031, 0.062, 0.108                    | 0.079                             | Y                                                 | 0.096, 0.103, 0.106, 0.110, 0.141, 0.187                      | 0.4                                             |

|                |                                                                                             |       |   |                                                                                            |     |
|----------------|---------------------------------------------------------------------------------------------|-------|---|--------------------------------------------------------------------------------------------|-----|
| Cabbages, head | 0.027, 2 x 0.037, 0.043, 0.083, 0.097, 0.12, 0.13, 0.18                                     | 0.079 | Y | 0.106, 2 x 0.116, 0.122, 0.162, 0.176, 0.199, 0.209, 0.259                                 | 0.5 |
| Lettuce, head  | 3 x <0.017, 0.017, 0.031, 0.034, 0.043, 0.063                                               | 0.079 | Y | 4 x 0.096, 0.110, 0.113, 0.122, 0.142                                                      | 0.4 |
| Soyabean (dry) | 8 x <0.017, 0.023, 0.029, 0.030, 2 x 0.035, 0.063, 0.087, 0.115, 0.123, 0.168, 0.193, 0.533 | 1.26  | Y | 8 x 1.277, 1.283, 1.289, 1.290, 2 x 1.295, 1.323, 1.347, 1.375, 1.383, 1.428, 1.453, 1.793 | 4.0 |

† The MRL proposed for DFA relates to the CXLs established for flupyradifurone

### 3.6 Final MRL Proposals

Within this assessment the MRLs required for flupyradifurone can be based on the IT requests or the CXL. MRLs also need to be established for DFA which may arise in primary and rotational crops, and these may also be related to the IT request or the CXL. The final MRLs proposed are summarised in Tables 3.5.2-5 and 3.5.2-6 for flupyradifurone and DFA respectively.

**Table 3.5.2-5 MRLs recommended by HSE (flupyradifurone)**

| Product code                                              | Product      | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | MRL in exporting country <sup>(a)</sup> (mg/kg) | Comments                                                            |
|-----------------------------------------------------------|--------------|-------------------------|-------------------------------|-------------------------------------------------|---------------------------------------------------------------------|
| <b>Enforcement residue definition for flupyradifurone</b> |              |                         |                               |                                                 |                                                                     |
| 0152000                                                   | Strawberries | 0.4                     | 1.5                           | 0.4                                             | The MRL is based on the CXL.<br><br>No health effects are expected. |

| Product code | Product                            | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | MRL in exporting country <sup>(a)</sup> (mg/kg) | Comments                                                                                                                                         |
|--------------|------------------------------------|-------------------------|-------------------------------|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 0211000      | Potatoes                           | 0.01*                   | 0.05                          | 0.05                                            | The MRL is based on the CXL.<br><br>No health effects are expected.                                                                              |
| 0212000      | Tropical root and tuber vegetables | 0.01*                   | 0.05                          | 0.05                                            | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on potato.<br><br>No health effects are expected.                   |
| 0241000      | Flowering brassicas                | 0.01*                   | 0.6                           | 0.6                                             | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on broccoli and cauliflower.<br><br>No health effects are expected. |

| Product code | Product                 | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | MRL in exporting country <sup>(a)</sup> (mg/kg) | Comments                                                                                                                            |
|--------------|-------------------------|-------------------------|-------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0242010      | Brussels sprouts        | 0.01*                   | 0.09                          | 0.09                                            | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |
| 0242020      | Head cabbages           | 0.01*                   | 1.5                           | 0.3                                             | <p>The MRL is based on the CXL.</p> <p>No health effects are expected.</p>                                                          |
| 0243010      | Chinese cabbage/pe-tsai | 0.01*                   | 4                             | 4                                               | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on kale.</p> <p>No health effects are expected.</p> |

| <b>Product code</b> | <b>Product</b> | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>MRL in exporting country<sup>(a)</sup> (mg/kg)</b> | <b>Comments</b>                                                                                                                     |
|---------------------|----------------|--------------------------------|--------------------------------------|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0243020             | Kales          | 0.01*                          | 4                                    | 4                                                     | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |
| 0244000             | Kohlrabies     | 0.01*                          | 0.09                                 | 0.09                                                  | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |

| <b>Product code</b> | <b>Product</b>                       | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>MRL in exporting country<sup>(a)</sup> (mg/kg)</b> | <b>Comments</b>                                                                                                                                              |
|---------------------|--------------------------------------|--------------------------------|--------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0251010             | Lamb's lettuces/corn salads          | 0.03                           | 6                                    | 6                                                     | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on lettuce (open leaf varieties).</p> <p>No health effects are expected.</p> |
| 0251020             | Lettuces                             | 5                              | 6                                    | 6                                                     | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p>                          |
| 0251040             | Cresses and other sprouts and shoots | 0.03                           | 6                                    | 6                                                     | <p>The MRL is based on the IT request.</p>                                                                                                                   |
| 0251050             | Land cresses                         | 0.03                           | 6                                    | 6                                                     | <p>The MRL is extrapolated from data on lettuce (open leaf varieties).</p>                                                                                   |



| <b>Product code</b> | <b>Product</b>                                             | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>MRL in exporting country<sup>(a)</sup> (mg/kg)</b> | <b>Comments</b>                 |
|---------------------|------------------------------------------------------------|--------------------------------|--------------------------------------|-------------------------------------------------------|---------------------------------|
| 0251060             | Roman rocket/rucola                                        | 0.03                           | 6                                    | 6                                                     | No health effects are expected. |
| 0251070             | Red mustards                                               | 0.03                           | 6                                    | 6                                                     |                                 |
| 0251080             | Baby leaf crops (including brassica species)               | 0.03                           | 6                                    | 6                                                     |                                 |
| 0251990             | Others – Lettuce and other salad plants including brassica | 0.03                           | 6                                    | 6                                                     |                                 |
| 0252000             | Spinaches and similar leaves                               | 0.03                           | 6                                    | 6                                                     |                                 |
| 0256000             | Herbs and edible flowers                                   | 0.03                           | 6                                    | 40                                                    |                                 |

| Product code | Product   | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | MRL in exporting country <sup>(a)</sup> (mg/kg) | Comments                                                                                                                            |
|--------------|-----------|-------------------------|-------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0401070      | Soyabeans | 0.01*                   | 1.5                           | 1.5                                             | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |

\* Indicates that the MRL is set at the limit of quantification/determination

<sup>(a)</sup> The exporting country is outlined in Appendix E.

**Table 3.5.2-6 MRLs recommended by HSE (difluoroacetic acid (DFA) (from the use of flupyradifurone))**

| Product code                    | Product                     | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | MRL in exporting country <sup>(a)</sup> (mg/kg) | Comments                                                                                         |
|---------------------------------|-----------------------------|-------------------------|-------------------------------|-------------------------------------------------|--------------------------------------------------------------------------------------------------|
| <b>Enforcement origin: DFA,</b> | <b>residue expressed as</b> | <b>definition DFA</b>   | <b>for</b>                    | <b>products</b>                                 | <b>of plant</b>                                                                                  |
| 0152000                         | Strawberries                | 0.03                    | 2                             | 0.3                                             | <p>The MRL is linked to the CXL for flupyradifurone .</p> <p>No health effects are expected.</p> |

| Product code | Product                            | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | MRL in exporting country <sup>(a)</sup> (mg/kg) | Comments                                                                                                                                         |
|--------------|------------------------------------|-------------------------|-------------------------------|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 0211000      | Potatoes                           | 0.09                    | 0.5                           | n/a                                             | The MRL is linked to the CXL for flupyradifurone.<br><br>No health effects are expected.                                                         |
| 0212000      | Tropical root and tuber vegetables | 0.09                    | 0.5                           | n/a                                             | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on potato.<br><br>No health effects are expected.                   |
| 0241000      | Flowering brassicas                | 0.02*                   | 0.5 <sup>†</sup>              | 0.7                                             | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on broccoli and cauliflower.<br><br>No health effects are expected. |

| Product code | Product                 | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | MRL in exporting country <sup>(a)</sup> (mg/kg) | Comments                                                                                                                            |
|--------------|-------------------------|-------------------------|-------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0242010      | Brussels sprouts        | 0.02*                   | 0.3 <sup>†</sup>              | 0.4                                             | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |
| 0242020      | Head cabbages           | 0.02*                   | 0.5                           | 0.4                                             | <p>The MRL is linked to the CXL for flupyradifurone .</p> <p>No health effects are expected.</p>                                    |
| 0243010      | Chinese cabbage/pet-sai | 0.02*                   | 0.5 <sup>†</sup>              | 0.7                                             | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on kale.</p> <p>No health effects are expected.</p> |

| Product code | Product    | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | MRL in exporting country <sup>(a)</sup> (mg/kg) | Comments                                                                                                                            |
|--------------|------------|-------------------------|-------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0243020      | Kales      | 0.02*                   | 0.5 <sup>†</sup>              | 0.7                                             | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |
| 0244000      | Kohlrabies | 0.02*                   | 0.4                           | 0.4                                             | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |

| Product code | Product                              | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | MRL in exporting country <sup>(a)</sup> (mg/kg) | Comments                                                                                                                                              |
|--------------|--------------------------------------|-------------------------|-------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0251010      | Lamb's lettuces/corn salads          | 0.04                    | 0.3                           | 0.3                                             | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on lettuce (open leaf varieties).<br><br>No health effects are expected. |
| 0251020      | Lettuces                             | 0.09                    | 0.4                           | 0.2                                             | The MRL is linked to the CXL for flupyradifurone.<br><br>No health effects are expected.                                                              |
| 0251040      | Cresses and other sprouts and shoots | 0.04                    | 0.3                           | 0.3                                             | The MRL is based on the IT request.                                                                                                                   |
| 0251050      | Land cresses                         | 0.04                    | 0.3                           | 0.3                                             | The MRL is extrapolated from data on lettuce (open leaf varieties).                                                                                   |
| 0251060      | Roman rocket/rucola                  | 0.04                    | 0.3                           | 0.3                                             | No health effects are expected.                                                                                                                       |

| Product code | Product                                                    | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | MRL in exporting country <sup>(a)</sup> (mg/kg) | Comments                                                                                                                            |
|--------------|------------------------------------------------------------|-------------------------|-------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0251070      | Red mustards                                               | 0.04                    | 0.3                           | 0.3                                             |                                                                                                                                     |
| 0251080      | Baby leaf crops (including brassica species)               | 0.04                    | 0.3                           | 0.3                                             |                                                                                                                                     |
| 0251990      | Others – Lettuce and other salad plants including brassica | 0.04                    | 0.3                           | 0.3                                             |                                                                                                                                     |
| 0252000      | Spinach and similar leaves                                 | 0.04                    | 0.3                           | 0.3                                             |                                                                                                                                     |
| 0256000      | Herbs and edible flowers                                   | 0.04                    | 0.3                           | 0.3                                             |                                                                                                                                     |
| 0401070      | Soyabeans                                                  | 0.05                    | 0.6                           | n/a                                             | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |

\* Indicates that the MRL is set at the limit of quantification/determination.

n/a MRLs for DFA not set in the exporting country (USA/Canada).

<sup>(a)</sup> The exporting country is outlined in Appendix E.

† It should be noted that the higher MRL in the exporting country is owing to the impact of accumulation from year-on-year use being considered. GB MRLs at this time have not applied this consideration as it is not required by the data requirements that are applicable

to flupyradifurone. Consideration of accumulation from year-on-year use will be addressed separately as part of the MRL supplementary information assessment.



## Further information on the MRL proposals

### 0152000 Strawberries

The flupyradifurone MRL proposal in/on strawberries is based on primary residues only, while the DFA MRL proposal in/on strawberries includes both primary and rotational residues.

The trials for the notified protected use in the EU (2 x 125 g a.s./ha) support an MRL for strawberries (0152000) of 0.4 mg/kg for flupyradifurone and 0.3 mg/kg for DFA (including primary and rotational residues). The current flupyradifurone MRL in the exporting jurisdiction (EU) is 0.4 mg/kg for flupyradifurone and 0.3 mg/kg for DFA.

It should be noted that primary residue trials undertaken with one application at 1 x 125 g a.s./ha have also been provided which support an MRL of 0.6 mg/kg for flupyradifurone and 0.3 mg/kg for DFA (including primary and rotational residues). Since these MRLs do not match the MRLs in the exporting jurisdiction (EU) HSE does not recommend that the MRLs are amended based on these data.

The CXL for flupyradifurone in/on strawberries is based on primary residues only, while the MRL proposal for DFA in/on strawberries based on the flupyradifurone CXL includes both primary and rotational residues.

The CXL for flupyradifurone on strawberries adopted by Codex in 2017 (1.5 mg/kg) is higher than the MRL required for the import tolerance request (0.4 mg/kg). The trials data supporting the CXL are summarised in Table 3.2-2 and support the CXL of 1.5 mg/kg. The data comply with the GB residue definitions and the CXL is sufficiently supported by data. The assessment of data was undertaken by JMPR in 2016. As there are no risks to UK consumers (see Section 8) HSE recommends adoption of the CXL of 1.5 mg/kg as a GB MRL for flupyradifurone in strawberries (0152000).

The proposed MRL for DFA on strawberries based on the JMPR data used to set the CXL for flupyradifurone (2 mg/kg) is higher than the MRL required for the import tolerance request (0.3 mg/kg). The trials data supporting the proposed MRL are summarised in Table 3.2-2 and support the proposed MRL of 2 mg/kg. As there are no risks to UK consumers (see Section 8) HSE recommends the adoption of the CXL of 2 mg/kg as a GB MRL for DFA in strawberries (0152000).

### 0211000 Potatoes

The flupyradifurone MRL proposal in/on potatoes is based on primary residues only, while the DFA MRL proposal in/on potatoes includes both primary and rotational residues.

The trials for the notified use in the USA and Canada support an MRL for potatoes (0211000) of 0.05 mg/kg for flupyradifurone and 0.5 mg/kg for DFA (based on primary and

rotational residues). The current flupyradifurone MRL in the exporting countries (USA/Canada) is 0.05 mg/kg. MRLs for DFA are not set in the exporting countries.

The CXL for flupyradifurone in/on potatoes is based on primary residues only, while the MRL proposal for DFA in/on potatoes based on the flupyradifurone CXL includes both primary and rotational residues.

The CXL for flupyradifurone in potato adopted by Codex in 2017 (0.05 mg/kg) is the same as the MRL required for the import tolerance request (0.05 mg/kg). The trials data supporting the CXL are summarised in Table 3.2-2 and support the CXL of 0.05 mg/kg. The data comply with the GB residue definitions and the CXL is sufficiently supported by data. The assessment of data was undertaken by JMPR in 2016. As there are no risks to UK consumers (see Section 8) HSE recommends the adoption of the CXL of 0.05 mg/kg as a GB MRL for flupyradifurone in potatoes (0211000).

The proposed MRL for DFA on potatoes based on the JMPR primary and rotational data used to set the flupyradifurone CXL (0.5 mg/kg) is the same as the MRL required for the import tolerance request (0.5 mg/kg). The trials data supporting the CXL are summarised in Table 3.2-2 and Table 3.5.2-4 and support the CXL of 0.5 mg/kg (taking account of both primary and rotational residues). As there are no risks to UK consumers (see Section 8) HSE recommends the adoption of the proposed MRL of 0.5 mg/kg as a GB MRL for DFA in potatoes (0211000).

## **0212000 Tropical root and tuber vegetables**

The flupyradifurone MRL proposal in/on tropical root and tuber vegetables is based on primary residues only, while the DFA MRL proposal in/on tropical root and tuber vegetables includes both primary and rotational residues.

The trials for the notified use in the USA/Canada support an MRL for tropical root and tuber vegetables (0212000) of 0.05 mg/kg for flupyradifurone and 0.5 mg/kg for DFA (based on primary and rotational residues). The current flupyradifurone MRL in the exporting countries (USA/Canada) is 0.05 mg/kg. MRLs for DFA are not set in the exporting countries.

CXLs have not been established for flupyradifurone in tropical root and tuber vegetables.

## **0233010 Melons**

## **0233020 Pumpkins**

It should be noted that the applicant has requested the GB MRLs for DFA in melons (0233010) and pumpkins (0233020) are raised from 0.15 mg/kg to 0.3 mg/kg to take account of accumulation from year-on-year use. GB MRLs at this time have not applied this consideration as it is not required by the data requirements that are applicable to

flupyradifurone. Consideration of accumulation from year-on-year use will be addressed separately as part of the MRL supplementary information assessment. Therefore, no change to the DFA MRLs are required for melons (0233010) and pumpkins (0233020).

### **0241000 Flowering brassicas**

The flupyradifurone and DFA MRL proposals in/on flowering brassicas are based on primary residues only.

The trials for the notified use in the EU support an MRL for flowering brassicas (0241000) of 0.6 mg/kg for flupyradifurone and 0.5 mg/kg for DFA. The current MRLs in the exporting jurisdiction (EU) are 0.6 mg/kg for flupyradifurone and 0.7 mg/kg for DFA. The difference in the proposed MRL for DFA (0.5 mg/kg) and the exporting MRL (0.7 mg/kg) is owing to the impact of accumulation from year on year use being considered. GB MRLs at this time have not applied this consideration as it is not required by the data requirements that are applicable to flupyradifurone. Consideration of accumulation from year-on-year use will be addressed separately as part of the MRL supplementary information assessment.

CXLs are set for flupyradifurone in/on cauliflower but no other flowering brassicas.

The CXL for flupyradifurone in/on cauliflower is based on primary residues only, while the MRL proposal for DFA in/on cauliflower based on the flupyradifurone CXL includes both primary and rotational residues.

The CXL for flupyradifurone in cauliflower adopted by Codex in 2017 (6 mg/kg) is higher than the MRL required for the import tolerance request (0.6 mg/kg). The trials data supporting the CXL are summarised in Table 3.2-2 and support the CXL of 6 mg/kg. The data comply with the GB residue definitions and the CXL is sufficiently supported by data. The assessment of data was undertaken by JMPR in 2016. However, the residues for risk assessment result in potential risks to UK consumers (see Section 8). Therefore HSE does not recommend the adoption of the CXL of 6 mg/kg as a GB MRL for flupyradifurone in cauliflowers (0241020).

The proposed MRL for DFA on cauliflowers based on the JMPR primary and rotational data used to set the flupyradifurone CXL (0.4 mg/kg) is lower than the MRL required for the import tolerance request (0.5 mg/kg). In addition, the CXL for flupyradifurone is not being adopted as it results in consumer risk concerns (see Section 8). Therefore, HSE does not recommend the adoption of the proposed MRL based on the JMPR data as a GB MRL for DFA in cauliflowers (0241020).

### **0242020 Head cabbages**

The flupyradifurone MRL proposal in/on head cabbage is based on primary residues only, while the DFA MRL proposal in/on head cabbage includes both primary and rotational residues.

The trials for the notified use in the EU support an MRL for head cabbages (0242020) of 0.3 mg/kg for flupyradifurone and 0.3 mg/kg for DFA (based on primary and rotational residues). The current MRLs in the exporting jurisdiction (EU) are 0.3 mg/kg for flupyradifurone and 0.4 mg/kg for DFA. The difference in the proposed MRL for DFA (0.3 mg/kg) and the exporting MRL (0.4 mg/kg) is owing to the impact of accumulation from year on year use being considered. GB MRLs at this time have not applied this consideration as it is not required by the data requirements that are applicable to flupyradifurone. Consideration of accumulation from year-on-year use will be addressed separately as part of the MRL supplementary information assessment.

The CXL for flupyradifurone in/on head cabbage is based on primary residues only, while the MRL proposal for DFA in/on head cabbage based on the flupyradifurone CXL includes both primary and rotational residues.

The CXL for flupyradifurone in head cabbage adopted by Codex in 2017 (1.5 mg/kg) is higher than the MRL required for the import tolerance request (0.3 mg/kg). The trials data supporting the CXL are summarised in Table 3.2-2 and support the CXL of 1.5 mg/kg. The data comply with the GB residue definitions and the CXL is sufficiently supported by data. The assessment of data was undertaken by JMPR in 2016. As there are no risks to UK consumers (see Section 8) HSE recommends the adoption of the CXL of 1.5 mg/kg as a GB MRL for flupyradifurone in head cabbage (0242020).

The proposed MRL for DFA on head cabbages based on the JMPR primary and rotational data used to set the flupyradifurone CXL (0.5 mg/kg) is higher than the MRL required for the import tolerance request (0.4 mg/kg). The trials data supporting the CXL are summarised in Table 3.2-2 and Table 3.5.2-4 and support the CXL of 0.5 mg/kg (taking account of both primary and rotational residues). The data comply with the GB residue definitions and the CXL is sufficiently supported by data. As there are no risks to UK consumers (see Section 8) HSE recommends the adoption of the CXL of 0.5 mg/kg as a GB MRL for DFA in head cabbage (0242020).

### **0242010 Brussels sprouts**

The flupyradifurone MRL proposal in/on Brussels sprouts is based on primary residues only, while the DFA MRL proposal in/on Brussels sprouts includes both primary and rotational residues.

The trials for the notified use in the EU support an MRL for Brussels sprouts (0242010) of 0.09 mg/kg for flupyradifurone and 0.3 mg/kg for DFA (based on primary and rotational residues). The current MRLs in the exporting jurisdiction (EU) are 0.09 mg/kg for

flupyradifurone and 0.4 mg/kg for DFA. The difference in the proposed MRL for DFA (0.3 mg/kg) and the exporting MRL (0.4 mg/kg) is owing to the impact of accumulation from year on year use being considered. GB MRLs at this time have not applied this consideration as it is not required by the data requirements that are applicable to flupyradifurone. Consideration of accumulation from year-on-year use will be addressed separately as part of the MRL supplementary information assessment.

CXLs have not been established for flupyradifurone in/on Brussels sprouts.

#### **0243010 Chinese cabbages/pe-tsai**

##### **0243020 Kales**

The flupyradifurone and DFA MRL proposals in/on Chinese cabbages/pe-tsai and kales are based on primary residues only.

The trials for the notified use in the EU support an MRL for Chinese cabbages/pe-tsai (0243010) and kales (0243020) of 4 mg/kg for flupyradifurone and 0.5 mg/kg for DFA (based on primary and rotational residues). The current MRLs in the exporting jurisdiction (EU) are 4 mg/kg for flupyradifurone and 0.7 mg/kg for DFA. The difference in the proposed MRL for DFA (0.5 mg/kg) and the exporting MRL (0.4 mg/kg) is owing to the impact of accumulation from year on year use being considered. GB MRLs at this time have not applied this consideration as it is not required by the data requirements that are applicable to flupyradifurone. Consideration of accumulation from year-on-year use will be addressed separately as part of the MRL supplementary information assessment.

CXLs have not been established for flupyradifurone in/on kale and Chinese cabbages/pe-tsai.

##### **0244000 Kohlrabies**

The flupyradifurone MRL proposal in/on kohlrabies is based on primary residues only, while the DFA MRL proposal in/on kohlrabies includes both primary and rotational residues.

The trials for the notified use in the EU support an MRL for kohlrabies (0244000) of 0.09 mg/kg for flupyradifurone and 0.4 mg/kg for DFA (based on primary and rotational residues). The current MRLs in the exporting jurisdiction (EU) are 0.09 mg/kg for flupyradifurone and 0.4 mg/kg for DFA.

CXLs have not been established for flupyradifurone in/on kohlrabies.

##### **0251020 Lettuces**

The flupyradifurone MRL proposal in/on lettuces is based on primary residues only, while the DFA MRL proposal in/on lettuces includes both primary and rotational residues.

The trials for the notified use in the EU support an MRL for lettuces (0251020) of 6 mg/kg for flupyradifurone and 0.2 mg/kg for DFA (based on primary and rotational residues). The current MRLs in the exporting jurisdiction (EU) are 6 mg/kg for flupyradifurone and 0.2 mg/kg for DFA.

The CXL for flupyradifurone in/on head lettuce is based on primary residues only, while the MRL proposal for DFA in/on head lettuce based on the flupyradifurone CXL includes both primary and rotational residues.

The CXL for flupyradifurone in head lettuce adopted by Codex in 2017 (4 mg/kg) is lower than the MRL required for the import tolerance request (6 mg/kg). Therefore, HSE does not recommend the adoption of the CXL for flupyradifurone in lettuces (0251020).

The proposed MRL for DFA on head lettuces based on the JMPR primary and rotational data used to set the flupyradifurone CXL (0.4 mg/kg) is higher than the MRL required for the import tolerance request (0.2 mg/kg). The trials data supporting the CXL are summarised in Table 3.2-2 and Table 3.5.2-4 and support the CXL of 0.4 mg/kg (taking account of both primary and rotational residues). The data comply with the GB residue definitions and the CXL is sufficiently supported by data. As there are no risks to UK consumers (see Section 8) HSE recommends the adoption of the CXL of 0.4 mg/kg as a GB MRL for DFA in lettuces (0251020).

**0251000 Lettuces and salad plants (except lettuces (0251020) and escaroles/broad-leaved endives (0251030))**

**0252000 Spinaches and similar leaves**

**0256000 Herbs and edible flowers**

The flupyradifurone MRL proposals in/on lettuces and salad plants (except lettuce and escaroles), spinaches, and herbs and edible flowers are based on primary residues only, while the DFA MRL proposals include both primary and rotational residues.

As explained in Section 3.2, the notified use on lettuces and salad plants (0251000) (except lettuces (0251020) and escaroles/broad-leaved endives (0251030)), spinaches and similar leaves (0252000) and herbs and edible flowers (0256000) is supported by the trials on open leaf varieties of lettuce only.

The trials for the notified use in the EU support an MRL for lettuces and salad plants (0251000) (except lettuces (0251020) and escaroles/broad-leaved endives (0251030)), spinaches and similar leaves (0252000) and herbs and edible flowers (0256000) of 5 mg/kg for flupyradifurone and 0.3 mg/kg for DFA (based on primary and rotational residues). For flupyradifurone, the current MRLs in the exporting jurisdiction (EU) are 6 mg/kg for lettuces and salad plants (0251000) (except lettuces (0251020) and escaroles/broad-leaved endives (0251030)) and spinaches and similar leaves (0252000) and 40 mg/kg for herbs and edible flowers (0256000). For DFA, the current MRLs in the

exporting jurisdiction (EU) are 0.3 mg/kg for lettuces and salad plants (0251000) (except lettuces (0251020) and escaroles/broad-leaved endives (0251030)), spinaches and similar leaves (0252000) and herbs and edible flowers (0256000).

The difference in the proposed MRL for flupyradifurone in herbs and edible flowers (0256000) (5 mg/kg) and the MRL in the exporting jurisdiction (40 mg/kg) is due to the exporting MRL being based on an indoor use while the notified GAP is for an outdoor use.

CXLs have not been established for flupyradifurone in/on these commodities.

### **0401070 Soyabeans**

The flupyradifurone and DFA MRL proposals in/on soyabeans are based on primary residues only.

The trials for the notified use in the USA and Canada support an MRL for soyabeans (0401070) of 1.5 mg/kg for flupyradifurone and 0.6 mg/kg for DFA. The current flupyradifurone MRL in the exporting countries (USA/Canada) is 1.5 mg/kg. MRLs for DFA are not set in the exporting countries.

The CXL for flupyradifurone in/on soyabean is based on primary residues only, while the MRL proposal for DFA in/on soyabean based on the flupyradifurone CXL includes both primary and rotational residues.

The CXL for flupyradifurone in soyabeans adopted by Codex in 2017 (1.5 mg/kg) is the same as the MRL required for the import tolerance request (1.5 mg/kg). The trials data supporting the CXL are summarised in Table 3.2-2 and support the CXL of 1.5 mg/kg. The data comply with the GB residue definitions and the CXL is sufficiently supported by data. The assessment of data was undertaken by JMPR in 2016. However, the residues for risk assessment result in potential risks to UK consumers (see Section 8). Therefore HSE does not recommend the adoption of the CXL of 1.5 mg/kg as a GB MRL for flupyradifurone in soyabeans (0401070).

The proposed MRL for DFA on soyabeans based on the JMPR primary and rotational data used to set the flupyradifurone CXL (4 mg/kg) is higher than the MRL required for the import tolerance request (0.6 mg/kg). The trials data supporting the CXL are summarised in Table 3.2-2 and Table 3.5.2-4 and support the CXL of 4 mg/kg (taking account of both primary and rotational residues). The data comply with the GB residue definitions and the CXL is sufficiently supported by data. However, the residues for risk assessment result in potential risks to UK consumers (see Section 8). Therefore HSE does not recommend the adoption of the CXL of 4 mg/kg as a GB MRL for DFA in soyabeans (0401070).

## 4 Residues in livestock

### 4.1 Dietary burden

The dietary burden calculations have been undertaken using the OECD feeding tables (OECD guidance document on overview of residue chemistry studies Series 64/32) and the EFSA Animal Model 2017.

The following assumptions have been made:

- The highest likely inclusion rate of all crops which may have been treated has been used with the proviso that the aggregate does not exceed 100% diet.
- All produce eaten which may have been treated, has been treated and contains residues at the STMR/HR found in the trials considered to support the GAP.
- There is no loss of residue during transport, storage, preparation of feed prior to consumption.
- Default processing factors as set out in the EFSA Animal Model 2017 have been used unless other specific processing factors are available or residues <LOQ are expected.

As there are separate feeding studies available for flupyradifurone and DFA, separate dietary burdens have been undertaken below:

#### Flupyradifurone

Input values for flupyradifurone are summarised in Table 4.1-1 and the estimated animal intakes are summarised in Table 4.1-2.

**Table 4.1-1 Flupyradifurone input values for the dietary burden calculation**

Flupyradifurone, expressed as flupyradifurone

| Feed commodity    | Median        | dietary burden                                        | Maximum       | dietary burden                                      |
|-------------------|---------------|-------------------------------------------------------|---------------|-----------------------------------------------------|
|                   | Input (mg/kg) | Comment                                               | Input (mg/kg) | Comment                                             |
| <b>EFSA, 2015</b> |               |                                                       |               |                                                     |
| Alfalfa forage    | 0.01          | Barley green material rotational STMR (DAR, NL, 2015) | 0.02          | Barley green material rotational HR (DAR, NL, 2015) |
| Alfalfa hay       | 0.03          | Barley green material rotational STMR (DAR, NL,       | 0.05          | Barley green material rotational HR (DAR, NL,       |



|                        |      |                                                                                      |      |                                                                                    |
|------------------------|------|--------------------------------------------------------------------------------------|------|------------------------------------------------------------------------------------|
|                        |      | 2015) x default Pf<br>2.5                                                            |      | 2015) x default Pf<br>2.5                                                          |
| Alfalfa meal           | 0.03 | Barley green<br>material rotational<br>STMR (DAR, NL,<br>2015) x default Pf<br>2.5   | 0.05 | Barley green<br>material rotational<br>HR (DAR, NL,<br>2015) x default Pf<br>2.5   |
| Alfalfa silage         | 0.01 | Barley green<br>material rotational<br>STMR (DAR, NL,<br>2015) x default Pf<br>1.1   | 0.02 | Barley green<br>material rotational<br>HR (DAR, NL,<br>2015) x default Pf<br>1.1   |
| Barley forage          | 0.01 | Barley green<br>material rotational<br>STMR (DAR, NL,<br>2015)                       | 0.02 | Barley green<br>material rotational<br>HR (DAR, NL,<br>2015)                       |
| Barley silage          | 0.01 | Barley green<br>material rotational<br>STMR (DAR, NL,<br>2015) x default Pf<br>(1.3) | 0.03 | Barley green<br>material rotational<br>HR (DAR, NL,<br>2015) x default Pf<br>(1.3) |
| Bean vines<br>(fodder) | 0.01 | Barley green<br>material rotational<br>STMR (DAR, NL,<br>2015)                       | 0.02 | Barley green<br>material rotational<br>HR (DAR, NL,<br>2015)                       |
| Beet, mangel<br>fodder | 0.03 | Lettuce rotational<br>STMR (DAR, NL,<br>2015)                                        | 0.08 | Lettuce rotational<br>HR (DAR, NL,<br>2015)                                        |
| Beet, sugar tops       | 0.03 | Lettuce rotational<br>STMR (DAR, NL,<br>2015)                                        | 0.08 | Lettuce rotational<br>HR (DAR, NL,<br>2015)                                        |
| Clover forage          | 0.01 | Barley green<br>material rotational<br>STMR (DAR, NL,<br>2015)                       | 0.02 | Barley green<br>material rotational<br>HR (DAR, NL,<br>2015)                       |
| Clover hay             | 0.03 | Barley green<br>rotational STMR<br>(DAR, NL, 2015) x<br>default Pf 3                 | 0.06 | Barley green<br>material rotational<br>HR (DAR, NL,<br>2015) x default Pf<br>3     |
| Clover silage          | 0.01 | Barley green<br>material rotational                                                  | 0.02 | Barley green<br>material rotational                                                |

|                           |      | STMR (DAR, NL, 2015)                                                   |      | HR (DAR, NL, 2015)                                                   |
|---------------------------|------|------------------------------------------------------------------------|------|----------------------------------------------------------------------|
| Corn, field forage/silage | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Corn, field stover        | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Corn, pop stover          | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Cowpea forage             | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Cowpea hay                | 0.03 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 2.9 | 0.06 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 2.9 |
| Grass forage              | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Grass hay                 | 0.04 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 3.5 | 0.07 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 3.5 |
| Grass silage              | 0.02 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 1.6 | 0.03 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 1.6 |
| Lespedeza forage          | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                  |

|                   |      |                                                                        |      |                                                                      |
|-------------------|------|------------------------------------------------------------------------|------|----------------------------------------------------------------------|
| Lespedeza hay     | 0.04 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 4   | 0.08 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 4   |
| Millet forage     | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Millet straw      | 0.02 | Barley straw rotational STMR (EFSA, 2015)                              | 0.04 | Barley straw rotational HR (EFSA, 2015)                              |
| Oat forage        | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Oat hay           | 0.03 | Barley green material rotational STMR (DAR, NL, 2015) x Pf (3)         | 0.06 | Barley green material rotational HR (DAR, NL, 2015) x Pf (3)         |
| Pea vines (green) | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Pea hay           | 0.04 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 3.5 | 0.07 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 3.5 |
| Pea silage        | 0.02 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 1.6 | 0.03 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 1.6 |
| Rape forage       | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Rice straw        | 0.02 | Barley straw rotational STMR (EFSA, 2015)                              | 0.04 | Barley straw rotational HR (EFSA, 2015)                              |

|                  |      |                                                                          |      |                                                                        |
|------------------|------|--------------------------------------------------------------------------|------|------------------------------------------------------------------------|
| Rye forage       | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Sorghum forage   | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Sorghum stover   | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Sorghum silage   | 0.01 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf (0.6) | 0.01 | Barley green material rotational HR (DAR, NL, 2015) x default Pf (0.6) |
| Trefoil forage   | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Trefoil hay      | 0.03 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 2.8   | 0.06 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 2.8   |
| Triticale forage | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Triticale hay    | 0.03 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 2.9   | 0.06 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 2.9   |
| Triticale straw  | 0.02 | Barley straw rotational STMR (EFSA, 2015)                                | 0.04 | Barley straw rotational HR (EFSA, 2015)                                |
| Vetch forage     | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                    |

|                                  |      |                                                                          |      |                                                                        |
|----------------------------------|------|--------------------------------------------------------------------------|------|------------------------------------------------------------------------|
| Vetch hay                        | 0.03 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 2.8   | 0.06 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 2.8   |
| Wheat forage                     | 0.01 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.02 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Wheat hay                        | 0.04 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf (3.5) | 0.07 | Barley green material rotational HR (DAR, NL, 2015) x default Pf (3.5) |
| Carrot, culls                    | 0.01 | Potatoes rotational STMR (DAR, NL, 2015)                                 | 0.01 | Potatoes rotational HR (DAR, NL, 2015)                                 |
| Beet, sugar, dried pulp          | 0.01 | Potatoes rotational STMR (DAR, NL, 2015) x Pf (1)                        | -    | -                                                                      |
| Beet, sugar ensiled pulp         | 0.01 | Potatoes rotational STMR (DAR, NL, 2015) x Pf (1)                        | -    | -                                                                      |
| Beet, sugar molasses             | 0.01 | Potatoes rotational STMR (DAR, NL, 2015) x Pf (1)                        | -    | -                                                                      |
| <b>Previous data, HSE, 2025b</b> |      |                                                                          |      |                                                                        |
| Barley straw                     | 4.30 | Cereal straw STMR (JMPR, 2016)                                           | 23.0 | Cereal straw HR (JMPR, 2016)                                           |
| Oat straw                        | 4.30 | Cereal straw STMR (JMPR, 2016)                                           | 23.0 | Cereal straw HR (JMPR, 2016)                                           |
| Rye straw                        | 4.30 | Cereal straw STMR (JMPR, 2016)                                           | 23.0 | Cereal straw HR (JMPR, 2016)                                           |
| Wheat straw                      | 4.30 | Cereal straw STMR (JMPR, 2016)                                           | 23.0 | Cereal straw HR (JMPR, 2016)                                           |
| Barley grain                     | 0.27 | Cereal grain STMR (JMPR, 2016)                                           | -    | -                                                                      |

|                                             |      |                                                                                                        |   |   |
|---------------------------------------------|------|--------------------------------------------------------------------------------------------------------|---|---|
| Oat grain                                   | 0.27 | Cereal grain<br>STMR (JMPR,<br>2016)                                                                   | - | - |
| Rye grain                                   | 0.27 | Cereal grain<br>STMR (JMPR,<br>2016)                                                                   | - | - |
| Sorghum grain                               | 0.27 | Cereal grain<br>STMR (JMPR,<br>2016)                                                                   | - | - |
| Wheat grain                                 | 0.27 | Cereal grain<br>STMR (JMPR,<br>2016)                                                                   | - | - |
| Apple, pomace<br>wet                        | 1.10 | Pome fruit STMR<br>(JMPR, 2016) x<br>default Pf (5)                                                    | - | - |
| Brewer's grain,<br>dried                    | 0.89 | Cereal grain<br>STMR (JMPR,<br>2016) x default Pf<br>(3.3)                                             | - | - |
| Citrus, dried pulp                          | 0.24 | Orange STMR<br>(0.485 mg/kg)<br>(JMPR, 2016) x<br>pulp (byproduct) Pf<br>(0.5) (current<br>assessment) | - | - |
| Distiller's grain,<br>dried                 | 0.89 | Cereal grain<br>STMR (JMPR,<br>2016) x default Pf<br>(3.3)                                             | - | - |
| Wheat gluten<br>meal                        | 0.49 | Cereal grain<br>STMR (JMPR,<br>2016) x default Pf<br>(1.8)                                             | - | - |
| Wheat milled by-<br>pdts                    | 1.89 | Cereal grain<br>STMR (JMPR,<br>2016) x default Pf<br>(7)                                               | - | - |
| <b>JMPR data, CXL adopted by GB in 2024</b> |      |                                                                                                        |   |   |
| Sunflower meal                              | 0.20 | JMPR STMR (CXL<br>adopted by GB in<br>2024) x default Pf<br>2                                          | - | - |

| <b>JMPR data, CXL adopted by GB in 2025</b> |       |                                                                                                  |       |                                         |
|---------------------------------------------|-------|--------------------------------------------------------------------------------------------------|-------|-----------------------------------------|
| Bean, seed (dry)                            | 0.036 | Bean (dry) STMR (CXL)                                                                            | -     | -                                       |
| Pea (field pea), seed (dry)                 | 0.57  | Pea (dry) STMR (CXL)                                                                             | -     | -                                       |
| <b>Current assessment</b>                   |       |                                                                                                  |       |                                         |
| Cabbage, heads, leaves                      | 0.38  | Head cabbage STMR (CXL)                                                                          | 0.83  | Head cabbage HR (CXL)                   |
| Kale, leaves                                | 0.815 | Kale STMR (current assessment)                                                                   | 1.9   | Kale HR (current assessment)            |
| Soyabean forage                             | 3.29  | Soyabean forage STMR (current assessment)                                                        | 6.77  | Soyabean forage HR (current assessment) |
| Soyabean hay                                | 7.48  | Soyabean hay STMR (current assessment)                                                           | 17.36 | Soyabean hay HR (current assessment)    |
| Soyabean silage                             | 3.29  | Soyabean forage STMR (current assessment)                                                        | 6.77  | Soyabean forage HR (current assessment) |
| Cassava/tapioca roots                       | 0.01  | Potatoes STMR (current assessment)                                                               | 0.037 | Potatoes HR (current assessment)        |
| Potato culls                                | 0.01  | Potatoes STMR (CXL) (JMPR, 2016)                                                                 | 0.037 | Potatoes HR (CXL) (JMPR, 2016)          |
| Soybean seed                                | 0.063 | Soyabean (dry) STMR (current assessment)                                                         | -     | -                                       |
| Potato, process waste                       | 0.011 | Potatoes STMR (CXL) (0.01 mg/kg) x wet peel Pf 1.07 <sup>(a)</sup> (JMPR, 2016 <sup>(b)</sup> )) | -     | -                                       |
| Potato, dried pulp                          | 0.011 | Potatoes STMR (CXL) (0.01 mg/kg) x flakes Pf 1.13 <sup>(a)</sup> (JMPR, 2016 <sup>(b)</sup> ))   | -     | -                                       |
| Soybean, meal                               | 0.08  | Soyabean (dry) STMR (current assessment)                                                         | -     | -                                       |

|                |      |                                                                                    |   |   |
|----------------|------|------------------------------------------------------------------------------------|---|---|
|                |      | (0.063 mg/kg) x<br>default Pf 1.3                                                  |   |   |
| Soybean, hulls | 0.82 | Soyabean (dry)<br>STMR (current<br>assessment)<br>(0.063 mg/kg) x<br>default Pf 13 | - | - |

(a) Processing factors have been used to refine the inputs for potato process waste and potato dried pulp. As HSE recommends the adoption of the CXL for potato, JMPR processing data have been used to generate processing factors specifically for flupyradifurone.

Data on wet peel have been used to generate processing factors for the potato process waste input. For potato dried pulp, JMPR data on dried flakes was considered. As outlined in the JMPR report (2016), potato flakes were dried to a moisture content of less than 9%, relating to a DM content of 91%. As outlined in the OECD guidance, potato dried pulp is defined as having a DM content of 88%. Therefore, to ensure the residue input is modified to the correct DM content, the processing factor for dried flakes has been adjusted from a DM content of 91% (Pf: 1.09) to 88% (Pf: 1.13).

(b) JMPR values are based on data presented in the 2016 JMPR report on flupyradifurone ([5.12 FLUPYRADIFURONE 285.pdf](#))

The highest and median calculated animal intakes based on the inputs above are reported below, in Table 4.1-2.

**Table 4.1-2 Estimated animal intakes of flupyradifurone**

| Animal              | Median burden (mg/kg bw/day) | Maximum burden (mg/kg bw/day) | >0.1 mg /kg DM (Y/N) | Maximum burden (mg/kg DM) | Highest contributing commodity <sup>(a)</sup> | Previous maximum dietary burden (HSE, 2025b) (mg/kg DM) |
|---------------------|------------------------------|-------------------------------|----------------------|---------------------------|-----------------------------------------------|---------------------------------------------------------|
| Cattle (all diets)  | 0.086                        | 0.329                         | Y                    | 8.56                      | Barley straw                                  | 8.54                                                    |
| Cattle (dairy only) | 0.086                        | 0.329                         | Y                    | 8.56                      | Barley straw                                  | 8.54                                                    |



| <b>Animal</b>        | <b>Median burden (mg/kg bw/day)</b> | <b>Maximum burden (mg/kg bw/day)</b> | <b>&gt;0.1 mg /kg DM (Y/N)</b> | <b>Maximum burden (mg/kg DM)</b> | <b>Highest contributing commodity<sup>(a)</sup></b> | <b>Previous maximum dietary burden (HSE, 2025b) (mg/kg DM)</b> |
|----------------------|-------------------------------------|--------------------------------------|--------------------------------|----------------------------------|-----------------------------------------------------|----------------------------------------------------------------|
| Sheep (all diets)    | 0.160                               | 0.696                                | Y                              | 16.36                            | Barley straw                                        | 16.36                                                          |
| Sheep (ewe only)     | 0.125                               | 0.545                                | Y                              | 16.36                            | Barley straw                                        | 16.36                                                          |
| Swine (all diets)    | 0.041                               | 0.058                                | Y                              | 2.50                             | Kale leaves                                         | 1.29                                                           |
| Poultry (all diets)  | 0.105                               | 0.223                                | Y                              | 3.26                             | Wheat straw                                         | 3.26                                                           |
| Poultry (layer only) | 0.105                               | 0.223                                | Y                              | 3.26                             | Wheat straw                                         | 3.26                                                           |

(a) Considering the maximum dietary animal burden

Due to refinement via updated processing factors for potato, the maximum dietary burden for sheep and poultry is the same as that calculated previously (HSE, 2025b). Therefore, no further consideration of the likely residues of flupyradifurone in sheep and poultry commodities is required.

Based on the dietary burden calculations, consideration of the likely residues of flupyradifurone in cattle and swine is required as the trigger of 0.1 mg/kg dry matter is exceeded and the maximum dietary burden is higher than that previously calculated (HSE, 2025b).

The maximum dietary burden is 16.36 mg/kg DM for sheep (all diets).

Consideration was made of the livestock feeding studies as evaluated in the DAR (DAR, NL, 2015) to address potential residues in cattle and swine. Ruminant feeding studies were presented in the DAR (DAR, NL, 2015). Calculated STMRs, HRs and MRLs are presented in Table 4.3-1.

## DFA

Input values for DFA, expressed as flupyradifurone are summarised in Table 4.1-3 and the estimated animal intakes are summarised in Table 4.1-4.

It should be noted that in the feeding studies conducted with DFA, the feeding rates are expressed as DFA. The livestock dietary burden and an estimation of the DFA residues has been assessed initially as 'DFA expressed as flupyradifurone', reflecting the expression of DFA in the RD-RA.

Note that a Pf of 1 has been used when residues in RAC are <LOQ.

**Table 4.1-3 Input values for DFA, expressed as flupyradifurone**

DFA, expressed as flupyradifurone

| Feed commodity    | Median        | dietary burden                                                         | Maximum       | dietary burden                                                       |
|-------------------|---------------|------------------------------------------------------------------------|---------------|----------------------------------------------------------------------|
|                   | Input (mg/kg) | Comment                                                                | Input (mg/kg) | Comment                                                              |
| <b>EFSA, 2015</b> |               |                                                                        |               |                                                                      |
| Alfalfa forage    | 0.08          | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.37          | Barley green material rotational HR (DAR, NL, 2015)                  |
| Alfalfa hay       | 0.20          | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 2.5 | 0.93          | Barley green material rotational HR (DAR, NL, 2015) x default Pf 2.5 |
| Alfalfa meal      | 0.20          | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 2.5 | 0.93          | Barley green material rotational HR (DAR, NL, 2015) x default Pf 2.5 |
| Alfalfa silage    | 0.09          | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 1.1 | 0.41          | Barley green material rotational HR (DAR, NL, 2015) x default Pf 1.1 |
| Barley forage     | 0.08          | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.37          | Barley green material rotational HR (DAR, NL, 2015)                  |
| Barley silage     | 0.10          | Barley green material rotational                                       | 0.48          | Barley green material                                                |

|                           |       |                                                                                                                    |       |                                                                                                                |
|---------------------------|-------|--------------------------------------------------------------------------------------------------------------------|-------|----------------------------------------------------------------------------------------------------------------|
|                           |       | STMR (DAR, NL, 2015) x default Pf (1.3)                                                                            |       | rotational HR (DAR, NL, 2015) x default Pf (1.3)                                                               |
| Bean vines (fodder green) | 0.08  | Barley green material rotational STMR (DAR, NL, 2015)                                                              | 0.37  | Barley green material rotational HR (DAR, NL, 2015)                                                            |
| Beet, mangel fodder       | 0.11  | Potatoes rotational STMR (EFSA, 2015)                                                                              | 0.24  | Potatoes rotational HR (EFSA, 2015)                                                                            |
| Beet, sugar tops          | 0.071 | Sugar beet tops primary STMR (0.021 mg/kg) (COP 2022/02266) + Lettuce rotational STMR (0.05 mg/kg) (DAR, NL, 2015) | 0.159 | Sugar beet tops primary HR (0.039 mg/kg) (COP 2022/02266) + Lettuce rotational HR (0.12 mg/kg) (DAR, NL, 2015) |
| Clover forage             | 0.08  | Barley green material rotational STMR (DAR, NL, 2015)                                                              | 0.37  | Barley green material rotational HR (DAR, NL, 2015)                                                            |
| Clover hay                | 0.24  | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 3                                               | 1.11  | Barley green material rotational HR (DAR, NL, 2015) x default Pf 3                                             |
| Clover silage             | 0.08  | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 1                                               | 0.37  | Barley green material rotational HR (DAR, NL, 2015) x default Pf 1                                             |
| Corn, field forage        | 0.08  | Barley green material rotational STMR (DAR, NL, 2015)                                                              | 0.37  | Barley green material rotational HR (DAR, NL, 2015)                                                            |

|                    |      |                                                                        |      |                                                                      |
|--------------------|------|------------------------------------------------------------------------|------|----------------------------------------------------------------------|
| Corn, field stover | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Corn, pop stover   | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Cowpea forage      | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Cowpea hay         | 0.23 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 2.9 | 1.07 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 2.9 |
| Grass, forage      | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Grass hay          | 0.28 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 3.5 | 1.30 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 3.5 |
| Grass silage       | 0.13 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 1.6 | 0.59 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 1.6 |
| Lespedeza forage   | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                  |

|                   |      |                                                                        |      |                                                                      |
|-------------------|------|------------------------------------------------------------------------|------|----------------------------------------------------------------------|
| Lespedeza hay     | 0.32 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 4   | 1.48 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 4   |
| Millet forage     | 0.08 | Barley green material STMR (DAR, NL, 2015)                             | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Millet, straw     | 0.06 | Barley straw rotational STMR (EFSA, 2015)                              | 0.33 | Barley straw rotational HR (EFSA, 2015)                              |
| Oat forage        | 0.08 | Barley green material STMR (DAR, NL, 2015)                             | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Oat hay           | 0.24 | Barley green material STMR (DAR, NL, 2015) x default Pf (3)            | 1.11 | Barley green material rotational HR (DAR, NL, 2015) x default Pf (3) |
| Pea vines (green) | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                  | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                  |
| Pea hay           | 0.28 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 3.5 | 1.30 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 3.5 |
| Pea silage        | 0.13 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 1.6 | 0.59 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 1.6 |

|                       |      |                                                                          |      |                                                                        |
|-----------------------|------|--------------------------------------------------------------------------|------|------------------------------------------------------------------------|
| Rape forage           | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Rice straw            | 0.06 | Barley straw rotational STMR (EFSA, 2015)                                | 0.33 | Barley straw rotational HR (EFSA, 2015)                                |
| Rye forage            | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Sorghum forage        | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Sorghum, grain stover | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Sorghum silage        | 0.05 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf (0.6) | 0.22 | Barley green material rotational HR (DAR, NL, 2015) x default Pf (0.6) |
| Trefoil forage        | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Trefoil hay           | 0.22 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 2.8   | 1.04 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 2.8   |
| Triticale forage      | 0.08 | Barley green material rotational                                         | 0.37 | Barley green material                                                  |

|                 |      | STMR (DAR, NL, 2015)                                                     |      | rotational HR (DAR, NL, 2015)                                          |
|-----------------|------|--------------------------------------------------------------------------|------|------------------------------------------------------------------------|
| Triticale hay   | 0.23 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 2.9   | 1.07 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 2.9   |
| Triticale straw | 0.06 | Barley straw rotational STMR (EFSA, 2015)                                | 0.33 | Barley straw rotational HR (EFSA, 2015)                                |
| Vetch forage    | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Vetch hay       | 0.22 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf 2.8   | 1.04 | Barley green material rotational HR (DAR, NL, 2015) x default Pf 2.8   |
| Wheat forage    | 0.08 | Barley green material rotational STMR (DAR, NL, 2015)                    | 0.37 | Barley green material rotational HR (DAR, NL, 2015)                    |
| Wheat hay       | 0.28 | Barley green material rotational STMR (DAR, NL, 2015) x default Pf (3.5) | 1.30 | Barley green material rotational HR (DAR, NL, 2015) x default Pf (3.5) |
| Carrot culls    | 0.11 | Potatoes rotational STMR (EFSA, 2015)                                    | 0.24 | Potatoes rotational HR (EFSA, 2015)                                    |
| Swede roots     | 0.11 | Potatoes rotational STMR (EFSA, 2015)                                    | 0.24 | Potatoes rotational HR (EFSA, 2015)                                    |

|                           |      |                                                       |      |                                     |
|---------------------------|------|-------------------------------------------------------|------|-------------------------------------|
| Turnip roots              | 0.11 | Potatoes rotational STMR (EFSA, 2015)                 | 0.24 | Potatoes rotational HR (EFSA, 2015) |
| Corn, field (maize) grain | 0.33 | Barley grain rotational STMR (EFSA, 2015)             | -    | -                                   |
| Corn,pop grain            | 0.33 | Barley grain rotational STMR (EFSA, 2015)             | -    | -                                   |
| Cotton undelinted seed    | 0.08 | Oilseed rape rotational STMR (EFSA, 2015)             | -    | -                                   |
| Cowpea seed               | 0.08 | Oilseed rape rotational STMR (EFSA, 2015)             | -    | -                                   |
| Lupin seed                | 0.08 | Oilseed rape rotational STMR (EFSA, 2015)             | -    | -                                   |
| Millet grain              | 0.33 | Barley grain rotational STMR (EFSA, 2015)             | -    | -                                   |
| Triticale grain           | 0.33 | Barley grain rotational STMR (EFSA, 2015)             | -    | -                                   |
| Beet sugar dried pulp     | 1.89 | Potatoes rotational STMR (EFSA, 2015) x default Pf 18 | -    | -                                   |
| Beet sugar ensiled pulp   | 0.32 | Potatoes rotational STMR (EFSA, 2015) x default Pf 3  | -    | -                                   |



|                            |      |                                                            |   |   |
|----------------------------|------|------------------------------------------------------------|---|---|
| Beet sugar molasses        | 2.94 | Potatoes rotational STMR (EFSA, 2015) x default Pf 28      | - | - |
| Canola meal                | 0.15 | Oilseed rape rotational STMR (EFSA, 2015) x default Pf 2   | - | - |
| Corn, field milled by-pdts | 0.33 | Barley grain rotational STMR (EFSA, 2015) x default Pf 1   | - | - |
| Corn,field hominy meal     | 1.98 | Barley grain rotational STMR (EFSA, 2015) x default Pf 6   | - | - |
| Corn, field gluten feed    | 0.83 | Barley grain rotational STMR (EFSA, 2015) x default Pf 2.5 | - | - |
| Corn, field gluten, meal   | 0.33 | Barley grain rotational STMR (EFSA, 2015) x default Pf 1   | - | - |
| Cotton, meal               | 0.10 | Oilseed rape rotational STMR (EFSA, 2015) x default Pf 1.3 | - | - |
| Flaxseed/linseed meal      | 0.15 | Oilseed rape rotational STMR (EFSA, 2015) x default Pf 2   | - | - |
| Lupin seed meal            | 0.08 | Oilseed rape rotational STMR                               | - | - |

|                                                    |      |                                                                                                             |      |                                                    |
|----------------------------------------------------|------|-------------------------------------------------------------------------------------------------------------|------|----------------------------------------------------|
|                                                    |      | (EFSA, 2015) x<br>default Pf 1.1                                                                            |      |                                                    |
| Peanut meal                                        | 0.15 | Oilseed rape<br>rotational STMR<br>(EFSA, 2015) x<br>default Pf 2                                           | -    | -                                                  |
| Rape meal                                          | 0.15 | Oilseed rape<br>rotational STMR<br>(EFSA, 2015) x<br>default Pf 2                                           | -    | -                                                  |
| Rice bran/pollard                                  | 3.30 | Barley grain<br>rotational STMR<br>(EFSA, 2015) x<br>default Pf 10                                          | -    | -                                                  |
| Sunflower meal                                     | 0.15 | Oilseed rape<br>rotational STMR<br>(EFSA, 2015) x<br>default Pf 2                                           | -    | -                                                  |
| <b>JMPR data adopted by GB in 2025 (HSE, 2025)</b> |      |                                                                                                             |      |                                                    |
| Bean, seed (dry)                                   | 3.93 | Beans (dry) STMR<br>(0.15 mg/kg)<br>(JMPR data) + pea<br>(dry) rotational HR<br>(3.78 mg/kg)<br>(JMPR data) | -    | -                                                  |
| Pea (field pea),<br>seed (dry)                     | 4.01 | Peas (dry) STMR<br>(0.228 mg/kg)<br>(JMPR data) + pea<br>(dry) rotational HR<br>(3.78 mg/kg)<br>(JMPR data) | -    | -                                                  |
| <b>Previous data, HSE, 2025</b>                    |      |                                                                                                             |      |                                                    |
| Barley straw                                       | 0.83 | Cereals straw<br>STMR (JMPR,<br>2016) + barley                                                              | 2.59 | Cereals straw HR<br>(JMPR, 2016) +<br>barley straw |

|              |      |                                                                                                        |      |                                                                                                      |
|--------------|------|--------------------------------------------------------------------------------------------------------|------|------------------------------------------------------------------------------------------------------|
|              |      | straw rotational HR<br>(0.227 mg/kg)<br>(JMPR, 2016)                                                   |      | rotational HR<br>(0.227 mg/kg)<br>(JMPR, 2016)                                                       |
| Oat straw    | 0.83 | Cereals straw<br>STMR (JMPR,<br>2016) + barley<br>straw rotational HR<br>(0.227 mg/kg)<br>(JMPR, 2016) | 2.59 | Cereals straw HR<br>(JMPR, 2016) +<br>barley straw<br>rotational HR<br>(0.227 mg/kg)<br>(JMPR, 2016) |
| Rye straw    | 0.83 | Cereals straw<br>STMR (JMPR,<br>2016) + barley<br>straw rotational HR<br>(0.227 mg/kg)<br>(JMPR, 2016) | 2.59 | Cereals straw HR<br>(JMPR, 2016) +<br>barley straw<br>rotational HR<br>(0.227 mg/kg)<br>(JMPR, 2016) |
| Wheat straw  | 0.83 | Cereals straw<br>STMR (JMPR,<br>2016) + barley<br>straw rotational HR<br>(0.227 mg/kg)<br>(JMPR, 2016) | 2.59 | Cereals straw HR<br>(JMPR, 2016) +<br>barley straw<br>rotational HR<br>(0.227 mg/kg)<br>(JMPR, 2016) |
| Barley grain | 1.55 | Cereals grain<br>STMR (JMPR,<br>2016) + barley<br>grain rotational HR<br>(1.26 mg/kg)<br>(JMPR, 2016)  | -    | -                                                                                                    |
| Oat grain    | 1.55 | Cereals grain<br>STMR (JMPR,<br>2016) + barley<br>grain rotational HR<br>(1.26 mg/kg)<br>(JMPR, 2016)  | -    | -                                                                                                    |
| Rye grain    | 1.55 | Cereals grain<br>STMR (JMPR,<br>2016) + barley<br>grain rotational HR                                  | -    | -                                                                                                    |

|                           |       |                                                                                                                                      |   |   |
|---------------------------|-------|--------------------------------------------------------------------------------------------------------------------------------------|---|---|
|                           |       | (1.26 mg/kg)<br>(JMPR, 2016)                                                                                                         |   |   |
| Sorghum grain             | 1.55  | Cereals grain<br>STMR (JMPR,<br>2016) + barley<br>grain rotational HR<br>(1.26 mg/kg)<br>(JMPR, 2016)                                | - | - |
| Wheat grain               | 1.55  | Cereals grain<br>STMR (JMPR,<br>2016) + barley<br>grain rotational HR<br>(1.26 mg/kg)<br>(JMPR, 2016)                                | - | - |
| Apple, pomace<br>wet      | 1.16  | Pome fruit STMR<br>(JMPR, 2016) x<br>default Pf (5)                                                                                  | - | - |
| Brewer's grain<br>dried   | 0.899 | Cereals grain<br>STMR (JMPR,<br>2016) + barley<br>grain rotational HR<br>(1.26 mg/kg)<br>(JMPR, 2016) x Pf<br>(0.58) (HSE,<br>2025b) | - | - |
| Citrus pulp               | 0.007 | Orange STMR<br>(JMPR, 2016)<br>(0.007 mg/kg) x<br>pulp (byproduct) Pf<br>(1)                                                         | - | - |
| Distillers grain<br>dried | 0.899 | Cereals grain<br>STMR (JMPR,<br>2016) + barley<br>grain rotational HR<br>(1.26 mg/kg)<br>(JMPR, 2016) x Pf                           | - | - |

|                           |       |                                                                                                                            |       |                                                                         |
|---------------------------|-------|----------------------------------------------------------------------------------------------------------------------------|-------|-------------------------------------------------------------------------|
|                           |       | (0.58) (HSE, 2025b)                                                                                                        |       |                                                                         |
| Wheat gluten meal         | 0.84  | Cereals grain STMR (JMPR, 2016) + barley grain rotational HR (1.26 mg/kg) (JMPR, 2016) x gluten Pf (0.54) (HSE, 2025b)     | -     | -                                                                       |
| Wheat milled by-pdts      | 1.40  | Cereals grain STMR (JMPR, 2016) + barley grain rotational HR (1.26 mg/kg) (JMPR, 2016) x middlings Pf (0.904) (HSE, 2025b) | -     | -                                                                       |
| <b>Current assessment</b> |       |                                                                                                                            |       |                                                                         |
| Cabbage, heads, leaves    | 0.486 | Head cabbage STMR (CXL) (0.249 mg/kg) + rotational HR (CXL) (0.237 mg/kg)                                                  | 0.768 | Head cabbage HR (CXL) (0.531 mg/kg) + rotational HR (CXL) (0.237 mg/kg) |
| Kale, leaves              | 0.432 | Kale STMR (current assessment)                                                                                             | 0.90  | Kale HR (current assessment)                                            |
| Soyabean forage           | 1.40  | Soyabean forage STMR (current assessment)                                                                                  | 2.4   | Soyabean forage HR (current assessment)                                 |
| Soyabean hay              | 4.00  | Soyabean hay STMR (current assessment)                                                                                     | 8.19  | Soyabean hay HR (current assessment)                                    |

|                          |       |                                                                                                                                                             |       |                                                                                                                        |
|--------------------------|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|------------------------------------------------------------------------------------------------------------------------|
| Soyabean silage          | 0.70  | Soyabean forage<br>STMR (1.40<br>mg/kg) (current<br>assessment) x<br>default Pf (0.5)                                                                       | 1.20  | Soyabean forage<br>HR (2.4 mg/kg)<br>(current<br>assessment) x<br>default Pf (0.5)                                     |
| Cassava/tapioca<br>roots | 0.408 | Potatoes STMR<br>(current<br>assessment)<br>(0.051 mg/kg) +<br>rotational HR<br>(current<br>assessment)<br>(0.357 mg/kg)                                    | 0.444 | Potatoes HR<br>(current<br>assessment)<br>(0.087 mg/kg) +<br>rotational HR<br>(current<br>assessment)<br>(0.357 mg/kg) |
| Potato culls             | 0.462 | Potatoes STMR<br>(CXL) (0.051<br>mg/kg) + rotational<br>HR (CXL) (0.411<br>mg/kg)                                                                           | 0.498 | Potatoes HR<br>(CXL) (0.087<br>mg/kg) +<br>rotational HR<br>(CXL) (0.411<br>mg/kg)                                     |
| Soybean seed             | 0.09  | Soyabean STMR<br>(current<br>assessment)                                                                                                                    | -     | -                                                                                                                      |
| Potato, process<br>waste | 0.430 | Potatoes STMR<br>(CXL) (0.051<br>mg/kg) + rotational<br>HR (CXL) (0.411<br>mg/kg) x wet peel<br>Pf 0.93 <sup>(a)</sup> (JMPR,<br>2016 <sup>(b)</sup> )      | -     | -                                                                                                                      |
| Potato, dried pulp       | 0.845 | Potatoes STMR<br>(CXL) (0.051<br>mg/kg) + rotational<br>HR (CXL) (0.411<br>mg/kg) x potato<br>flakes Pf 2.11 <sup>(a)</sup><br>(JMPR, 2016 <sup>(b)</sup> ) | -     | -                                                                                                                      |

|                |      |                                                                              |   |   |
|----------------|------|------------------------------------------------------------------------------|---|---|
| Soybean, meal  | 0.12 | Soyabean STMR<br>(current<br>assessment) (0.09<br>mg/kg) x default Pf<br>1.3 | - | - |
| Soybean, hulls | 1.17 | Soyabean STMR<br>(current<br>assessment) (0.09<br>mg/kg) + default Pf<br>13  | - | - |

(a) Processing factors have been used to refine the inputs for potato process waste and potato dried pulp. As HSE recommends the adoption of the CXL for potato, JMPR processing data have been used to generate processing factors specifically for DFA.

Data on wet peel have been used to generate processing factors for the potato process waste input. For potato dried pulp, JMPR data on dried flakes was considered. As outlined in the JMPR report (2016), potato flakes were dried to a moisture content of less than 9%, relating to a DM content of 91%. As outlined in the OECD guidance, potato dried pulp is defined as having a DM content of 88%. Therefore, to ensure the residue input is modified to the correct DM content, the processing factor for dried flakes has been adjusted from a DM content of 91% (Pf: 1.83) to 88% (Pf: 2.11).

(b) JMPR values are based on data presented in the 2016 JMPR report on flupyradifurone ([5.12 FLUPYRADIFURONE 285.pdf](#))

The highest and median calculated animal intakes based on the inputs above are reported below, Table 4.1-4.

**Table 4.1-4 Estimated animal intakes of DFA, expressed as flupyradifurone**

| Animal              | Median burden (mg/kg bw/day) | Maximum burden (mg/kg bw/day) | >0.1 mg /kg DM (Y/N) | Maximum burden (mg/kg DM) | Highest contributing commodity <sup>(a)</sup> | Previous maximum dietary burden (HSE, 2025b) (mg/kg DM) |
|---------------------|------------------------------|-------------------------------|----------------------|---------------------------|-----------------------------------------------|---------------------------------------------------------|
| Cattle (all diets)  | 0.127                        | 0.151                         | Y                    | 3.91                      | Kale leaves                                   | 8.59                                                    |
| Cattle (dairy only) | 0.127                        | 0.151                         | Y                    | 3.91                      | Kale leaves                                   | 7.50                                                    |

| <b>Animal</b>        | <b>Median burden (mg/kg bw/day)</b> | <b>Maximum burden (mg/kg bw/day)</b> | <b>&gt;0.1 mg /kg DM (Y/N)</b> | <b>Maximum burden (mg/kg DM)</b> | <b>Highest contributing commodity<sup>(a)</sup></b> | <b>Previous maximum dietary burden (HSE, 2025b) (mg/kg DM)</b> |
|----------------------|-------------------------------------|--------------------------------------|--------------------------------|----------------------------------|-----------------------------------------------------|----------------------------------------------------------------|
| Sheep (all diets)    | 0.118                               | 0.132                                | Y                              | 3.50                             | Rice bran/pollard                                   | 9.07                                                           |
| Sheep (ewe only)     | 0.111                               | 0.117                                | Y                              | 3.50                             | Bean seed                                           | 9.07                                                           |
| Swine (all diets)    | 0.071                               | 0.080                                | Y                              | 3.45                             | Kale leaves                                         | 7.57                                                           |
| Poultry (all diets)  | 0.153                               | 0.188                                | Y                              | 2.74                             | Soyabean hay                                        | 4.08                                                           |
| Poultry (layer only) | 0.153                               | 0.188                                | Y                              | 2.74                             | Soyabean hay                                        | 4.08                                                           |

(a) Considering the maximum dietary animal burden

Due to refinement via updated processing factors for potato, the maximum dietary burden for all animals is lower than that calculated previously (HSE, 2025b). Therefore, no consideration of DFA MRLs are required for products of animal origin as the notified uses will be accommodated by the existing DFA MRLs. However, DFA is included in the RD-RA for products of animal origin. As the dietary burden of flupyradifurone has increased for cattle and swine relevant to the previous assessment (HSE, 2025b), updated RD-RA values have been generated. Despite the dietary burden of DFA from direct consumption of DFA being lower relevant to the previous assessment (HSE, 2025b), further consideration of DFA residues in cattle and swine is required.



## 4.2 Nature of residues (Animal metabolism studies)

Metabolism in livestock was investigated in lactating goats (ruminants) and laying hens (poultry) for the approval of the active substance (EFSA, 2015). Metabolism in rat was also considered for approval of the active.

A summary of the available livestock metabolism data is presented below (EFSA, 2015):

*“Livestock metabolism studies conducted with <sup>14</sup>C-flupyradifurone labelled on the pyridinyl or furanone moiety at the dose rate of ca. 1 mg/kg bw over 5-6 days (goat) or 14 days (hen) were submitted. In ruminant, the degradation of the parent compound was limited, flupyradifurone accounting for 24%-35% in milk and kidney up to 81%-99% in fat. The metabolism was more extensive in hen, and flupyradifurone almost not detected in any poultry matrices in the <sup>14</sup>C-furanone study (<3% TRR) and in the range of 1% (liver) to 20% TRR (eggs) in the <sup>14</sup>C-pyridinyl study. The main components identified in hen were the hydroxy-flupyradifurone metabolites (18% TRR in eggs) and its sulphate conjugated in fat and liver (16-23% TRR) and the acetyl-AMCP metabolite in egg, fat and muscle (23 to 40% TRR). As for plants, the metabolic picture given by these studies is incomplete as the <sup>14</sup>C labelling on the difluoroethyl amino group is missing. The feeding studies conducted with animals dosed with flupyradifurone alone, revealed that DFA is a major marker of the residues in poultry matrices and in a lesser extent, in ruminant matrices. Based on these studies the residue definitions were proposed as ‘sum of flupyradifurone and DFA expressed as flupyradifurone’ for risk assessment and as flupyradifurone and as DFA as for plant two separate residue definitions were proposed for enforcement respectively. Cow and poultry feeding studies were provided where animals were dosed with the parent flupyradifurone only while, considering the residues anticipated in rotational crops, animals are expected to be mostly exposed to the DFA metabolite. The experts in the expert meeting TC 107 were therefore of the opinion that further feeding studies where animals are dosed with the DFA metabolite should be requested to derive reliable MRLs for products of animal origin. Provisionally and pending the submission of the requested data, MRL for animal products were derived from the feeding studies conducted with the parent flupyradifurone alone and considering a transfer factor approach proposed by the applicant.”*

**Table 4.2-1 Summary of the available animal metabolism studies**

| Animal  | Dosing rate     | Duration | Comment                             |
|---------|-----------------|----------|-------------------------------------|
| Poultry | 1.02 mg/kg bw/d | 14 days  | ca. 4.6N                            |
| Goat    | 1.00 mg/kg bw/d | 5 days   | ca. 1.4N                            |
| Pig     | Not required    | -        | Rat and ruminant metabolism similar |

The residue definition for risk assessment (RD-RA) in animals has been agreed as:

- Sum of flupyradifurone and DFA expressed as flupyradifurone

The residue definition for enforcement (RD-Enf) in animals has been agreed as:

Two separate residue definitions:

- 1) Flupyradifurone
- 2) DFA (expressed as DFA)

## 4.3 Magnitude of residues

### Flupyradifurone

Livestock feeding studies were undertaken on flupyradifurone in lactating cows (ruminants) for the approval of the active substance (EFSA, 2015).

Lactating cows were dosed with flupyradifurone, at a rate of 4.8, 23, 50, and 135 mg/kg DM (which equates to 0.18, 0.90, 1.84 and 4.90 mg/kg bw/day). The study duration was 29 day. Residues of flupyradifurone and metabolite DFA were analysed for.

A summary of the available feeding studies for flupyradifurone is presented below (EFSA, 2015):

*“The feeding studies conducted with animals dosed with flupyradifurone alone, revealed that DFA is a major marker of the residues in poultry matrices and in a lesser extent, in ruminant matrices. Based on these studies the residue definitions were proposed as ‘sum of flupyradifurone and DFA expressed as flupyradifurone’ for risk assessment and as flupyradifurone and as DFA as for plant two separate residue definitions were proposed for enforcement respectively. Cow and poultry feeding studies were provided where animals were dosed with the parent flupyradifurone only while, considering the residues anticipated in rotational crops, animals are expected to be mostly exposed to the DFA metabolite. The experts in the expert meeting TC 107 were therefore of the opinion that further feeding studies where animals are dosed with the DFA metabolite should be requested to derive reliable MRLs for products of animal origin. Provisionally and pending the submission of the requested data, MRL for animal products were derived from the feeding studies conducted with the parent flupyradifurone alone and considering a transfer factor approach proposed by the applicant.”*

### Estimation of flupyradifurone levels

For flupyradifurone the feeding studies dosed with flupyradifurone have been used to calculate chronic, acute and MRL values for cattle and swine as set out in Table 4.3-1.

**RD-Enf: Two separate residue definitions: 1.) Flupyradifurone 2.) DFA, expressed as DFA**

**RD-RA: Sum of flupyradifurone and DFA, expressed as flupyradifurone**

In **bold** MRL proposals exceed current GB MRLs.

**Table 4.3-1 MRL, STMR and HR proposals derived from the livestock feeding studies dosed with flupyradifurone**

| <b>Flupyradifurone</b>                                                                              |                              |                               |                                         |                         |                             |                         |                                   |                                 |
|-----------------------------------------------------------------------------------------------------|------------------------------|-------------------------------|-----------------------------------------|-------------------------|-----------------------------|-------------------------|-----------------------------------|---------------------------------|
| <b>Beef and Dairy cattle</b>                                                                        |                              |                               |                                         |                         |                             |                         |                                   |                                 |
| <b>Closest feeding level<sup>(a)</sup></b><br><b>0.18 mg/kg bw</b><br><b>0.5N rate (dairy only)</b> | <b>Residue closest level</b> | <b>at the feeding (mg/kg)</b> | <b>Estimated 1N<sup>(b)</sup></b>       | <b>value at (mg/kg)</b> | <b>MRL proposal (mg/kg)</b> | <b>CF<sup>(d)</sup></b> | <b>STMR<sub>Enf</sub> (mg/kg)</b> | <b>HR<sub>Enf</sub> (mg/kg)</b> |
|                                                                                                     | <b>Mean</b>                  | <b>Highest</b>                | <b>STMR<sub>Enf</sub><sup>(c)</sup></b> | <b>HR<sub>Enf</sub></b> |                             |                         |                                   |                                 |
| Muscle                                                                                              | 0.04                         | 0.05                          | 0.02                                    | 0.09                    | 0.1                         | n/a                     | 0.02                              | 0.09                            |
| Fat                                                                                                 | 0.02                         | 0.03                          | 0.01                                    | 0.05                    | 0.06                        | n/a                     | 0.01                              | 0.05                            |
| Liver                                                                                               | 0.15                         | 0.17                          | 0.07                                    | 0.46                    | 0.5                         | n/a                     | 0.07                              | 0.46                            |
| Kidney                                                                                              | 0.16                         | 0.22                          | 0.08                                    | 0.41                    | 0.4                         | n/a                     | 0.08                              | 0.41                            |
| Milk <sup>(e)</sup>                                                                                 | 0.02                         | 0.03 <sup>(f)</sup>           | 0.01                                    | 0.04                    | 0.05                        | n/a                     | 0.01                              | 0.04                            |
| <b>Pig</b>                                                                                          |                              |                               |                                         |                         |                             |                         |                                   |                                 |
| <b>Closest feeding level<sup>(a)</sup></b><br><b>0.18 mg/kg bw</b><br><b>3.1N rate (breeding)</b>   | <b>Residue closest level</b> | <b>at the feeding (mg/kg)</b> | <b>Estimated at 1N<sup>(b)</sup></b>    | <b>value (mg/kg)</b>    | <b>MRL proposal (mg/kg)</b> | <b>CF<sup>(d)</sup></b> | <b>STMR<sub>Enf</sub> (mg/kg)</b> | <b>HR<sub>Enf</sub> (mg/kg)</b> |
|                                                                                                     | <b>Mean</b>                  | <b>Highest</b>                | <b>STMR<sub>Enf</sub></b>               | <b>HR<sub>Enf</sub></b> |                             |                         |                                   |                                 |
| Muscle                                                                                              | 0.04                         | 0.05                          | 0.01                                    | 0.02                    | <b>0.015</b>                | n/a                     | 0.01                              | 0.02                            |
| Fat                                                                                                 | 0.02                         | 0.03                          | <0.01                                   | 0.01                    | 0.01*                       | n/a                     | <0.01                             | 0.01                            |
| Liver                                                                                               | 0.15                         | 0.17                          | 0.03                                    | 0.06                    | <b>0.06</b>                 | n/a                     | 0.03                              | 0.06                            |
| Kidney                                                                                              | 0.16                         | 0.22                          | 0.04                                    | 0.07                    | <b>0.08</b>                 | n/a                     | 0.04                              | 0.07                            |

- (a) Closest feeding level and N dose rate related to the maximum dietary burden (see Table 4.2-1)
- (b) Residues may have been derived by the application of a transfer factor, by interpolation or by linear regression.
- (c) Median dietary burden considered to derive the STMR values at 1N dose rate.
- (d) CF: conversion factor for risk assessment (see Section 4.4)
- (e) For milk, HR and STMR derived from the mean residue level observed at the relevant feeding level (FAO, 2009). The HR is used as the basis of the MRL. The STMR is used in both the acute and chronic consumer risk assessments.
- (f) Mean residue at the feeding level closest to the maximum dietary burden.

### **Estimation of DFA levels**

As the calculated dietary burden of flupyradifurone is higher for cattle and swine than that previously calculated (HSE, 2025b), consideration of DFA residues in cattle and swine is also required to calculate RD-RA values.

Therefore, the livestock feeding study dosed with flupyradifurone has been considered to calculate DFA residues arising from the consumption of flupyradifurone and the subsequent metabolism into DFA.

To calculate the DFA residues in cattle and swine arising from direct consumption of DFA, the livestock feeding study dosed with DFA has been considered.

**RD-Enf: Two separate residue definitions: 1.) Flupyradifurone 2.) DFA, expressed as DFA**

**RD-RA: Sum of flupyradifurone and DFA, expressed as flupyradifurone**

**Table 4.3-2 STMR and HR proposals derived from the livestock feeding studies dosed with flupyradifurone**  
DFA, expressed as flupyradifurone

| <b>Beef and Dairy cattle</b>                                                          |                              |                               |                                                    |           |                         |                     |                   |
|---------------------------------------------------------------------------------------|------------------------------|-------------------------------|----------------------------------------------------|-----------|-------------------------|---------------------|-------------------|
| <b>Closest feeding level<sup>(a)</sup><br/>0.18 mg/kg bw<br/>0.5N rate (dairy)</b>    | <b>Residue closest level</b> | <b>at the feeding (mg/kg)</b> | <b>Estimated value at 1N<sup>(b)</sup> (mg/kg)</b> |           | <b>CF<sup>(d)</sup></b> | <b>STMR (mg/kg)</b> | <b>HR (mg/kg)</b> |
|                                                                                       | <b>Mean</b>                  | <b>Highest</b>                | <b>STMR<sup>(c)</sup></b>                          | <b>HR</b> |                         |                     |                   |
| Muscle                                                                                | 0.02                         | 0.02                          | 0.02                                               | 0.03      | n/a                     | 0.02                | 0.03              |
| Fat                                                                                   | 0.02                         | 0.02                          | 0.02                                               | 0.03      | n/a                     | 0.02                | 0.03              |
| Liver                                                                                 | 0.02                         | 0.02                          | 0.02                                               | 0.03      | n/a                     | 0.02                | 0.03              |
| Kidney                                                                                | 0.02                         | 0.02                          | 0.01                                               | 0.04      | n/a                     | 0.01                | 0.04              |
| Milk <sup>(e)</sup>                                                                   | 0.02                         | 0.02 <sup>(f)</sup>           | 0.02                                               | 0.02      | n/a                     | 0.02                | 0.02              |
| <b>Swine</b>                                                                          |                              |                               |                                                    |           |                         |                     |                   |
| <b>Closest feeding level<sup>(a)</sup><br/>0.18 mg/kg bw<br/>3.1N rate (Breeding)</b> | <b>Residue closest level</b> | <b>at the feeding (mg/kg)</b> | <b>Estimated value at 1N<sup>(b)</sup> (mg/kg)</b> |           | <b>CF<sup>(d)</sup></b> | <b>STMR (mg/kg)</b> | <b>HR (mg/kg)</b> |
|                                                                                       | <b>Mean</b>                  | <b>Highest</b>                | <b>STMR</b>                                        | <b>HR</b> |                         |                     |                   |
| Muscle                                                                                | 0.02                         | 0.02                          | 0.02                                               | 0.02      | n/a                     | 0.02                | 0.02              |
| Fat                                                                                   | 0.02                         | 0.02                          | 0.02                                               | 0.02      | n/a                     | 0.02                | 0.02              |
| Liver                                                                                 | 0.02                         | 0.02                          | 0.02                                               | 0.02      | n/a                     | 0.02                | 0.02              |
| Kidney                                                                                | 0.02                         | 0.02                          | <0.01                                              | 0.01      | n/a                     | <0.01               | 0.01              |

- (a) Closest feeding level of flupyradifurone and N dose rate related to the maximum dietary burden (see Table 4.2-1)
- (b) Residues may have been derived by the application of a transfer factor, by interpolation or by linear regression.
- (c) Median dietary burden considered to derive the STMR values at 1N dose rate.
- (d) CF: conversion factor for risk assessment (see Section 4.4)
- (e) For milk, HR and STMR derived from the mean residue level observed at the relevant feeding level (FAO, 2009). The HR is used as the basis of the MRL. The STMR is used in both the acute and chronic consumer risk assessments.
- (f) Mean residue at the feeding level closest to the maximum dietary burden.

**Table 4.3-3 STMR and HR proposals derived from the livestock feeding studies dosed with DFA**

DFA, expressed as flupyradifurone

| <b>Beef and Dairy cattle</b>                                                           |                              |                               |                                                        |           |                         |                     |                   |
|----------------------------------------------------------------------------------------|------------------------------|-------------------------------|--------------------------------------------------------|-----------|-------------------------|---------------------|-------------------|
| <b>Closest feeding level<sup>(a)</sup><br/>0.099 mg/kg bw<br/>0.7N rate (dairy)</b>    | <b>Residue closest level</b> | <b>at the feeding (mg/kg)</b> | <b>Estimated value (mg/kg)<br/>at 1N<sup>(b)</sup></b> |           | <b>CF<sup>(d)</sup></b> | <b>STMR (mg/kg)</b> | <b>HR (mg/kg)</b> |
|                                                                                        | <b>Mean</b>                  | <b>Highest</b>                | <b>STMR<sup>(c)</sup></b>                              | <b>HR</b> |                         |                     |                   |
| Muscle                                                                                 | 0.21                         | 0.27                          | 0.27                                                   | 0.41      | n/a                     | 0.27                | 0.41              |
| Fat                                                                                    | 0.22                         | 0.39                          | 0.29                                                   | 0.60      | n/a                     | 0.29                | 0.60              |
| Liver                                                                                  | 0.16                         | 0.19                          | 0.22                                                   | 0.30      | n/a                     | 0.22                | 0.30              |
| Kidney                                                                                 | 0.32                         | 0.36                          | 0.41                                                   | 0.54      | n/a                     | 0.41                | 0.54              |
| Milk <sup>(e)</sup>                                                                    | 0.04                         | 0.05 <sup>(f)</sup>           | 0.05                                                   | 0.06      | n/a                     | 0.05                | 0.06              |
| <b>Swine</b>                                                                           |                              |                               |                                                        |           |                         |                     |                   |
| <b>Closest feeding level<sup>(a)</sup><br/>0.099 mg/kg bw<br/>1.2N rate (Breeding)</b> | <b>Residue closest level</b> | <b>at the feeding (mg/kg)</b> | <b>Estimated value (mg/kg)<br/>at 1N<sup>(b)</sup></b> |           | <b>CF<sup>(d)</sup></b> | <b>STMR (mg/kg)</b> | <b>HR (mg/kg)</b> |
|                                                                                        | <b>Mean</b>                  | <b>Highest</b>                | <b>STMR</b>                                            | <b>HR</b> |                         |                     |                   |
| Muscle                                                                                 | 0.21                         | 0.27                          | 0.15                                                   | 0.22      | n/a                     | 0.15                | 0.22              |
| Fat                                                                                    | 0.22                         | 0.39                          | 0.16                                                   | 0.40      | n/a                     | 0.16                | 0.40              |
| Liver                                                                                  | 0.16                         | 0.19                          | 0.12                                                   | 0.16      | n/a                     | 0.12                | 0.16              |
| Kidney                                                                                 | 0.32                         | 0.36                          | 0.23                                                   | 0.29      | n/a                     | 0.23                | 0.29              |



- (a) Closest feeding level of flupyradifurone and N dose rate related to the maximum dietary burden (see Table 4.2-1)
- (b) Residues may have been derived by the application of a transfer factor, by interpolation or by linear regression.
- (c) Median dietary burden considered to derive the STMR values at 1N dose rate.
- (d) CF: conversion factor for risk assessment (see Section 4.4)
- (e) For milk, HR and STMR derived from the mean residue level observed at the relevant feeding level (FAO, 2009). The HR is used as the basis of the MRL. The STMR is used in both the acute and chronic consumer risk assessments.
- (f) Mean residue at the feeding level closest to the maximum dietary burden.

The total residues of DFA arising in cattle and swine following exposure to flupyradifurone and DFA are presented below in Table 4.3-4. The resulting RD-RA values are calculated and compared to the RD-RA values from the previous assessment (HSE, 2025b) in Table 4.3-5. As the RD-RA values are lower than those calculated in the previous assessment (HSE, 2025b), the updated values have not been used in the consumer risk assessment in Section 7.

**Table 4.3-4 Total DFA residues arising in cattle and swine**

All residues expressed as flupyradifurone

| Animal matrix         | DFA residues arising from consumption of flupyradifurone |            | DFA residues arising from consumption of DFA |            | Total DFA residues |            |
|-----------------------|----------------------------------------------------------|------------|----------------------------------------------|------------|--------------------|------------|
|                       | STMR (mg/kg)                                             | HR (mg/kg) | STMR (mg/kg)                                 | HR (mg/kg) | STMR (mg/kg)       | HR (mg/kg) |
| <b>Beef and dairy</b> |                                                          |            |                                              |            |                    |            |
| Muscle                | 0.02                                                     | 0.03       | 0.27                                         | 0.41       | 0.29               | 0.44       |
| Fat                   | 0.02                                                     | 0.03       | 0.29                                         | 0.60       | 0.31               | 0.63       |
| Liver                 | 0.02                                                     | 0.03       | 0.22                                         | 0.30       | 0.24               | 0.33       |
| Kidney                | 0.01                                                     | 0.04       | 0.41                                         | 0.54       | 0.42               | 0.58       |
| Milk                  | 0.02                                                     | 0.02       | 0.05                                         | 0.06       | 0.07               | 0.08       |
| <b>Pig</b>            |                                                          |            |                                              |            |                    |            |
| Muscle                | 0.02                                                     | 0.02       | 0.15                                         | 0.22       | 0.17               | 0.24       |
| Fat                   | 0.02                                                     | 0.02       | 0.16                                         | 0.40       | 0.18               | 0.42       |
| Liver                 | 0.02                                                     | 0.02       | 0.12                                         | 0.16       | 0.14               | 0.18       |
| Kidney                | <0.01                                                    | 0.01       | 0.23                                         | 0.29       | 0.24               | 0.30       |

**Table 4.3-5 RD-RA residues arising in cattle and swine**

All residues expressed as flupyradifurone

RD-RA: Sum of flupyradifurone and DFA, expressed as flupyradifurone

| Animal matrix         | Total DFA    |            | Flupyradifurone |            | RD- RA       |            | RD- RA previous assessment (HSE, 2025b) |            |
|-----------------------|--------------|------------|-----------------|------------|--------------|------------|-----------------------------------------|------------|
|                       | STMR (mg/kg) | HR (mg/kg) | STMR (mg/kg)    | HR (mg/kg) | STMR (mg/kg) | HR (mg/kg) | STMR (mg/kg)                            | HR (mg/kg) |
| <b>Beef and dairy</b> |              |            |                 |            |              |            |                                         |            |
| Muscle                | 0.29         | 0.44       | 0.02            | 0.09       | 0.31         | 0.53       | 0.58                                    | 0.90       |
| Fat                   | 0.31         | 0.63       | 0.01            | 0.05       | 0.32         | 0.68       | 0.60                                    | 1.23       |
| Liver                 | 0.24         | 0.33       | 0.07            | 0.46       | 0.31         | 0.79       | 0.58                                    | 1.12       |
| Kidney                | 0.42         | 0.58       | 0.08            | 0.41       | 0.50         | 0.99       | 0.91                                    | 1.48       |
| Milk                  | 0.07         | 0.08       | 0.01            | 0.04       | 0.08         | 0.12       | 0.13                                    | 0.18       |
| <b>Pig</b>            |              |            |                 |            |              |            |                                         |            |
| Muscle                | 0.17         | 0.24       | 0.01            | 0.02       | 0.18         | 0.26       | 0.48                                    | 0.65       |
| Fat                   | 0.18         | 0.42       | <0.01           | 0.01       | 0.19         | 0.43       | 0.51                                    | 0.93       |
| Liver                 | 0.14         | 0.18       | 0.03            | 0.06       | 0.17         | 0.24       | 0.45                                    | 0.53       |
| Kidney                | 0.24         | 0.30       | 0.04            | 0.07       | 0.28         | 0.37       | 0.72                                    | 0.88       |

The DFA residues arising in cattle and swine from the direct consumption of flupyradifurone are the same as those previously calculated (HSE, 2025b) for all commodities except swine kidney. For swine kidney a HR of <0.01 mg/kg was previously calculated whereas the current evaluation results in a HR of 0.01 mg/kg. As the previous evaluation (HSE, 2025b) considered <LOQ values at LOQ as a worst case, the HR for swine kidney arising in this evaluation is considered acceptably covered by the previous evaluation (HSE, 2025b) including for MRL and consumer risk assessment purposes.

#### **4.4 Conversion factor for risk assessment for products of animal origin**

The residue definitions for enforcement (RD-Enf) and risk assessment (RD-RA) are different, however as stated in the EFSA Conclusion for flupyradifurone (EFSA, 2015) a conversion factor is not appropriate.

## 5 Residues in honey

Not applicable to import tolerances where no MRLs for the import of honey have been requested.

## 6 MRLs for products not covered in Sections 3 and 4

This section is to cover MRLs that can be extrapolated to other products included in Part 1 of the GB MRL Statutory Register but are not covered in Sections 3 and 4 of this ER/RO. Examples include MRLs for edible offals (other than liver and kidney) or MRLs to cover products derived from other species such as goat or equine.

**Table 6.1 MRL recommendations for additional products listed in Part 1 of the GB MRL Statutory Register and supported by the assessment**

Enforcement residue definitions for products of animal origin: Flupyradifurone

| Product code | Product                                             | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                          |
|--------------|-----------------------------------------------------|-------------------------|-------------------------------|-----------------------------------------------------------------------------------|
| 1011050      | Edible offals (other than liver and kidney) - swine | 0.05                    | 0.08                          | The MRL is extrapolated from swine kidney.<br><br>No health effects are expected. |

## 7 Consumer risk assessment

### 7.1 Dietary exposure

#### UK NEDIs and NESTIs

The UK NEDIs and NESTIs for the active substance and commodities listed in Table 7.1-1 have been calculated for ten consumer groups using the UK chronic and acute models (versions 1.1 and 1.2 respectively) as detailed in Regulatory Update 21/2005. The following assumptions have been made:

- For the NESTIs, upper range of normal (97.5<sup>th</sup> percentile) consumption of each individual crop which may have been treated.
- For the NEDIs, the 'Rees-Day' approach is taken which sums the two highest 97.5<sup>th</sup> percentile intakes and the mean intakes for all remaining commodities.
- All produce eaten which may have been treated has been treated and contains residues at the levels given in the table below.
- There is no loss of residue during transport or storage, or processing of foods prior to consumption.

#### Sum of flupyradifurone and DFA, expressed as flupyradifurone

The input values for the UK risk assessment for the sum of flupyradifurone and DFA, expressed as flupyradifurone are given in Table 7.1-1.

Uses considered as part of the current assessment are **in bold**.

**Table 7.1-1 Input values for the UK consumer risk assessment (sum of flupyradifurone and DFA, expressed as flupyradifurone)**

| Commodity        | Chronic risk assessment     |                                                          | Acute risk assessment |                                                    |
|------------------|-----------------------------|----------------------------------------------------------|-----------------------|----------------------------------------------------|
|                  | Input (mg/kg)               | Comment                                                  | Input (mg/kg)         | Comment                                            |
| <b>Risk DFA,</b> | <b>assessment expressed</b> | <b>residue definition: as flupyradifurone</b>            | <b>Sum of</b>         | <b>flupyradifurone and</b>                         |
| Grapefruit       | 0.053                       | Citrus fruit STMR (0.312 mg/kg) (HSE, 2025b) x Pf (0.17) | N/A                   | Acute assessment only performed for notified uses. |
| Lemons           | 0.054                       | Citrus fruit STMR (0.32 mg/kg) (HSE,                     |                       |                                                    |



|              |       |                                                                                      |  |  |
|--------------|-------|--------------------------------------------------------------------------------------|--|--|
|              |       | 2025b (JMPR, 2016 <sup>(a)</sup> )) x Pf (0.17)                                      |  |  |
| Limes        | 0.054 | Citrus fruit STMR (0.32 mg/kg) (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> )) x Pf (0.17) |  |  |
| Mandarins    | 0.053 | Citrus fruit STMR (0.312 mg/kg) (HSE, 2025b) x Pf (0.17)                             |  |  |
| Oranges      | 0.086 | Orange STMR (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> )) (0.505 mg/kg) x Pf (0.17)      |  |  |
| Almonds      | 0.07  | MRL†                                                                                 |  |  |
| Brazil nuts  | 0.07  | MRL†                                                                                 |  |  |
| Cashew nuts  | 0.07  | MRL†                                                                                 |  |  |
| Chestnuts    | 0.07  | MRL†                                                                                 |  |  |
| Coconuts     | 0.07  | MRL†                                                                                 |  |  |
| Hazelnuts    | 0.07  | MRL†                                                                                 |  |  |
| Pecan nuts   | 0.07  | MRL†                                                                                 |  |  |
| Pistachios   | 0.07  | MRL†                                                                                 |  |  |
| Walnuts      | 0.07  | MRL†                                                                                 |  |  |
| Peanuts      | 0.07  | MRL†                                                                                 |  |  |
| Apples       | 0.45  | Pome fruit STMR (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> ))                            |  |  |
| Pears        | 0.45  | Pome fruit STMR (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> ))                            |  |  |
| Apricots     | 0.07  | MRL†                                                                                 |  |  |
| Peaches      | 0.07  | MRL†                                                                                 |  |  |
| Plums        | 0.07  | MRL†                                                                                 |  |  |
| Cherries     | 0.07  | MRL†                                                                                 |  |  |
| Table grapes | 0.63  | Grape STMR (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> ))                                 |  |  |
| Wine grapes  | 0.63  | Grape STMR (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> ))                                 |  |  |

| <b>Strawberries</b>     | <b>0.525</b> | <b>Strawberry STMR<br/>(current<br/>assessment<br/>(JMPR, 2016<sup>(a)</sup>))</b>                                     | <b>0.94</b>  | <b>Strawberry HR<br/>(current<br/>assessment (JMPR,<br/>2016<sup>(a)</sup>))</b>                                  |
|-------------------------|--------------|------------------------------------------------------------------------------------------------------------------------|--------------|-------------------------------------------------------------------------------------------------------------------|
| Blackberries            | 6.3          | MRL†                                                                                                                   | N/A          | Acute assessment only performed for notified uses.                                                                |
| Loganberries            | 6.3          | MRL†                                                                                                                   |              |                                                                                                                   |
| Raspberries             | 6.3          | MRL†                                                                                                                   |              |                                                                                                                   |
| Gooseberries            | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| Blackcurrants           | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| Red currants            | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| White currants          | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| Avocados                | 1.05         | MRL†                                                                                                                   |              |                                                                                                                   |
| Bananas                 | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| Dates                   | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| Figs                    | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| Kiwi fruit              | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| Lychees                 | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| Mangoes                 | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| <b>Olives</b>           | 0.495        | Olive STMR (CXL)<br>(adopted in 2026)<br>(HSE, 2026)                                                                   | <b>3.31</b>  | <b>Olive HR (current<br/>assessment)</b>                                                                          |
| Passion fruit           | 0.07         | MRL†                                                                                                                   | N/A          | Acute assessment only performed for notified uses.                                                                |
| Pineapples              | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| Pomegranates            | 0.07         | MRL†                                                                                                                   |              |                                                                                                                   |
| Beetroot                | 0.28         | MRL†                                                                                                                   |              |                                                                                                                   |
| Carrots                 | 0.28         | MRL†                                                                                                                   |              |                                                                                                                   |
| Celeriac                | 0.28         | MRL†                                                                                                                   |              |                                                                                                                   |
| Horseradish             | 0.28         | MRL†                                                                                                                   |              |                                                                                                                   |
| Jerusalem<br>artichokes | 0.28         | MRL†                                                                                                                   |              |                                                                                                                   |
| Parsnips                | 0.28         | MRL†                                                                                                                   |              |                                                                                                                   |
| Radishes                | 0.28         | MRL†                                                                                                                   |              |                                                                                                                   |
| Salsify                 | 0.28         | MRL†                                                                                                                   |              |                                                                                                                   |
| Swedes                  | 0.28         | MRL†                                                                                                                   |              |                                                                                                                   |
| Turnips                 | 0.28         | MRL†                                                                                                                   |              |                                                                                                                   |
| <b>Yam</b>              | <b>0.417</b> | <b>Tropical root and<br/>tuber vegetables<br/>STMR (0.06 mg/kg)<br/>+ potatoes<br/>rotational HR<br/>(0.357 mg/kg)</b> | <b>0.453</b> | <b>Tropical root and<br/>tuber vegetables HR<br/>(0.096 mg/kg) +<br/>potatoes rotational<br/>HR (0.357 mg/kg)</b> |

|               |       | (current<br>assessment)                                                                                     |     | (current<br>assessment)                            |
|---------------|-------|-------------------------------------------------------------------------------------------------------------|-----|----------------------------------------------------|
| Garlic        | 0.19  | MRL†                                                                                                        | N/A | Acute assessment only performed for notified uses. |
| Onions        | 0.19  | MRL†                                                                                                        |     |                                                    |
| Spring onions | 0.19  | MRL†                                                                                                        |     |                                                    |
| Tomatoes      | 0.62  | Tomato STMR (0.305 mg/kg) + cucumber rotational HR (0.315 mg/kg) (HSE, 2025b)                               |     |                                                    |
| Peppers       | 0.933 | Pepper STMR (0.243 mg/kg) + cucumber rotational HR (0.69 mg/kg) (HSE, 2025b)                                |     |                                                    |
| Aubergines    | 0.887 | Aubergine STMR (0.197 mg/kg) + cucumber rotational HR (0.69 mg/kg) (HSE, 2025b)                             |     |                                                    |
| Marrows       | 0.443 | Cucumber/gherkin STMR (0.128 mg/kg) + cucumber rotational HR (0.315 mg/kg) (HSE, 2025b)                     |     |                                                    |
| Cucumbers     | 0.905 | Cucumber STMR (0.215 mg/kg) + cucumber rotational HR (0.69 mg/kg) (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> )) |     |                                                    |
| Gourd         | 0.443 | Cucumber/gherkin STMR (0.128 mg/kg) + cucumber rotational HR (0.315 mg/kg) (HSE, 2025b)                     |     |                                                    |
| Courgettes    | 0.443 | Cucumber/gherkin STMR (0.128 mg/kg) + cucumber rotational HR (0.315                                         |     |                                                    |

|                         |              |                                                                                                                    |              |                                                                                                                  |
|-------------------------|--------------|--------------------------------------------------------------------------------------------------------------------|--------------|------------------------------------------------------------------------------------------------------------------|
|                         |              | mg/kg) (HSE, 2025b)                                                                                                |              |                                                                                                                  |
| Melons                  | 0.46         | MRL†                                                                                                               |              |                                                                                                                  |
| Sweet corn              | 0.46         | MRL†                                                                                                               |              |                                                                                                                  |
| <b>Broccoli</b>         | <b>0.27</b>  | <b>Flowering brassica primary STMR (current assessment)</b>                                                        | <b>0.824</b> | <b>Flowering brassica primary HR (current assessment)</b>                                                        |
| <b>Cauliflower</b>      | <b>0.27</b>  | <b>Flowering brassica primary STMR (current assessment)</b>                                                        | <b>0.824</b> | <b>Flowering brassica primary HR (current assessment)</b>                                                        |
| <b>Brussels sprouts</b> | <b>0.277</b> | <b>Brussels sprouts primary STMR (0.16 mg/kg) + cabbage rotational HR (0.117 mg/kg) (current assessment)</b>       | <b>0.427</b> | <b>Brussels sprouts primary HR (0.31 mg/kg) + cabbage rotational HR (0.117 mg/kg) (current assessment)</b>       |
| <b>Head cabbage</b>     | <b>1.25</b>  | <b>Surrogate for kale. Highest STMR of head cabbage and kale: kale STMR (current assessment)</b>                   | <b>2.24</b>  | <b>Surrogate for kale. Highest HR of head cabbage and kale: kale HR (current assessment)</b>                     |
| <b>Chinese cabbage</b>  | <b>1.25</b>  | <b>Kale STMR (current assessment)</b>                                                                              | <b>2.24</b>  | <b>Kale HR (current assessment)</b>                                                                              |
| <b>Kohl Rabi</b>        | <b>0.358</b> | <b>Kohlrabi primary STMR (0.19 mg/kg) + cauliflower/ broccoli rotational HR (0.168 mg/kg) (current assessment)</b> | <b>0.418</b> | <b>Kohlrabi primary HR (0.25 mg/kg) + cauliflower/ broccoli rotational HR (0.168 mg/kg) (current assessment)</b> |
| <b>Cress</b>            | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b>                                | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b>                               |
| <b>Lettuce</b>          | <b>1.3</b>   | <b>Head lettuce primary STMR</b>                                                                                   | <b>3.813</b> | <b>Head lettuce primary HR (3.813</b>                                                                            |

|                      |             | (current assessment)<br>(JMPR, 2016(a))                                             |              | mg/kg) (current assessment)                                                        |
|----------------------|-------------|-------------------------------------------------------------------------------------|--------------|------------------------------------------------------------------------------------|
| <b>Spinach</b>       | <b>1.07</b> | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b> | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b> |
| Watercress           | 0.15        | MRL†                                                                                | N/A          | Acute assessment only performed for notified uses.                                 |
| Chicory              | 0.15        | MRL†                                                                                |              |                                                                                    |
| <b>Parsley</b>       | <b>1.07</b> | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b> | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b> |
| Beans with pods      | 2.63        | STMR (HSE, 2025a)                                                                   | N/A          | Acute assessment only performed for notified uses.                                 |
| Runner beans         | 1.21        | MRL†                                                                                |              |                                                                                    |
| Beans without pods   | 1.17        | STMR (HSE, 2025a)                                                                   |              |                                                                                    |
| Peas with pods       | 2.68        | STMR (HSE, 2025a)                                                                   |              |                                                                                    |
| Peas without pods    | 2.78        | STMR (HSE, 2025a)                                                                   |              |                                                                                    |
| Beansprouts          | 0.15        | MRL†                                                                                |              |                                                                                    |
| Asparagus            | 0.25        | MRL†                                                                                |              |                                                                                    |
| Bamboo shoots        | 0.25        | MRL†                                                                                |              |                                                                                    |
| Celery               | 0.25        | MRL†                                                                                |              |                                                                                    |
| Fennel               | 0.25        | MRL†                                                                                |              |                                                                                    |
| Globe artichokes     | 0.25        | MRL†                                                                                |              |                                                                                    |
| Leeks                | 0.25        | MRL†                                                                                |              |                                                                                    |
| Rhubarb              | 0.25        | MRL†                                                                                |              |                                                                                    |
| Cultivated mushrooms | 0.07        | MRL†                                                                                |              |                                                                                    |
| Beans                | 3.22        | STMR (HSE, 2025a)                                                                   |              |                                                                                    |
| Lentils              | 2.41        | MRL†                                                                                |              |                                                                                    |
| Dried Peas           | 3.605       | STMR (HSE, 2025a)                                                                   |              |                                                                                    |

|                            |              |                                                                                                                        |              |                                                                                                                     |
|----------------------------|--------------|------------------------------------------------------------------------------------------------------------------------|--------------|---------------------------------------------------------------------------------------------------------------------|
| <b>Oilseeds</b>            | 0.713        | Oilseed STMR (CXL) (adopted 2026 (HSE, 2026)                                                                           | <b>2.64</b>  | <b>Surrogate for soyabean. Soyabean primary HR (2.64 mg/kg) (current assessment)</b>                                |
| <b>Potatoes</b>            | <b>0.472</b> | <b>Potatoes primary STMR (0.061 mg/kg) + potatoes rotational HR (0.411 mg/kg) (current assessment (JMPR, 2016(a)))</b> | <b>0.551</b> | <b>Potatoes primary HR (0.14 mg/kg) + potatoes rotational HR (0.411 mg/kg) (current assessment (JMPR, 2016(a)))</b> |
| Tea (dried leaves)         | 0.35         | MRL†                                                                                                                   | N/A          | Acute assessment only performed for notified uses.                                                                  |
| Hops (dried 0.25% of beer) | 19           | MRL†                                                                                                                   |              |                                                                                                                     |
| Oats                       | 0.79         | Cereal grain STMR (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> ))                                                            |              |                                                                                                                     |
| Barley                     | 0.79         | Cereal grain STMR (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> ))                                                            |              |                                                                                                                     |
| Millet                     | 0.91         | MRL†                                                                                                                   |              |                                                                                                                     |
| Buckwheat                  | 0.91         | MRL†                                                                                                                   |              |                                                                                                                     |
| Maize                      | 0.91         | MRL†                                                                                                                   |              |                                                                                                                     |
| Wheat                      | 0.79         | Cereal grain STMR (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> ))                                                            |              |                                                                                                                     |
| Rice grain                 | 0.91         | MRL†                                                                                                                   |              |                                                                                                                     |
| Rye                        | 0.79         | Cereal grain STMR (HSE, 2025b (JMPR, 2016 <sup>(a)</sup> ))                                                            |              |                                                                                                                     |
| Poultry                    | 1.06         | Poultry liver STMR (HSE, 2025b)                                                                                        |              |                                                                                                                     |
| Meat fat                   | 0.71         | Sheep fat STMR (HSE, 2025b)                                                                                            |              |                                                                                                                     |
| Meat excl. poultry & offal | 0.71         | Sheep fat STMR (HSE, 2025b)                                                                                            |              |                                                                                                                     |

|                      |      |                                 |
|----------------------|------|---------------------------------|
| All types of kidney  | 1.14 | Sheep kidney STMR (HSE, 2025b)  |
| All types of liver   | 1.06 | Poultry liver STMR (HSE, 2025b) |
| Other types of offal | 1.14 | Sheep kidney STMR (HSE, 2025b)  |
| Eggs                 | 0.37 | Eggs STMR (HSE, 2025b)          |
| Milk                 | 0.15 | Sheep milk STMR (HSE, 2025b)    |
| Sugar beet           | 0.07 | MRL†                            |

(a) JMPR values are based on data presented in the 2016 JMPR report on flupyradifurone ([5.12 FLUPYRADIFURONE 285.pdf](#))

† Flu. MRL + DFA MRL (expressed as flu.)

N/A Acute risk assessment undertaken only for the uses considered as part of the current assessment

Model outputs for the UK chronic and acute models (versions 1.1 and 1.2 respectively) are presented in Appendix B.

## PRIMo

The PRIMo IEDIs and IESTIs for the sum of flupyradifurone and DFA, expressed as flupyradifurone and commodities listed in Table 7.1-2 have been calculated using PRIMo revision 3.1 – Pesticide Residues Intake Model.

The following assumptions have been made:

- All produce eaten which may have been treated, has been treated and contains residues at the levels given below.
- There is no loss of residue during transport, storage or processing of foods prior to consumption

### Sum of flupyradifurone and DFA, expressed as flupyradifurone

The input values for the PRIMo risk assessment are given in Table 7.1-2.

Uses considered as part of the current assessment are **In bold**.

**Table 7.1-2 Input values for the PRIMo consumer risk assessment (sum of flupyradifurone and DFA, expressed as flupyradifurone)**

| Commodity  | Chronic              | risk assessment                                                                     | Acute         | risk assessment                                    |
|------------|----------------------|-------------------------------------------------------------------------------------|---------------|----------------------------------------------------|
|            | Input (mg/kg)        | Comment                                                                             | Input (mg/kg) | Comment                                            |
| Risk DFA,  | assessment expressed | residue definition: as flupyradifurone                                              | Sum of        | flupyradifurone and                                |
| Grapefruit | 0.053                | Citrus fruit STMR (0.312 mg/kg) (HSE, 2025b) x Pf (0.17)                            | N/A           | Acute assessment performed only for notified uses. |
| Lemons     | 0.054                | Citrus fruit STMR (0.32 mg/kg) (HSE, 2025b (JMPR 2016 <sup>(a)</sup> )) x Pf (0.17) |               |                                                    |
| Limes      | 0.054                | Citrus fruit STMR (0.32 mg/kg) HSE, 2025b (JMPR 2016 <sup>(a)</sup> )) x Pf (0.17)  |               |                                                    |
| Mandarins  | 0.053                | Citrus fruit STMR (0.312 mg/kg) (HSE, 2025b) x Pf (0.17)                            |               |                                                    |
| Oranges    | 0.086                | Orange STMR HSE, 2025b (JMPR 2016 <sup>(a)</sup> )) (0.505 mg/kg) x Pf (0.17)       |               |                                                    |
| Apples     | 0.45                 | Pome fruit STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))                            |               |                                                    |
| Pears      | 0.45                 | Pome fruit STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))                            |               |                                                    |
| Quinces    | 0.45                 | Pome fruit STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))                            |               |                                                    |



|                          |              |                                                                                                                                   |              |                                                                                                                                |
|--------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------|
| Medlar                   | 0.45         | Pome fruit STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))                                                                          |              |                                                                                                                                |
| Loquats/Japanese medlars | 0.45         | Pome fruit STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))                                                                          |              |                                                                                                                                |
| Other pome fruits        | 0.45         | Pome fruit STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))                                                                          |              |                                                                                                                                |
| Table grapes             | 0.63         | Grape STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))                                                                               |              |                                                                                                                                |
| Wine grapes              | 0.63         | Grape STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))                                                                               |              |                                                                                                                                |
| <b>Strawberries</b>      | <b>0.525</b> | <b>Strawberry STMR (current assessment (JMPR, 2016<sup>(a)</sup>))</b>                                                            | <b>0.94</b>  | <b>Strawberry HR (current assessment (JMPR, 2016<sup>(a)</sup>))</b>                                                           |
| <b>Table olives</b>      | 0.495        | Olive STMR (CXL) (HSE, 2026)                                                                                                      | -            | Not performed as the notified use is covered by the adoption of the CXL (HSE, 2026)                                            |
| <b>Potatoes</b>          | <b>0.472</b> | <b>Potatoes primary STMR (0.061 mg/kg) + potatoes rotational HR (0.411 mg/kg) (current assessment (JMPR, 2016<sup>(a)</sup>))</b> | <b>0.551</b> | <b>Potatoes primary HR (0.14 mg/kg) + potatoes rotational HR (0.411 mg/kg) (current assessment (JMPR, 2016<sup>(a)</sup>))</b> |

|                                                 |              |                                                                                                                                 |              |                                                                                                                                |
|-------------------------------------------------|--------------|---------------------------------------------------------------------------------------------------------------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------|
| <b>Cassava roots/manioc</b>                     | <b>0.417</b> | <b>Tropical root and tuber vegetables<br/>STMR (0.06 mg/kg) + potatoes rotational HR (0.357 mg/kg)<br/>(current assessment)</b> | <b>0.453</b> | <b>Tropical root and tuber vegetables<br/>HR (0.096 mg/kg) + potatoes rotational HR (0.357 mg/kg)<br/>(current assessment)</b> |
| <b>Sweet potatoes</b>                           | <b>0.417</b> | <b>Tropical root and tuber vegetables<br/>STMR (0.06 mg/kg) + potatoes rotational HR (0.357 mg/kg)<br/>(current assessment)</b> | <b>0.453</b> | <b>Tropical root and tuber vegetables<br/>HR (0.096 mg/kg) + potatoes rotational HR (0.357 mg/kg)<br/>(current assessment)</b> |
| <b>Yams</b>                                     | <b>0.417</b> | <b>Tropical root and tuber vegetables<br/>STMR (0.06 mg/kg) + potatoes rotational HR (0.357 mg/kg)<br/>(current assessment)</b> | <b>0.453</b> | <b>Tropical root and tuber vegetables<br/>HR (0.096 mg/kg) + potatoes rotational HR (0.357 mg/kg)<br/>(current assessment)</b> |
| <b>Arrowroots</b>                               | <b>0.417</b> | <b>Tropical root and tuber vegetables<br/>STMR (0.06 mg/kg) + potatoes rotational HR (0.357 mg/kg)<br/>(current assessment)</b> | <b>0.453</b> | <b>Tropical root and tuber vegetables<br/>HR (0.096 mg/kg) + potatoes rotational HR (0.357 mg/kg)<br/>(current assessment)</b> |
| <b>Other tropical root and tuber vegetables</b> | <b>0.417</b> | <b>Tropical root and tuber vegetables<br/>STMR (0.06 mg/kg) + potatoes rotational HR (0.357 mg/kg)<br/>(current assessment)</b> | <b>0.453</b> | <b>Tropical root and tuber vegetables<br/>HR (0.096 mg/kg) + potatoes rotational HR (0.357 mg/kg)<br/>(current assessment)</b> |

|            |       |                                                                                                                     |     |                                                    |
|------------|-------|---------------------------------------------------------------------------------------------------------------------|-----|----------------------------------------------------|
| Tomatoes   | 0.62  | Tomato STMR (0.305 mg/kg) + cucumber rotational HR (0.315 mg/kg) (HSE, 2025b)                                       | N/A | Acute assessment performed only for notified uses. |
| Peppers    | 0.933 | Pepper STMR (0.243 mg/kg) + cucumber rotational HR (0.69 mg/kg) (HSE, 2025b)                                        |     |                                                    |
| Aubergines | 0.887 | Aubergine STMR (0.197 mg/kg) + cucumber rotational HR (0.69 mg/kg) (HSE, 2025b)                                     |     |                                                    |
| Cucumbers  | 0.905 | Cucumber STMR (0.215 mg/kg) + cucumber rotational HR (0.69 mg/kg) (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))          |     |                                                    |
| Gherkins   | 0.443 | Cucumber/gherkin STMR (0.128 mg/kg) + cucumber rotational HR (0.315 mg/kg) (HSE, 2025b (JMPR 2016 <sup>(a)</sup> )) |     |                                                    |
| Courgettes | 0.443 | Cucumber/gherkin STMR (0.128 mg/kg) + cucumber rotational HR (0.315 mg/kg) (HSE, 2025b)                             |     |                                                    |

|                                  |              |                                                                                                              |              |                                                                                                            |
|----------------------------------|--------------|--------------------------------------------------------------------------------------------------------------|--------------|------------------------------------------------------------------------------------------------------------|
| Other cucurbits – edible peel    | 0.443        | Cucumber/gherkin STMR (0.128 mg/kg) + cucumber rotational HR (0.315 mg/kg) (HSE, 2025b)                      |              |                                                                                                            |
| <b>Broccoli</b>                  | <b>0.27</b>  | <b>Flowering brassica primary STMR (current assessment)</b>                                                  | <b>0.824</b> | <b>Flowering brassica primary HR (current assessment)</b>                                                  |
| <b>Cauliflower</b>               | <b>0.27</b>  | <b>Flowering brassica primary STMR (current assessment)</b>                                                  | <b>0.824</b> | <b>Flowering brassica primary HR (current assessment)</b>                                                  |
| <b>Other flowering brassicas</b> | <b>0.27</b>  | <b>Flowering brassica primary STMR (current assessment)</b>                                                  | <b>0.824</b> | <b>Flowering brassica primary HR (current assessment)</b>                                                  |
| <b>Brussels sprouts</b>          | <b>0.277</b> | <b>Brussels sprouts primary STMR (0.16 mg/kg) + cabbage rotational HR (0.117 mg/kg) (current assessment)</b> | <b>0.427</b> | <b>Brussels sprouts primary HR (0.31 mg/kg) + cabbage rotational HR (0.117 mg/kg) (current assessment)</b> |
| <b>Head cabbage</b>              | <b>0.907</b> | <b>Head cabbage STMR (0.67 mg/kg) + rotational HR (0.237 mg/kg) (CXL) (JMPR 2016<sup>(a)</sup>)</b>          | <b>1.537</b> | <b>Head cabbage HR (1.3 mg/kg) + rotational HR (0.237 mg/kg) (CXL) (JMPR 2016<sup>(a)</sup>)</b>           |
| <b>Chinese cabbages/pe-tsai</b>  | <b>1.25</b>  | <b>Kale STMR (current assessment)</b>                                                                        | <b>2.24</b>  | <b>Kale HR (current assessment)</b>                                                                        |
| <b>Kales</b>                     | <b>1.25</b>  | <b>Kale STMR (current assessment)</b>                                                                        | <b>2.24</b>  | <b>Kale HR (current assessment)</b>                                                                        |

|                                           |              |                                                                                                                    |              |                                                                                                                  |
|-------------------------------------------|--------------|--------------------------------------------------------------------------------------------------------------------|--------------|------------------------------------------------------------------------------------------------------------------|
| <b>Kohl Rabi</b>                          | <b>0.358</b> | <b>Kohlrabi primary STMR (0.19 mg/kg) + cauliflower/ broccoli rotational HR (0.168 mg/kg) (current assessment)</b> | <b>0.418</b> | <b>Kohlrabi primary HR (0.25 mg/kg) + cauliflower/ broccoli rotational HR (0.168 mg/kg) (current assessment)</b> |
| <b>Lamb's lettuce/corn salads</b>         | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b>                                | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b>                               |
| <b>Lettuces</b>                           | <b>1.12</b>  | <b>Head lettuce primary STMR (0.803 mg/kg) (current assessment)</b>                                                | <b>3.813</b> | <b>Head lettuce primary HR (3.813 mg/kg) (current assessment)</b>                                                |
| <b>Cress and other sprouts and shoots</b> | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b>                                | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b>                               |
| <b>Land cress</b>                         | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b>                                | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b>                               |
| <b>Roman rocket/rucola</b>                | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b>                                | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b>                               |
| <b>Red mustards</b>                       | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b>                                | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b>                               |

|                                                     |              |                                                                                     |              |                                                                                    |
|-----------------------------------------------------|--------------|-------------------------------------------------------------------------------------|--------------|------------------------------------------------------------------------------------|
| <b>Baby leaf crops (including brassica species)</b> | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b> | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b> |
| <b>Other lettuce and other salad plants</b>         | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b> | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b> |
| <b>Spinaches</b>                                    | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b> | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b> |
| <b>Purslanes</b>                                    | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b> | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b> |
| <b>Chards/beet leaves</b>                           | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b> | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b> |
| <b>Other spinach and similar</b>                    | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b> | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b> |
| <b>Herbs and edible flowers</b>                     | <b>1.07</b>  | <b>Lettuce (open leaf varieties) primary STMR (1.07 mg/kg) (current assessment)</b> | <b>3.813</b> | <b>Lettuce (open leaf varieties) primary HR (3.813 mg/kg) (current assessment)</b> |
| <b>Rapeseeds/canola seeds</b>                       | <b>0.275</b> | <b>Oilseed rape (CXL) (HSE, 2026)</b>                                               | <b>N/A</b>   | <b>Acute assessment performed only for notified uses.</b>                          |

|                                  |             |                                                             |             |                                                                                     |
|----------------------------------|-------------|-------------------------------------------------------------|-------------|-------------------------------------------------------------------------------------|
| <b>Soyabeans</b>                 | <b>0.15</b> | <b>Soyabean primary STMR (current assessment)</b>           | <b>2.64</b> | <b>Soyabean primary HR (current assessment)</b>                                     |
| <b>Olives for oil production</b> | 0.495       | Olive STMR (CXL) (HSE, 2026)                                | -           | Not performed as the notified use is covered by the adoption of the CXL (HSE, 2026) |
| Oats                             | 0.79        | Cereal grain STMR ((HSE, 2025b (JMPR 2016 <sup>(a)</sup> )) | N/A         | Acute assessment performed only for notified uses.                                  |
| Barley                           | 0.79        | Cereal grain STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))  |             |                                                                                     |
| Wheat                            | 0.79        | Cereal grain STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))  |             |                                                                                     |
| Rye                              | 0.79        | Cereal grain STMR (HSE, 2025b (JMPR 2016 <sup>(a)</sup> ))  |             |                                                                                     |
| Swine: muscle/meat               | 0.48        | Swine muscle STMR (HSE, 2025b)                              |             |                                                                                     |
| Swine: fat                       | 0.51        | Swine fat STMR (HSE, 2025b)                                 |             |                                                                                     |
| Swine: liver                     | 0.45        | Swine liver STMR (HSE, 2025b)                               |             |                                                                                     |
| Swine: kidney                    | 0.72        | Swine kidney STMR (HSE, 2025b)                              |             |                                                                                     |
| Swine: edible offal              | 0.72        | Swine kidney STMR (HSE, 2025b)                              |             |                                                                                     |
| Swine: other products            | 0.72        | Swine kidney STMR (HSE, 2025b)                              |             |                                                                                     |

|                        |      |                                 |
|------------------------|------|---------------------------------|
| Bovine: muscle/meat    | 0.58 | Bovine muscle STMR (HSE, 2025b) |
| Bovine: fat            | 0.60 | Bovine fat STMR (HSE, 2025b)    |
| Bovine: liver          | 0.58 | Bovine liver STMR (HSE, 2025b)  |
| Bovine: kidney         | 0.91 | Bovine kidney STMR (HSE, 2025b) |
| Bovine: edible offal   | 0.91 | Bovine kidney STMR (HSE, 2025b) |
| Bovine: other products | 0.91 | Bovine kidney STMR (HSE, 2025b) |
| Sheep: muscle/meat     | 0.70 | Sheep muscle STMR (HSE, 2025b)  |
| Sheep: fat             | 0.71 | Sheep fat STMR (HSE, 2025b)     |
| Sheep: liver           | 0.91 | Sheep liver STMR (HSE, 2025b)   |
| Sheep: kidney          | 1.14 | Sheep kidney STMR (HSE, 2025b)  |
| Sheep: edible offal    | 1.14 | Sheep kidney STMR (HSE, 2025b)  |
| Sheep: other products  | 1.14 | Sheep kidney STMR (HSE, 2025b)  |
| Goat: muscle/meat      | 0.70 | Sheep muscle STMR (HSE, 2025b)  |
| Goat: fat              | 0.71 | Sheep fat STMR (HSE, 2025b)     |



|                        |      |                                  |
|------------------------|------|----------------------------------|
| Goat: liver            | 0.91 | Sheep liver STMR (HSE, 2025b)    |
| Goat: kidney           | 1.14 | Sheep kidney STMR (HSE, 2025b)   |
| Goat: edible offal     | 1.14 | Sheep kidney STMR (HSE, 2025b)   |
| Goat: other products   | 1.14 | Sheep kidney STMR (HSE, 2025b)   |
| Equine: muscle/meat    | 0.70 | Sheep muscle STMR (HSE, 2025b)   |
| Equine: fat            | 0.71 | Sheep fat STMR (HSE, 2025b)      |
| Equine: liver          | 0.91 | Sheep liver STMR (HSE, 2025b)    |
| Equine: kidney         | 1.14 | Sheep kidney STMR (HSE, 2025b)   |
| Equine: edible offal   | 1.14 | Sheep kidney STMR (HSE, 2025b)   |
| Equine: other products | 1.14 | Sheep kidney STMR (HSE, 2025b)   |
| Poultry: muscle/meat   | 0.58 | Poultry muscle STMR (HSE, 2025b) |
| Poultry: fat           | 0.12 | Poultry fat STMR (HSE, 2025b)    |
| Poultry: liver         | 1.06 | Poultry liver STMR (HSE, 2025b)  |
| Poultry: kidney        | 1.06 | Poultry liver STMR (HSE, 2025b)  |

|                                                  |      |                                 |
|--------------------------------------------------|------|---------------------------------|
| Poultry: edible offal                            | 1.06 | Poultry liver STMR (HSE, 2025b) |
| Poultry: other products                          | 1.06 | Poultry liver STMR (HSE, 2025b) |
| Other farmed terrestrial animals: muscle/meat    | 0.70 | Sheep muscle STMR (HSE, 2025b)  |
| Other farmed terrestrial animals: fat            | 0.71 | Sheep fat STMR (HSE, 2025b)     |
| Other farmed terrestrial animals: liver          | 0.91 | Sheep liver STMR (HSE, 2025b)   |
| Other farmed terrestrial animals: kidney         | 1.14 | Sheep kidney STMR (HSE, 2025b)  |
| Other farmed terrestrial animals: edible offal   | 1.14 | Sheep kidney STMR (HSE, 2025b)  |
| Other farmed terrestrial animals: other products | 1.14 | Sheep kidney STMR (HSE, 2025b)  |
| Cattle: milk                                     | 0.13 | Bovine milk STMR (HSE, 2025b)   |
| Sheep: milk                                      | 0.15 | Sheep milk STMR (HSE, 2025b)    |
| Goat: milk                                       | 0.15 | Sheep milk STMR (HSE, 2025b)    |
| Horse: milk                                      | 0.15 | Sheep milk STMR (HSE, 2025b)    |
| Others: milk                                     | 0.15 | Sheep milk STMR (HSE, 2025b)    |

|                                     |       |                                        |
|-------------------------------------|-------|----------------------------------------|
| Eggs                                | 0.37  | Poultry egg STMR (HSE, 2025b)          |
| Honey and other apiculture products | 0.359 | STMR (HSE, 2025a)                      |
| Beans (with pods)                   | 2.63  | JMPR STMR <sup>(a)</sup> (HSE, 2025a)  |
| Beans (without pods)                | 1.17  | JMPR STMR <sup>(a)</sup> (HSE, 2025a)  |
| Peas (with pods)                    | 2.68  | JMPR STMR <sup>(a)</sup> (HSE, 2025a)  |
| Peas (without pods)                 | 2.78  | JMPR STMR <sup>(a)</sup> (HSE, 2025a)  |
| Beans                               | 3.22  | JMPR STMR <sup>(a)</sup> (HSE, 2025a)  |
| Peas                                | 3.605 | JMPR STMR <sup>(a)</sup> (HSE, 2025a)  |
| Sesame seeds                        | 0.15  | JMPR STMR <sup>(b)</sup> (HSE, 2024)   |
| Sunflower seeds                     | 0.713 | JMPR STMR <sup>(b)</sup> (HSE, 2024)   |
| All other commodities               | MRL   | Flu. MRL + DFA MRL (expressed as flu.) |

(a) JMPR values are based on data presented in the 2016 JMPR report on flupyradifurone ([5.12 FLUPYRADIFURONE 285.pdf](#))

(b) 54<sup>th</sup> session CCPR

N/A - Acute risk assessment undertaken only for the uses considered as part of the current assessment

Model outputs for EFSA PRIMo revision 3.1 are presented in Appendix B.

## Conclusion

The highest UK NEDI for the sum of flupyradifurone and DFA, expressed as flupyradifurone was 75% of the ADI (toddler). The highest PRIMo IEDI was 62% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with flupyradifurone.

The highest UK NESTI for the sum of flupyradifurone and DFA, expressed as flupyradifurone was 64.3% of the ARfD (infant/head cabbage). The highest PRIMo IESTI was 97% of the ARfD (children/lettuces). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with flupyradifurone.

It should be noted that the adoption of the CXL for cauliflowers results in a PRIMo IESTI and NESTI of 100.4% of the ARfD (for children and infants, respectively). The adoption of the CXL for soyabeans results in a NESTI of 105.2% of the ARfD (4-6 year olds). Therefore, the adoption of the CXLs for cauliflowers and soyabean is not recommended.

## **7.2 Other routes of exposure**

Not applicable.

## 8 The conclusion of the competent authority

Sufficiently validated analytical methods for the determination of flupyradifurone and its metabolite DFA in plant and animal commodities, in line with the enforcement residue definition for products of plant and animal origin, are available to support the products under consideration in the MRL application.

Toxicological reference values for flupyradifurone were established for the approval of the active substance: an ADI of 0.064 mg/kg bw/day and an ARfD of 0.15 mg/kg bw. The reference values of flupyradifurone are also applicable to the metabolite DFA, as stated in the EFSA Conclusion (EFSA Conclusion, 2015).

Metabolism in primary crops was investigated following foliar spray in fruits (apple), pulses/oilseeds (cotton) and cereals (rice) and following bare soil application in fruit (tomato), root/tuber (potato) and cereals (rice) for the approval of flupyradifurone (EFSA, 2015). As a consistent metabolic pathway was observed across crops from at least 3 crop groups, the available data are sufficient to support all crops groups.

The residue definition for risk assessment (RD-RA) in plants has been agreed as:

- Sum of flupyradifurone and DFA expressed as flupyradifurone

The residue definition for enforcement (RD-Enf) in plants has been agreed as:

1. Flupyradifurone
2. DFA (expressed as DFA)

Sixteen greenhouse trials on strawberries, 26 outdoor trials on potatoes, 16 outdoor trials on flowering brassicas (8 cauliflower and 8 broccoli), 12 outdoor trials on head cabbage, 8 outdoor trials on Brussels sprouts, 6 outdoor trials on kale, 4 outdoor trials on kohlrabi, 22 outdoor trials on lettuce, 20 outdoor trials on soyabean and 8 trials on olives were submitted. The trials are supported by validated analytical methods and storage stability data.

It should be noted that the notified use on table olives and olives for oil production is covered by the CXLs adopted as GB MRLs in February 2026 (HSE, 2026), for both flupyradifurone and DFA.

Hydrolysis of flupyradifurone under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation were assessed for the approval of the active substance (EFSA, 2015). The hydrolysis data demonstrate that flupyradifurone is stable under standard conditions, therefore specific residue definitions for processed commodities are not required. No data are available on the stability of the major metabolite DFA under processing conditions (EFSA, 2015). However, as concluded during the active approval, the structural similarity between DFA and trifluoroacetic acid (TFA), which is very stable under hydrolysis conditions, suggests that DFA is unlikely to degrade under hydrolysis conditions (DAR, NL, 2015).

Newly submitted data on the magnitude of residues in processed commodities of soyabean and olive have been evaluated as part of this assessment.

For import tolerance based MRLs, residues in rotational crops are not typically considered. However, specific MRLs are established in the GB MRL Statutory Register for DFA that may arise in both primary and rotational crops from the use of flupyradifurone. Therefore, residues in rotational crops need to be considered further.

Flupyradifurone is very persistent in soil and has the potential to accumulate from year-on-year use. DFA is persistent in soil. As the approval of flupyradifurone was assessed in accordance with the data requirements outlined in Assimilated Regulation 544/2011, the accumulation of residues of flupyradifurone and its metabolite DFA in the soil has not been considered within this assessment. In addition, there are specific MRL supplementary requirements to address this issue, as outlined as footnotes in the GB MRL Statutory Register. Therefore, the consideration of the MRL supplementary information requirements for the accumulation and plateau concentrations will be addressed and considered separately.

Residues in rotational crops were considered for the approval of the active substance. The metabolism studies demonstrated that residues of flupyradifurone in rotational crops are expected to be  $>0.01$  mg/kg. Metabolism in rotational crops was found to be via a similar pathway to primary crops therefore specific residue definitions for rotational crops are not required.

The magnitude of flupyradifurone and its metabolite DFA in rotational crops was investigated for the approval of the active substance. After application to bare soil at 200 – 250 g a.s./ha, residues of flupyradifurone are expected to be  $<0.01$  mg/kg in all food commodities except lettuce (leafy veg) and barley straw (cereal straw), while residues of metabolite DFA, expressed as DFA, are expected to be  $>0.01$  mg/kg in all food commodities. As there is a separate residue definition for enforcement for the metabolite DFA, further consideration of rotational residues was made for the import tolerances.

New data on the magnitude of residues in rotational crops have been submitted on commodities relevant to the notified uses and have been evaluated as part of this

application. After application to bare soil at 175 – 300 g a.s./ha, residues of flupyradifurone are expected to be <0.01 mg/kg in root and tuber vegetables, flowering brassicas, head brassicas and oilseeds. Residues of DFA, expressed as DFA, are expected to be >0.01 mg/kg in root and tuber vegetables, flowering brassicas, head brassicas and oilseeds.

For the consideration of rotational residues present in crops imported from the USA/Canada (potatoes, tropical root and tuber vegetables and soyabean), rotational residues are scaled to the critical USA/Canadian GAP (1 x 410 g a.s./ha) notified under a previous ER/RO (HSE, 2025b). This results in expected rotational residues of flupyradifurone of <0.01 mg/kg and residues of DFA, expressed as DFA of >0.01 mg/kg in these crops.

For the consideration of rotational residues present in crops imported from the EU (flowering brassicas, head brassicas, Brussels sprouts, kale, Chinese cabbage, kohlrabi and leafy vegetables and herbs), rotational residues are scaled to the notified critical EU GAP (2 x 125 g a.s./ha) with a 25% crop interception. This results in expected rotational residues of flupyradifurone of <0.01 mg/kg in these crops except for leafy vegetables and herbs in which residues of flupyradifurone of >0.01 mg/kg are expected. Rotational residues of DFA, expressed as DFA, >0.01 mg/kg are expected in these crops.

The maximum livestock dietary burden for flupyradifurone exceeded the trigger of 0.1 mg/kg dry matter for all animals. The maximum livestock dietary burden for the metabolite DFA, expressed as flupyradifurone, exceeded the trigger of 0.1 mg/kg dry matter for all animals. On this basis further consideration of the residues in products of animal origin (POAO) was required.

Metabolism of flupyradifurone in livestock was considered for the approval of the active substance. The approval assessment concluded that the metabolic pathways in rodents and ruminants are comparable; the findings in ruminants can therefore be extrapolated to pigs.

The residue definition for risk assessment (RD-RA) in animals has been agreed as:

- Sum of flupyradifurone and DFA, expressed as flupyradifurone

The residue definition for enforcement (RD-Enf) in livestock has been agreed as:

1. Flupyradifurone
2. DFA (expressed as DFA)

A data gap was identified during approval of flupyradifurone (EFSA, 2015) for the submission of new animal feeding studies conducted with DFA. New feeding studies to address this data gap were submitted and evaluated under a previous ER/RO (HSE, 2025a).

Due to an increase in the livestock dietary burden and by consideration of the available feeding studies, MRLs for various POAO (products of animal origin) are recommended to be amended.

The highest UK NEDI for the sum of flupyradifurone and DFA, expressed as flupyradifurone was 75% of the ADI (toddler). The highest PRIMo IEDI was 62% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with flupyradifurone.

The highest UK NESTI for the sum of flupyradifurone and DFA, expressed as flupyradifurone was 64.3% of the ARfD (infant/head cabbage). The highest PRIMo IESTI was 97% of the ARfD (children/lettuces). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with flupyradifurone.

It should be noted that the adoption of the CXL for cauliflowers results in a PRIMo IESTI and NESTI of 100.4% of the ARfD (for children and infants, respectively). The adoption of the CXL for soyabeans results in a NESTI of 105.2% of the ARfD (4-6 year olds). Therefore, the adoption of the CXLs for cauliflowers and soyabean is not recommended.

HSE concludes that sufficient data have been provided to support the setting of new MRLs for the notified uses of flupyradifurone on strawberries, potatoes, tropical root and tuber vegetables, flowering brassicas, Brussels sprouts, head cabbage, kale, Chinese cabbages/pe-tsai, kohlrabi, lettuces and salad plants (except escaroles/broad-leaved endives), spinach and similar leaves, herbs and edible flowers and soyabean. The data are also sufficient to support new MRLs for products of animal origin. The new MRLs will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected.

As noted previously, the import tolerance request for olives is covered by the CXL adopted for flupyradifurone in 2025 and adopted as a GB MRL in February 2026 (HSE, 2026). The notified GAP is covered by both the flupyradifurone CXL and the DFA MRL linked to the flupyradifurone CXL.

HSE recommends that the MRLs outlined in Tables 8.1 and 8.2 are amended in the GB MRL Statutory Register.

**Table 8.1 MRLs recommended by HSE (flupyradifurone)**

| Product code       | Product                   | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments             |
|--------------------|---------------------------|-------------------------|-------------------------------|----------------------|
| <b>Enforcement</b> | <b>residue definition</b> | <b>for</b>              | <b>products of</b>            | <b>plant origin:</b> |
| Flupyradifurone    |                           |                         |                               |                      |



| <b>Product code</b> | <b>Product</b>                     | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>                                                                                                                                  |
|---------------------|------------------------------------|--------------------------------|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 0152000             | Strawberries                       | 0.4                            | 1.5                                  | The MRL is based on the CXL.<br><br>No health effects are expected.                                                                              |
| 0211000             | Potatoes                           | 0.01*                          | 0.05                                 | The MRL is based on the CXL.<br><br>No health effects are expected.                                                                              |
| 0212000             | Tropical root and tuber vegetables | 0.01*                          | 0.05                                 | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on potato.<br><br>No health effects are expected.                   |
| 0241000             | Flowering brassicas                | 0.01*                          | 0.6                                  | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on broccoli and cauliflower.<br><br>No health effects are expected. |

| <b>Product code</b> | <b>Product</b>           | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>                                                                                                                     |
|---------------------|--------------------------|--------------------------------|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0242010             | Brussels sprouts         | 0.01*                          | 0.09                                 | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |
| 0242020             | Head cabbages            | 0.01*                          | 1.5                                  | <p>The MRL is based on the CXL.</p> <p>No health effects are expected.</p>                                                          |
| 0243010             | Chinese cabbages/pe-tsai | 0.01*                          | 4                                    | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on kale.</p> <p>No health effects are expected.</p> |
| 0243020             | Kales                    | 0.01*                          | 4                                    | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |

| <b>Product code</b> | <b>Product</b>                       | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>                                                                                                                                              |
|---------------------|--------------------------------------|--------------------------------|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0244000             | Kohlrabies                           | 0.01*                          | 0.09                                 | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p>                          |
| 0251010             | Lamb's lettuces/corn salads          | 0.03                           | 6                                    | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on lettuce (open leaf varieties).</p> <p>No health effects are expected.</p> |
| 0251020             | Lettuces                             | 5                              | 6                                    | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p>                          |
| 0251040             | Cresses and other sprouts and shoots | 0.03                           | 6                                    | <p>The MRLs are based on the IT request.</p>                                                                                                                 |

| Product code                                                                            | Product                                                            | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                                     |
|-----------------------------------------------------------------------------------------|--------------------------------------------------------------------|-------------------------|-------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| 0251050                                                                                 | Land cresses                                                       | 0.03                    | 6                             | The MRLs are extrapolated from data on lettuce (open leaf varieties).<br><br>No health effects are expected.                 |
| 0251060                                                                                 | Roman rocket/rucola                                                | 0.03                    | 6                             |                                                                                                                              |
| 0251070                                                                                 | Red mustards                                                       | 0.03                    | 6                             |                                                                                                                              |
| 0251080                                                                                 | Baby leaf crops (including brassica species)                       | 0.03                    | 6                             |                                                                                                                              |
| 0251990                                                                                 | Others - Lettuce and other salad plants including brassica species | 0.03                    | 6                             |                                                                                                                              |
| 0252000                                                                                 | Spinach and similar leaves                                         | 0.03                    | 6                             |                                                                                                                              |
| 0256000                                                                                 | Herbs and edible flowers                                           | 0.03                    | 6                             |                                                                                                                              |
| 0401070                                                                                 | Soyabeans                                                          | 0.01*                   | 1.5                           | The MRL is based on the IT request.<br><br>The MRL is sufficiently supported by data.<br><br>No health effects are expected. |
| <b>Enforcement residue definition for products of animal origin:</b><br>Flupyradifurone |                                                                    |                         |                               |                                                                                                                              |

| Product code | Product                                             | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                          |
|--------------|-----------------------------------------------------|-------------------------|-------------------------------|-----------------------------------------------------------------------------------|
| 1011010      | Muscle – swine                                      | 0.01*                   | 0.015                         | The MRL is sufficiently supported by data.<br><br>No health effects are expected. |
| 1011030      | Liver – swine                                       | 0.04                    | 0.06                          | The MRL is sufficiently supported by data.<br><br>No health effects are expected. |
| 1011040      | Kidney – swine                                      | 0.05                    | 0.08                          | The MRL is sufficiently supported by data.<br><br>No health effects are expected. |
| 1011050      | Edible offals (other than liver and kidney) – swine | 0.05                    | 0.08                          | The MRL is extrapolated from swine kidney.<br><br>No health effects are expected. |

\* Indicates that the MRL is set at the limit of quantification/determination

**Table 8.2 MRLs recommended by HSE (difluoroacetic acid (DFA) (from the use of flupyradifurone)**

| Product code                         | Product                  | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments             |
|--------------------------------------|--------------------------|-------------------------|-------------------------------|----------------------|
| <b>Enforcement</b><br>DFA, expressed | <b>residue</b><br>as DFA | <b>definition</b>       | <b>for products of</b>        | <b>plant origin:</b> |

| <b>Product code</b> | <b>Product</b>                     | <b>Existing GB MRL (mg/kg)</b> | <b>New or amended GB MRL (mg/kg)</b> | <b>Comments</b>                                                                                                                                  |
|---------------------|------------------------------------|--------------------------------|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 0152000             | Strawberries                       | 0.03                           | 2                                    | The MRL is linked to the CXL for flupyradifurone.<br><br>No health effects are expected.                                                         |
| 0211000             | Potatoes                           | 0.09                           | 0.5                                  | The MRL is linked to the CXL for flupyradifurone.<br><br>No health effects are expected.                                                         |
| 0212000             | Tropical root and tuber vegetables | 0.09                           | 0.5                                  | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on potato.<br><br>No health effects are expected.                   |
| 0241000             | Flowering brassicas                | 0.02*                          | 0.5 <sup>†</sup>                     | The MRL is based on the IT request.<br><br>The MRL is extrapolated from data on broccoli and cauliflower.<br><br>No health effects are expected. |

| Product code | Product                  | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                                            |
|--------------|--------------------------|-------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0242010      | Brussels sprouts         | 0.02*                   | 0.3 <sup>†</sup>              | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |
| 0242020      | Head cabbages            | 0.02*                   | 0.5                           | <p>The MRL is linked to the CXL for flupyradifurone.</p> <p>No health effects are expected.</p>                                     |
| 0243010      | Chinese cabbages/pe-tsai | 0.02*                   | 0.5 <sup>†</sup>              | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on kale.</p> <p>No health effects are expected.</p> |
| 0243020      | Kales                    | 0.02*                   | 0.5 <sup>†</sup>              | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |

| Product code | Product                              | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                                                                     |
|--------------|--------------------------------------|-------------------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0244000      | Kohlrabies                           | 0.02*                   | 0.4                           | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p>                          |
| 0251010      | Lamb's lettuces/corn salads          | 0.04                    | 0.3                           | <p>The MRL is based on the IT request.</p> <p>The MRL is extrapolated from data on lettuce (open leaf varieties).</p> <p>No health effects are expected.</p> |
| 0251020      | Lettuces                             | 0.09                    | 0.4                           | <p>The MRL is linked to the CXL for flupyradifurone.</p> <p>No health effects are expected.</p>                                                              |
| 0251040      | Cresses and other sprouts and shoots | 0.04                    | 0.3                           | <p>The MRLs are based on the IT request.</p> <p>The MRLs are extrapolated from data on lettuce (open leaf varieties).</p>                                    |
| 0251050      | Land cresses                         | 0.04                    | 0.3                           |                                                                                                                                                              |



| Product code | Product                                                            | Existing GB MRL (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                                                                            |
|--------------|--------------------------------------------------------------------|-------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 0251060      | Roman rocket/rucola                                                | 0.04                    | 0.3                           | No health effects are expected.                                                                                                     |
| 0251070      | Red mustards                                                       | 0.04                    | 0.3                           |                                                                                                                                     |
| 0251080      | Baby leaf crops (including brassica species)                       | 0.04                    | 0.3                           |                                                                                                                                     |
| 0251990      | Others - Lettuce and other salad plants including brassica species | 0.04                    | 0.3                           |                                                                                                                                     |
| 0252000      | Spinach and similar leaves                                         | 0.04                    | 0.3                           |                                                                                                                                     |
| 0256000      | Herbs and edible flowers                                           | 0.04                    | 0.3                           |                                                                                                                                     |
| 0401070      | Soyabeans                                                          | 0.05                    | 0.6                           | <p>The MRL is based on the IT request.</p> <p>The MRL is sufficiently supported by data.</p> <p>No health effects are expected.</p> |

\* Indicates that the MRL is set at the limit of quantification/determination

† It should be noted that the higher MRL in the exporting country is owing to the impact of accumulation from year-on-year use being considered. GB MRLs at this time have not applied this consideration as it is not required by the data requirements that are applicable to flupyradifurone. Consideration of accumulation from year-on-year use will be addressed separately as part of the MRL supplementary information assessment.

## References

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## Appendix A – GAPs notified in the MRL application

| Crop and/or situation (a)                   | GB or Country For Import Tolerance | Product name   | F,G or I (b) | Pests or Group of pests controlled (c) | Preparation |                | Application       |                                     |                    |                                    | Application rate per treatment                  |                              |                        | PHI (days) (m) | Remarks              |
|---------------------------------------------|------------------------------------|----------------|--------------|----------------------------------------|-------------|----------------|-------------------|-------------------------------------|--------------------|------------------------------------|-------------------------------------------------|------------------------------|------------------------|----------------|----------------------|
|                                             |                                    |                |              |                                        | Type (d-f)  | Conc. a.s. (i) | method kind (f-h) | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | kg a.s /hL min-max (l)                          | Water (L/ha) min-max         | kg a.s./ha min-max (l) |                |                      |
| Strawberries                                | EU                                 | Sivanto SL 200 | G            | Aphids                                 | SL          | 200            | Foliar spray      | 12-89                               | 1-2                | 10                                 | 0.0125 – 0.0417                                 | 300-1000                     | 0.125                  | 3              |                      |
| Potatoes                                    | USA/Canada                         | Sivanto SL 200 | F            | Aphids, leaf-hoppers                   | SL          | 200            | Foliar spray      | All stages                          | 1-2                | 7                                  | 0.0218 - 0.218 (ground), 0.537 – 1.079 (aerial) | 94-467 (ground), 19 (aerial) | 0.102-0.205            | 7              | Max 0.410 kg a.s./ha |
| Root and tuber vegetable except sugar beets | USA/Canada                         | Sivanto SL 200 | F            | Aphids, Whitefly, leaf-hopper          | SL          | 200            | Foliar spray      | All stages                          | 1-2                | 7-10                               | 0.0362 – 0.218 (ground), 0.537 – 1.079 (aerial) | 94-282 (ground), 19 (aerial) | 0.102-0.205            | 7              | Max 0.410 kg a.s./ha |
| Flowering brassica                          | EU                                 | Sanium SL 25   | F            | Aphids                                 | SL          | 25             | Foliar spray      | 12-49                               | 2                  | 10                                 | 0.0125 – 0.025                                  | 500-1000                     | 0.125                  | 3              |                      |
| Head brassica                               | EU                                 | Sanium SL 25   | F            | Aphids                                 | SL          | 25             | Foliar spray      | 12-49                               | 2                  | 10                                 | 0.0125 – 0.025                                  | 500-1000                     | 0.125                  | 3              |                      |
| Brussels sprouts                            | EU                                 | Sanium SL 25   | F            | Aphids                                 | SL          | 25             | Foliar spray      | 12-49                               | 2                  | 10                                 | 0.0125 – 0.025                                  | 500-1000                     | 0.125                  | 3              |                      |
| Kale, Chinese cabbage                       | EU                                 | Sanium SL 25   | F            | Aphids                                 | SL          | 25             | Foliar spray      | 12-49                               | 2                  | 10                                 | 0.0125 – 0.025                                  | 500-1000                     | 0.125                  | 3              |                      |
| Kohlrabi                                    | EU                                 | Sanium SL 25   | F            | Aphids                                 | SL          | 25             | Foliar spray      | 12-49                               | 2                  | 10                                 | 0.0125 – 0.025                                  | 500-1000                     | 0.125                  | 3              |                      |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Crop and/or situation (a)                                                                                                          | GB or Country For Import Tolerance | Product name   | F,G or I (b) | Pests or Group of pests controlled (c) | Preparation |                | Application       |                                     |                    |                                    | Application rate per treatment                  |                              |                        | PHI (days) (m) | Remarks              |
|------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------|--------------|----------------------------------------|-------------|----------------|-------------------|-------------------------------------|--------------------|------------------------------------|-------------------------------------------------|------------------------------|------------------------|----------------|----------------------|
|                                                                                                                                    |                                    |                |              |                                        | Type (d-f)  | Conc. a.s. (i) | method kind (f-h) | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | kg a.s./hL min-max (l)                          | Water (L/ha) min-max         | kg a.s./ha min-max (l) |                |                      |
| Lettuce and salad plants except escaroles/broad-leaved endives<br><br>Spinaches and similar leaves<br><br>Herbs and edible flowers | EU                                 | Sivanto        | F            | Whitefly, Aphids, leaf-hopper          | SL          | 200            | Foliar spray      | All stages                          | 1-2                | 10                                 | 0.0125 – 0.0625                                 | 200-1000                     | 0.125                  | 3              | Max 0.250 kg a.s./ha |
| Soybean                                                                                                                            | USA/Canada                         | Sivanto SL 200 | F            | Aphids, whitefly, leaf-hopper          | SL          | 200            | Foliar spray      | All stages                          | 1-2                | 10                                 | 0.0362 – 0.218 (ground), 0.537 – 1.079 (aerial) | 94-282 (ground), 19 (aerial) | 0.102-0.205            | 21             | Max 0.410 kg a.s./ha |
| Table olive<br>Olive for oil production                                                                                            | EU                                 | Sivanto SL 200 | F            | Olive fruit fly, meadow frog hopper    | SL          | 200            | Foliar spray      | 55-85                               | 1                  | -                                  | 0.015 – 0.03                                    | 500-1200                     | 0.150                  | 14             |                      |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
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| <p>(a) For crops, the GB and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) State if the use is outdoor, field use (F) or glasshouse (G) or indoor use (I).</p> <p>(c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</p> <p>(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
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# Appendix B – UK models and Pesticide Residues Intake Model (PRIMo)

Table B.1 Chronic risk assessment undertaken using UK model version 1.1

|                           |  |                              |  |  |  |  |  |  |  |  |  |
|---------------------------|--|------------------------------|--|--|--|--|--|--|--|--|--|
| ADI                       |  | TOTAL INTAKES (mg/kg bw/day) |  |  |  |  |  |  |  |  |  |
| 0.064                     |  |                              |  |  |  |  |  |  |  |  |  |
| source of ADI (optional)  |  |                              |  |  |  |  |  |  |  |  |  |
| EFSA, 2025                |  |                              |  |  |  |  |  |  |  |  |  |
| Pesticide name (optional) |  |                              |  |  |  |  |  |  |  |  |  |
| Flupyradifurone           |  |                              |  |  |  |  |  |  |  |  |  |
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The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                |       |  |         |         |         |         |         |         |         |         |         |         |
|--------------------------------|-------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Pistachios                     | 0.07  |  | 0.00003 | L/C     | 0.00002 | L/C     | 0.00002 | L/C     | L/C     | 0.00001 | L/C     | L/C     |
| Walnuts                        | 0.07  |  | 0.00001 | L/C     | 0.00003 | 0.00000 | 0.00000 | 0.00000 | 0.00001 | 0.00001 | 0.00001 | 0.00000 |
| Peanuts                        | 0.07  |  | 0.00003 | 0.00004 | 0.00008 | 0.00006 | 0.00004 | 0.00005 | 0.00002 | 0.00003 | 0.00003 | 0.00001 |
| <b>Pome fruit</b>              |       |  |         |         |         |         |         |         |         |         |         |         |
| Apples                         | 0.45  |  | 0.00121 | 0.00379 | 0.00669 | 0.00425 | 0.00338 | 0.00185 | 0.00161 | 0.00150 | 0.00099 | 0.00048 |
| Pears                          | 0.45  |  | 0.00063 | 0.00115 | 0.00294 | 0.00164 | 0.00099 | 0.00083 | 0.00065 | 0.00085 | 0.00102 | 0.00054 |
| <b>Stone fruit</b>             |       |  |         |         |         |         |         |         |         |         |         |         |
| Apricots                       | 0.07  |  | 0.00003 | 0.00009 | 0.00007 | 0.00004 | 0.00003 | 0.00003 | 0.00002 | 0.00005 | 0.00003 | 0.00003 |
| Peaches                        | 0.07  |  | 0.00010 | 0.00009 | 0.00022 | 0.00011 | 0.00008 | 0.00005 | 0.00003 | 0.00007 | 0.00007 | 0.00003 |
| Plums                          | 0.07  |  | 0.00006 | 0.00003 | 0.00015 | 0.00009 | 0.00006 | 0.00002 | 0.00002 | 0.00005 | 0.00005 | 0.00001 |
| Cherries                       | 0.07  |  | 0.00003 | 0.00010 | 0.00007 | 0.00011 | 0.00004 | 0.00005 | 0.00004 | 0.00004 | 0.00002 | 0.00001 |
| <b>Berries and small fruit</b> |       |  |         |         |         |         |         |         |         |         |         |         |
| Table grapes                   | 0.63  |  | 0.00083 | 0.00104 | 0.00296 | 0.00136 | 0.00163 | 0.00070 | 0.00040 | 0.00128 | 0.00084 | 0.00029 |
| Wine grapes                    | 0.63  |  | 0.00620 | 0.00077 | 0.00056 | 0.00057 | 0.00020 | 0.00064 | 0.00222 | 0.00612 | 0.00419 | 0.00092 |
| <i>Wine</i>                    |       |  |         |         |         |         |         |         |         |         |         |         |
| Strawberries                   | 0.525 |  | 0.00031 | 0.00101 | 0.00105 | 0.00071 | 0.00047 | 0.00036 | 0.00027 | 0.00051 | 0.00054 | 0.00027 |
| Blackberries                   | 6.3   |  | 0.00071 | L/C     | 0.01225 | 0.00040 | 0.00208 | 0.00159 | 0.00060 | 0.00196 | 0.00166 | 0.00027 |
| Loganberries                   | 6.3   |  | 0.00051 | 0.00377 | 0.00713 | 0.00104 | 0.00318 | 0.00160 | 0.00102 | 0.00138 | 0.00100 | 0.00064 |
| Raspberries                    | 6.3   |  | 0.00261 | L/C     | 0.01499 | 0.00412 | 0.00634 | 0.00165 | 0.00043 | 0.00252 | 0.00526 | 0.00236 |
| Gooseberries                   | 0.07  |  | 0.00002 | 0.00004 | 0.00005 | 0.00002 | 0.00002 | 0.00002 | 0.00001 | 0.00005 | 0.00006 | 0.00002 |
| Blackcurrants                  | 0.07  |  | 0.00004 | 0.00008 | 0.00013 | 0.00013 | 0.00010 | 0.00007 | 0.00008 | 0.00002 | 0.00004 | 0.00002 |
| Red currants                   | 0.07  |  | 0.00001 | L/C     | 0.00006 | L/C     | 0.00000 | 0.00001 | 0.00000 | 0.00000 | 0.00002 | L/C     |
| White currants                 | 0.07  |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| <b>Miscellaneous fruit</b>     |       |  |         |         |         |         |         |         |         |         |         |         |
| Avocados                       | 1.05  |  | 0.00082 | L/C     | 0.00133 | L/C     | L/C     | L/C     | 0.00034 | 0.00072 | 0.00055 | L/C     |
| Bananas                        | 0.07  |  | 0.00014 | 0.00049 | 0.00046 | 0.00031 | 0.00024 | 0.00014 | 0.00010 | 0.00015 | 0.00012 | 0.00013 |
| Dates                          | 0.07  |  | 0.00002 | L/C     | 0.00003 | 0.00003 | 0.00001 | 0.00000 | L/C     | 0.00003 | 0.00005 | 0.00002 |
| Figs                           | 0.07  |  | 0.00002 | 0.00003 | 0.00003 | 0.00001 | 0.00001 | 0.00000 | 0.00000 | 0.00005 | 0.00001 | 0.00000 |
| Kiwi fruit                     | 0.07  |  | 0.00005 | L/C     | 0.00016 | 0.00014 | 0.00008 | 0.00007 | 0.00016 | 0.00009 | 0.00004 | 0.00001 |
| Lychees                        | 0.07  |  | 0.00002 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Mangoes                        | 0.07  |  | 0.00005 | L/C     | 0.00011 | 0.00010 | 0.00012 | 0.00004 | 0.00026 | 0.00004 | 0.00001 | L/C     |
| Olives                         | 0.495 |  | 0.00013 | L/C     | 0.00030 | 0.00030 | L/C     | 0.00003 | L/C     | 0.00010 | 0.00022 | L/C     |
| Passion fruit                  | 0.07  |  | 0.00001 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00002 | L/C     | L/C     |
| Pineapples                     | 0.07  |  | 0.00008 | 0.00036 | 0.00033 | 0.00047 | 0.00017 | 0.00010 | 0.00007 | 0.00008 | 0.00005 | 0.00004 |
| Pomegranates                   | 0.07  |  | 0.00008 | 0.00004 | 0.00006 | 0.00003 | 0.00003 | 0.00004 | 0.00000 | 0.00004 | 0.00004 | 0.00007 |

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|                                        |       |  |         |         |         |         |         |         |         |         |         |         |
|----------------------------------------|-------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| <b>Root and tuber vegetables</b>       |       |  |         |         |         |         |         |         |         |         |         |         |
| Beetroot                               | 0.28  |  | 0.00010 | L/C     | 0.00042 | 0.00011 | 0.00009 | 0.00010 | 0.00007 | 0.00013 | 0.00014 | 0.00005 |
| Carrots                                | 0.28  |  | 0.00020 | 0.00098 | 0.00069 | 0.00053 | 0.00034 | 0.00024 | 0.00028 | 0.00025 | 0.00027 | 0.00022 |
| Celeriac                               | 0.28  |  | 0.00010 | L/C     | L/C     | 0.00001 | 0.00002 | L/C     | L/C     | L/C     | L/C     | L/C     |
| Horseradish                            | 0.28  |  | 0.00000 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00000 | L/C     |
| Jerusalem artichokes                   | 0.28  |  | 0.00005 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Parsnips                               | 0.28  |  | 0.00009 | 0.00026 | 0.00033 | 0.00020 | 0.00014 | 0.00011 | 0.00007 | 0.00012 | 0.00017 | 0.00008 |
| Radishes                               | 0.28  |  | 0.00009 | L/C     | 0.00027 | L/C     | 0.00006 | 0.00003 | 0.00003 | 0.00008 | 0.00007 | 0.00003 |
| Salsify                                | 0.28  |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Swedes                                 | 0.28  |  | 0.00014 | 0.00078 | 0.00048 | 0.00019 | 0.00022 | 0.00017 | 0.00013 | 0.00014 | 0.00019 | 0.00014 |
| Turnips                                | 0.28  |  | 0.00010 | L/C     | 0.00028 | 0.00024 | 0.00016 | 0.00016 | 0.00009 | 0.00004 | 0.00017 | 0.00011 |
| Yam                                    | 0.417 |  | 0.00122 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| <b>Bulb vegetables</b>                 |       |  |         |         |         |         |         |         |         |         |         |         |
| Garlic                                 | 0.19  |  | 0.00001 | L/C     | 0.00001 | 0.00002 | 0.00003 | 0.00001 | 0.00002 | 0.00003 | 0.00003 | L/C     |
| Onions                                 | 0.19  |  | 0.00010 | 0.00021 | 0.00021 | 0.00018 | 0.00015 | 0.00014 | 0.00010 | 0.00014 | 0.00010 | 0.00006 |
| Spring onions                          | 0.19  |  | 0.00005 | L/C     | 0.00003 | 0.00012 | 0.00003 | 0.00002 | 0.00002 | 0.00005 | 0.00005 | 0.00002 |
| <b>Fruting vegetables</b>              |       |  |         |         |         |         |         |         |         |         |         |         |
| Tomatoes                               | 0.62  |  | 0.00085 | 0.00113 | 0.00163 | 0.00119 | 0.00114 | 0.00067 | 0.00083 | 0.00110 | 0.00090 | 0.00083 |
| Peppers                                | 0.933 |  | 0.00034 | L/C     | 0.00075 | 0.00038 | 0.00063 | 0.00030 | 0.00027 | 0.00057 | 0.00053 | 0.00018 |
| Aubergines                             | 0.887 |  | 0.00028 | L/C     | 0.00136 | 0.00067 | 0.00024 | 0.00047 | 0.00034 | 0.00055 | 0.00036 | L/C     |
| Marrows                                | 0.443 |  | 0.00022 | L/C     | 0.00069 | 0.00017 | 0.00027 | 0.00028 | 0.00011 | 0.00023 | 0.00061 | 0.00029 |
| Cucumbers                              | 0.905 |  | 0.00037 | 0.00020 | 0.00219 | 0.00140 | 0.00094 | 0.00047 | 0.00042 | 0.00049 | 0.00043 | 0.00016 |
| Gourd                                  | 0.443 |  | 0.00024 | L/C     | L/C     | L/C     | L/C     | 0.00012 | L/C     | 0.00009 | L/C     | L/C     |
| Courgettes                             | 0.443 |  | 0.00019 | 0.00066 | 0.00105 | 0.00057 | 0.00035 | 0.00019 | 0.00017 | 0.00025 | 0.00023 | 0.00020 |
| Melons                                 | 0.46  |  | 0.00114 | 0.00140 | 0.00241 | 0.00162 | 0.00140 | 0.00099 | 0.00127 | 0.00117 | 0.00137 | 0.00045 |
| Sweet corn                             | 0.46  |  | 0.00024 | 0.00047 | 0.00104 | 0.00050 | 0.00054 | 0.00023 | 0.00028 | 0.00026 | 0.00038 | 0.00016 |
| <b>Brassica vegetables</b>             |       |  |         |         |         |         |         |         |         |         |         |         |
| Broccoli                               | 0.27  |  | 0.00017 | 0.00031 | 0.00046 | 0.00033 | 0.00028 | 0.00019 | 0.00017 | 0.00018 | 0.00026 | 0.00009 |
| Cauliflower                            | 0.27  |  | 0.00024 | 0.00085 | 0.00059 | 0.00045 | 0.00023 | 0.00020 | 0.00023 | 0.00033 | 0.00031 | 0.00018 |
| Brussels sprouts                       | 0.277 |  | 0.00017 | 0.00065 | 0.00050 | 0.00040 | 0.00020 | 0.00026 | 0.00017 | 0.00022 | 0.00027 | 0.00013 |
| Head cabbage                           | 1.25  |  | 0.00068 | 0.00220 | 0.00213 | 0.00158 | 0.00093 | 0.00090 | 0.00066 | 0.00095 | 0.00145 | 0.00092 |
| Chinese cabbage                        | 1.25  |  | 0.00062 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00063 | 0.00044 | L/C     |
| Kohl Rabi                              | 0.358 |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| <b>Leaf vegetables and fresh herbs</b> |       |  |         |         |         |         |         |         |         |         |         |         |

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|                                 |       |  |         |         |         |         |         |         |         |         |         |         |
|---------------------------------|-------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Cress                           | 1.07  |  | 0.00004 | L/C     | 0.00005 | 0.00007 | 0.00002 | 0.00004 | 0.00003 | 0.00008 | 0.00010 | 0.00004 |
| Lettuce                         | 1.3   |  | 0.00081 | 0.00046 | 0.00111 | 0.00089 | 0.00094 | 0.00053 | 0.00057 | 0.00092 | 0.00070 | 0.00036 |
| Spinach                         | 1.07  |  | 0.00056 | 0.00107 | 0.00168 | 0.00092 | 0.00094 | 0.00067 | 0.00037 | 0.00073 | 0.00060 | 0.00038 |
| Watercress                      | 0.15  |  | 0.00002 | L/C     | L/C     | 0.00001 | 0.00001 | 0.00003 | L/C     | 0.00003 | 0.00005 | L/C     |
| Chicory                         | 0.15  |  | 0.00001 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00001 | L/C     | L/C     |
| Parsley                         | 1.07  |  | 0.00018 | L/C     | 0.00012 | L/C     | 0.00017 | 0.00004 | 0.00002 | 0.00018 | 0.00019 | 0.00039 |
| <b>Legume vegetables</b>        |       |  |         |         |         |         |         |         |         |         |         |         |
| Beans with pods                 | 2.63  |  | 0.00138 | 0.00317 | 0.00506 | 0.00346 | 0.00176 | 0.00094 | 0.00185 | 0.00104 | 0.00191 | 0.00082 |
| Runner Beans                    | 1.21  |  | 0.00075 | L/C     | 0.00179 | 0.00060 | 0.00090 | 0.00070 | 0.00060 | 0.00183 | 0.00119 | 0.00068 |
| Beans without pods              | 1.17  |  | 0.00051 | 0.00069 | 0.00281 | 0.00045 | 0.00123 | 0.00044 | 0.00049 | 0.00074 | 0.00094 | 0.00062 |
| Peas with pods                  | 2.68  |  | 0.00076 | L/C     | 0.00126 | 0.00339 | 0.00061 | 0.00077 | 0.00045 | 0.00068 | 0.00137 | L/C     |
| Peas without pods               | 2.78  |  | 0.00214 | 0.00668 | 0.00566 | 0.00388 | 0.00285 | 0.00204 | 0.00256 | 0.00242 | 0.00278 | 0.00202 |
| Beansprouts                     | 0.15  |  | 0.00006 | L/C     | 0.00013 | 0.00008 | 0.00008 | 0.00005 | 0.00004 | 0.00006 | 0.00009 | 0.00003 |
| <b>Stem vegetables</b>          |       |  |         |         |         |         |         |         |         |         |         |         |
| Asparagus                       | 0.25  |  | 0.00010 | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00005 | 0.00020 | 0.00011 | L/C     |
| Bamboo shoots                   | 0.25  |  | 0.00004 | L/C     | 0.00007 | L/C     | 0.00001 | 0.00006 | 0.00001 | 0.00005 | 0.00002 | L/C     |
| Celery                          | 0.25  |  | 0.00008 | 0.00011 | 0.00011 | 0.00007 | 0.00004 | 0.00006 | 0.00005 | 0.00011 | 0.00012 | 0.00003 |
| Fennel                          | 0.25  |  | 0.00010 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Globe artichokes                | 0.25  |  | 0.00008 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | 0.00005 | L/C     | L/C     |
| Leeks                           | 0.25  |  | 0.00012 | L/C     | 0.00016 | 0.00009 | 0.00008 | 0.00009 | 0.00006 | 0.00012 | 0.00014 | 0.00009 |
| Rhubarb                         | 0.25  |  | 0.00010 | 0.00018 | 0.00028 | 0.00006 | 0.00013 | 0.00003 | 0.00004 | 0.00009 | 0.00017 | 0.00010 |
| <b>Fungi mushrooms</b>          |       |  |         |         |         |         |         |         |         |         |         |         |
| Cultivated mushrooms            | 0.07  |  | 0.00003 | 0.00003 | 0.00007 | 0.00003 | 0.00003 | 0.00002 | 0.00003 | 0.00005 | 0.00003 | 0.00002 |
| <b>Pulses</b>                   |       |  |         |         |         |         |         |         |         |         |         |         |
| Beans                           | 3.22  |  | 0.00502 | 0.01902 | 0.01519 | 0.01079 | 0.00919 | 0.00674 | 0.00684 | 0.00564 | 0.00453 | 0.00314 |
| Lentils                         | 2.41  |  | 0.00173 | 0.00349 | 0.00445 | 0.00474 | 0.00156 | 0.00298 | 0.00121 | 0.00169 | 0.00121 | 0.00058 |
| dried Peas                      | 3.605 |  | 0.00244 | L/C     | 0.00629 | 0.00167 | 0.00264 | 0.00430 | 0.00231 | 0.00206 | 0.00385 | 0.00260 |
| <b>Oils</b>                     |       |  |         |         |         |         |         |         |         |         |         |         |
| <b>Oilseeds</b>                 | 0.713 |  | 0.00227 | 0.00450 | 0.00517 | 0.00510 | 0.00399 | 0.00288 | 0.00251 | 0.00334 | 0.00228 | 0.00275 |
| <b>Potatoes</b>                 | 0.472 |  | 0.00153 | 0.00526 | 0.00434 | 0.00390 | 0.00331 | 0.00252 | 0.00215 | 0.00167 | 0.00155 | 0.00150 |
| <i>canned/bottled Potatoes</i>  |       |  |         |         |         |         |         |         |         |         |         |         |
| <i>jacket Potatoes</i>          |       |  |         |         |         |         |         |         |         |         |         |         |
| <i>misc. Potato products</i>    |       |  |         |         |         |         |         |         |         |         |         |         |
| <i>dried (instant) Potatoes</i> |       |  |         |         |         |         |         |         |         |         |         |         |
| <i>boiled Potatoes</i>          |       |  |         |         |         |         |         |         |         |         |         |         |



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|                                   |      |  |         |         |         |         |         |         |         |         |         |         |
|-----------------------------------|------|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| <i>Crisps</i>                     |      |  |         |         |         |         |         |         |         |         |         |         |
| <i>Potato chips</i>               |      |  |         |         |         |         |         |         |         |         |         |         |
| <i>Tea (dried leaves)</i>         | 0.35 |  | 0.00007 | 0.00025 | 0.00009 | 0.00006 | 0.00004 | 0.00004 | 0.00005 | 0.00008 | 0.00007 | 0.00008 |
| <i>Hops (dried 0.25% of beer)</i> | 19   |  | 0.00118 | L/C     | L/C     | L/C     | L/C     | 0.00012 | 0.00104 | 0.00100 | 0.00118 | 0.00089 |
| <b>Cereals</b>                    |      |  |         |         |         |         |         |         |         |         |         |         |
| Oats                              | 0.79 |  | 0.00028 | 0.00173 | 0.00096 | 0.00061 | 0.00036 | 0.00028 | 0.00051 | 0.00050 | 0.00042 | 0.00045 |
| Barley                            | 0.79 |  | 0.00020 | L/C     | 0.00026 | 0.00027 | 0.00063 | 0.00015 | 0.00018 | 0.00020 | 0.00020 | 0.00012 |
| Millet                            | 0.91 |  | L/C     | L/C     | 0.00026 | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| Buckwheat                         | 0.91 |  | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     | L/C     |
| <i>Cornmeal &amp; Cornflour</i>   |      |  |         |         |         |         |         |         |         |         |         |         |
| Maize                             | 0.91 |  | 0.00006 | 0.00417 | 0.00066 | 0.00045 | 0.00017 | 0.00015 | 0.00015 | 0.00030 | 0.00013 | 0.00007 |
| Wheat                             | 0.79 |  | 0.00285 | 0.00222 | 0.00671 | 0.00702 | 0.00532 | 0.00394 | 0.00319 | 0.00336 | 0.00258 | 0.00273 |
| Rice                              | 0.91 |  | 0.00205 | 0.00255 | 0.00431 | 0.00338 | 0.00461 | 0.00358 | 0.00242 | 0.00183 | 0.00108 | 0.00044 |
| Rye                               | 0.79 |  | 0.00041 | 0.00108 | 0.00030 | 0.00035 | 0.00037 | 0.00020 | 0.00009 | 0.00047 | 0.00035 | 0.00012 |
| <b>Meat</b>                       |      |  |         |         |         |         |         |         |         |         |         |         |
| Poultry                           | 1.06 |  | 0.00172 | 0.00185 | 0.00319 | 0.00293 | 0.00190 | 0.00164 | 0.00160 | 0.00182 | 0.00172 | 0.00082 |
| Meat fat                          | 0.71 |  | 0.00012 | 0.00030 | 0.00051 | 0.00030 | 0.00021 | 0.00018 | 0.00017 | 0.00008 | 0.00015 | 0.00011 |
| Meat excl. poultry & offal        | 0.71 |  | 0.00134 | 0.00289 | 0.00294 | 0.00245 | 0.00217 | 0.00146 | 0.00148 | 0.00027 | 0.00127 | 0.00120 |
| All types of kidney               | 1.14 |  | 0.00033 | 0.00048 | 0.00154 | 0.00040 | 0.00027 | 0.00024 | 0.00034 | L/C     | 0.00054 | 0.00036 |
| All types of Liver                | 1.06 |  | 0.00050 | 0.00238 | 0.00253 | 0.00037 | 0.00046 | 0.00063 | 0.00031 | L/C     | 0.00073 | 0.00051 |
| Other types of offal              | 1.14 |  | 0.00079 | 0.00180 | 0.00248 | 0.00125 | 0.00107 | 0.00117 | 0.00053 | 0.00017 | 0.00087 | 0.00082 |
| Eggs                              | 0.37 |  | 0.00037 | 0.00176 | 0.00127 | 0.00086 | 0.00059 | 0.00053 | 0.00035 | 0.00040 | 0.00037 | 0.00052 |
| Milk                              | 0.15 |  | 0.00123 | 0.01464 | 0.00836 | 0.00442 | 0.00273 | 0.00177 | 0.00139 | 0.00145 | 0.00129 | 0.00176 |
| Sugar beet                        | 0.07 |  | 0.00098 | 0.00233 | 0.00390 | 0.00236 | 0.00220 | 0.00140 | 0.00135 | 0.00084 | 0.00074 | 0.00106 |
| <i>Refined sugar</i>              |      |  |         |         |         |         |         |         |         |         |         |         |

**Table B.2 Chronic risk assessment undertaken using PRIMo revision 3.1**

| Chronic risk assessment: JMPR methodology (IEDI/TMDI)          |                                |                   |                                         |                                              |                                  |                                          |                                  |                                          |                                  |                                   |                                                |
|----------------------------------------------------------------|--------------------------------|-------------------|-----------------------------------------|----------------------------------------------|----------------------------------|------------------------------------------|----------------------------------|------------------------------------------|----------------------------------|-----------------------------------|------------------------------------------------|
|                                                                |                                |                   | No of diets exceeding the ADI : --<br>- |                                              |                                  |                                          |                                  |                                          |                                  | Exposure resulting from           |                                                |
|                                                                | Calculated exposure (% of ADI) | MS Diet           | Exposure (µg/kg bw per day)             | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
| TMDI/NEDI/IEDI calculation (based on average food consumption) | 61.7%                          | NL toddler        | 39.49                                   | 12.1%                                        | Milk: Cattle                     | 10.0%                                    | Maize/corn                       | 7.6%                                     | Apples                           |                                   |                                                |
|                                                                | 33.8%                          | DE child          | 21.61                                   | 8.8%                                         | Apples                           | 5.2%                                     | Wheat                            | 4.0%                                     | Milk: Cattle                     |                                   |                                                |
|                                                                | 31.2%                          | NL child          | 19.95                                   | 5.1%                                         | Wheat                            | 5.0%                                     | Milk: Cattle                     | 4.1%                                     | Apples                           |                                   |                                                |
|                                                                | 31.0%                          | GEMS/Food G06     | 19.86                                   | 8.9%                                         | Wheat                            | 3.5%                                     | Tomatoes                         | 2.2%                                     | Rice                             |                                   |                                                |
|                                                                | 28.9%                          | FR child 3 15 yr  | 18.51                                   | 5.7%                                         | Wheat                            | 4.6%                                     | Milk: Cattle                     | 1.9%                                     | Beans (with pods)                |                                   |                                                |
|                                                                | 28.8%                          | DK child          | 18.45                                   | 6.8%                                         | Rye                              | 5.5%                                     | Wheat                            | 2.6%                                     | Milk: Cattle                     |                                   |                                                |
|                                                                | 27.8%                          | UK infant         | 17.77                                   | 7.9%                                         | Milk: Cattle                     | 3.2%                                     | Wheat                            | 2.5%                                     | Peas (without pods)              |                                   |                                                |
|                                                                | 26.9%                          | GEMS/Food G15     | 17.18                                   | 5.6%                                         | Wheat                            | 2.6%                                     | Potatoes                         | 1.4%                                     | Milk: Cattle                     |                                   |                                                |
|                                                                | 26.8%                          | RO general        | 17.14                                   | 6.3%                                         | Wheat                            | 2.8%                                     | Potatoes                         | 2.4%                                     | Milk: Cattle                     |                                   |                                                |
|                                                                | 26.4%                          | FR toddler 2 3 yr | 16.88                                   | 5.9%                                         | Milk: Cattle                     | 3.8%                                     | Wheat                            | 3.2%                                     | Beans (with pods)                |                                   |                                                |
|                                                                | 25.9%                          | GEMS/Food G08     | 16.60                                   | 5.0%                                         | Wheat                            | 2.9%                                     | Potatoes                         | 1.5%                                     | Swine: Muscle/meat               |                                   |                                                |
|                                                                | 25.9%                          | GEMS/Food G10     | 16.57                                   | 4.8%                                         | Wheat                            | 2.2%                                     | Potatoes                         | 1.8%                                     | Rice                             |                                   |                                                |
|                                                                | 25.7%                          | UK toddler        | 16.47                                   | 4.8%                                         | Wheat                            | 4.2%                                     | Milk: Cattle                     | 3.9%                                     | Beans                            |                                   |                                                |
|                                                                | 25.5%                          | IE adult          | 16.29                                   | 2.8%                                         | Wheat                            | 2.3%                                     | Sweet potatoes                   | 1.7%                                     | Potatoes                         |                                   |                                                |
|                                                                | 25.3%                          | GEMS/Food G07     | 16.21                                   | 5.2%                                         | Wheat                            | 2.8%                                     | Potatoes                         | 1.5%                                     | Wine grapes                      |                                   |                                                |
|                                                                | 23.9%                          | ES child          | 15.27                                   | 5.5%                                         | Wheat                            | 2.5%                                     | Milk: Cattle                     | 1.4%                                     | Potatoes                         |                                   |                                                |
|                                                                | 23.8%                          | GEMS/Food G11     | 15.22                                   | 4.5%                                         | Wheat                            | 2.9%                                     | Potatoes                         | 1.6%                                     | Milk: Cattle                     |                                   |                                                |
|                                                                | 23.6%                          | SE general        | 15.13                                   | 4.0%                                         | Bovine: Muscle/meat              | 4.0%                                     | Wheat                            | 3.1%                                     | Potatoes                         |                                   |                                                |
|                                                                | 22.0%                          | FI adult          | 14.10                                   | 15.7%                                        | Coffee beans                     | 0.9%                                     | Potatoes                         | 0.9%                                     | Rye                              |                                   |                                                |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                                                                                                                                         |                      |       |      |              |      |                                 |      |               |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------|------|--------------|------|---------------------------------|------|---------------|--|--|
| 20.1%                                                                                                                                                                                   | PT general           | 12.84 | 4.8% | Wheat        | 3.9% | Potatoes                        | 2.4% | Wine grapes   |  |  |
| 17.6%                                                                                                                                                                                   | DE general           | 11.28 | 2.5% | Milk: Cattle | 2.3% | Wheat                           | 1.7% | Apples        |  |  |
| 17.5%                                                                                                                                                                                   | IT toddler           | 11.17 | 8.2% | Wheat        | 2.1% | Other cereals                   | 1.4% | Tomatoes      |  |  |
| 17.4%                                                                                                                                                                                   | DE women<br>14-50 yr | 11.15 | 2.6% | Wheat        | 2.5% | Milk: Cattle                    | 1.8% | Apples        |  |  |
| 16.9%                                                                                                                                                                                   | NL general           | 10.83 | 2.4% | Wheat        | 1.8% | Potatoes                        | 1.7% | Milk: Cattle  |  |  |
| 15.5%                                                                                                                                                                                   | ES adult             | 9.90  | 2.9% | Wheat        | 1.1% | Lettuces                        | 1.0% | Milk: Cattle  |  |  |
| 15.4%                                                                                                                                                                                   | FR adult             | 9.89  | 2.7% | Wheat        | 2.3% | Wine grapes                     | 1.1% | Coffee beans  |  |  |
| 15.4%                                                                                                                                                                                   | FI 3 yr              | 9.86  | 3.5% | Potatoes     | 1.8% | Raspberries (red<br>and yellow) | 1.5% | Wheat         |  |  |
| 13.3%                                                                                                                                                                                   | FR infant            | 8.51  | 3.4% | Milk: Cattle | 2.0% | Beans (with pods)               | 1.4% | Potatoes      |  |  |
| 12.9%                                                                                                                                                                                   | IT adult             | 8.23  | 5.1% | Wheat        | 1.1% | Tomatoes                        | 1.0% | Other cereals |  |  |
| 12.6%                                                                                                                                                                                   | FI 6 yr              | 8.09  | 2.9% | Potatoes     | 1.3% | Raspberries (red<br>and yellow) | 1.2% | Wheat         |  |  |
| 12.0%                                                                                                                                                                                   | LT adult             | 7.70  | 2.3% | Potatoes     | 1.3% | Rye                             | 1.3% | Apples        |  |  |
| 11.8%                                                                                                                                                                                   | UK vegetarian        | 7.56  | 2.5% | Wheat        | 1.8% | Beans                           | 1.0% | Potatoes      |  |  |
| 10.8%                                                                                                                                                                                   | DK adult             | 6.91  | 1.4% | Wheat        | 1.1% | Milk: Cattle                    | 0.9% | Wine grapes   |  |  |
| 10.7%                                                                                                                                                                                   | UK adult             | 6.85  | 2.1% | Wheat        | 1.1% | Beans                           | 1.1% | Wine grapes   |  |  |
| 7.3%                                                                                                                                                                                    | PL general           | 4.64  | 2.5% | Potatoes     | 1.4% | Apples                          | 0.9% | Tomatoes      |  |  |
| 4.6%                                                                                                                                                                                    | IE child             | 2.94  | 1.4% | Wheat        | 0.7% | Milk: Cattle                    | 0.5% | Potatoes      |  |  |
| <b>Conclusion:</b><br>The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.<br>The long-term intake of residues of is unlikely to present a public health concern. |                      |       |      |              |      |                                 |      |               |  |  |

**Table B.3 Acute risk assessment undertaken using UK model version 1.2**

Acute Intakes (97.5th percentiles)

|                  |      |   | adult   |       | infant  |       | toddler |       | 4-6 year old child |       | 7-10 year old child |       |
|------------------|------|---|---------|-------|---------|-------|---------|-------|--------------------|-------|---------------------|-------|
| commodity        | HR   | P | NESTI   | %ARfD | NESTI   | %ARfD | NESTI   | %ARfD | NESTI              | %ARfD | NESTI               | %ARfD |
| <b>Oilseeds</b>  | 2.64 |   | 0.01582 | 10.5  | 0.03077 | 20.5  | 0.03559 | 23.7  | 0.03787            | 25.2  | 0.02883             | 19.2  |
| <b>Potatoes</b>  | 0.55 |   | 0.01324 | 8.8   | 0.08472 | 56.5  | 0.05858 | 39.1  | 0.04413            | 29.4  | 0.03034             | 20.2  |
| Strawberries     | 0.94 |   | 0.00247 | 1.6   | 0.00421 | 2.8   | 0.00460 | 3.1   | 0.00652            | 4.3   | 0.00454             | 3.0   |
| Olives           | 3.31 |   | 0.00279 | 1.9   | 0.00000 | 0.0   | 0.00603 | 4.0   | 0.01108            | 7.4   | 0.00372             | 2.5   |
| Yam              | 0.45 |   | 0.00986 | 6.6   | 0.00000 | 0.0   | 0.01973 | 13.2  | 0.00851            | 5.7   | 0.00000             | 0.0   |
| Broccoli         | 0.82 |   | 0.01060 | 7.1   | 0.01695 | 11.3  | 0.01725 | 11.5  | 0.02034            | 13.6  | 0.01848             | 12.3  |
| Cauliflower      | 0.82 |   | 0.01272 | 8.5   | 0.04774 | 31.8  | 0.02731 | 18.2  | 0.02866            | 19.1  | 0.01613             | 10.8  |
| Brussels sprouts | 0.43 |   | 0.00107 | 0.7   | 0.00312 | 2.1   | 0.00198 | 1.3   | 0.00300            | 2.0   | 0.00159             | 1.1   |
| Head cabbage     | 2.24 |   | 0.02717 | 18.1  | 0.09642 | 64.3  | 0.05700 | 38.0  | 0.07201            | 48.0  | 0.03940             | 26.3  |
| Chinese cabbage  | 2.24 |   | 0.03460 | 23.1  | 0.00000 | 0.0   | 0.02387 | 15.9  | 0.00000            | 0.0   | 0.04980             | 33.2  |
| Kohl Rabi        | 0.42 |   | 0.00000 | 0.0   | 0.00000 | 0.0   | 0.00000 | 0.0   | 0.00000            | 0.0   | 0.00000             | 0.0   |
| Cress            | 3.81 |   | 0.00065 | 0.4   | 0.00000 | 0.0   | 0.00110 | 0.7   | 0.00112            | 0.7   | 0.00062             | 0.4   |
| Lettuce          | 3.81 |   | 0.03763 | 25.1  | 0.04821 | 32.1  | 0.04602 | 30.7  | 0.06789            | 45.3  | 0.05127             | 34.2  |
| Spinach          | 3.81 |   | 0.00964 | 6.4   | 0.02007 | 13.4  | 0.01512 | 10.1  | 0.02163            | 14.4  | 0.01234             | 8.2   |
| Parsley          | 3.81 |   | 0.00249 | 1.7   | 0.00000 | 0.0   | 0.00118 | 0.8   | 0.00112            | 0.7   | 0.00417             | 2.8   |

|                  |      |   | 11-14 year old child |       | 15-18 year old child |       | vegetarian |       | Elderly - own home |       | Elderly - residential |       |
|------------------|------|---|----------------------|-------|----------------------|-------|------------|-------|--------------------|-------|-----------------------|-------|
| commodity        | HR   | P | NESTI                | %ARfD | NESTI                | %ARfD | NESTI      | %ARfD | NESTI              | %ARfD | NESTI                 | %ARfD |
| <b>Oilseeds</b>  | 2.64 |   | 0.02150              | 14.3  | 0.01852              | 12.3  | 0.02538    | 16.9  | 0.01251            | 8.3   | 0.01448               | 9.7   |
| <b>Potatoes</b>  | 0.55 |   | 0.02146              | 14.3  | 0.01602              | 10.7  | 0.01644    | 11.0  | 0.01309            | 8.7   | 0.01431               | 9.5   |
| Strawberries     | 0.94 |   | 0.00281              | 1.9   | 0.00218              | 1.5   | 0.00319    | 2.1   | 0.00247            | 1.6   | 0.00110               | 0.7   |
| Olives           | 3.31 |   | 0.00119              | 0.8   | 0.00107              | 0.7   | 0.00349    | 2.3   | 0.00253            | 1.7   | 0.00000               | 0.0   |
| Yam              | 0.45 |   | 0.01035              | 6.9   | 0.00422              | 2.8   | 0.00000    | 0.0   | 0.00000            | 0.0   | 0.00000               | 0.0   |
| Broccoli         | 0.82 |   | 0.01283              | 8.6   | 0.01151              | 7.7   | 0.01376    | 9.2   | 0.01050            | 7.0   | 0.00569               | 3.8   |
| Cauliflower      | 0.82 |   | 0.01372              | 9.1   | 0.01261              | 8.4   | 0.01911    | 12.7  | 0.01249            | 8.3   | 0.00834               | 5.6   |
| Brussels sprouts | 0.43 |   | 0.00124              | 0.8   | 0.00133              | 0.9   | 0.00166    | 1.1   | 0.00102            | 0.7   | 0.00074               | 0.5   |
| Head cabbage     | 2.24 |   | 0.03738              | 24.9  | 0.02679              | 17.9  | 0.03810    | 25.4  | 0.02965            | 19.8  | 0.02209               | 14.7  |
| Chinese cabbage  | 2.24 |   | 0.00460              | 3.1   | 0.05670              | 37.8  | 0.01973    | 13.2  | 0.00840            | 5.6   | 0.00000               | 0.0   |

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|           |      |  |         |      |         |      |         |      |         |      |         |      |
|-----------|------|--|---------|------|---------|------|---------|------|---------|------|---------|------|
| Kohl Rabi | 0.42 |  | 0.00561 | 3.7  | 0.00000 | 0.0  | 0.00000 | 0.0  | 0.00000 | 0.0  | 0.00000 | 0.0  |
| Cress     | 3.81 |  | 0.00052 | 0.3  | 0.00050 | 0.3  | 0.00144 | 1.0  | 0.00093 | 0.6  | 0.00062 | 0.4  |
| Lettuce   | 3.81 |  | 0.03178 | 21.2 | 0.03060 | 20.4 | 0.04190 | 27.9 | 0.02687 | 17.9 | 0.01504 | 10.0 |
| Spinach   | 3.81 |  | 0.01169 | 7.8  | 0.00620 | 4.1  | 0.01366 | 9.1  | 0.00814 | 5.4  | 0.00538 | 3.6  |
| Parsley   | 3.81 |  | 0.00110 | 0.7  | 0.00038 | 0.3  | 0.00457 | 3.0  | 0.00166 | 1.1  | 0.00160 | 1.1  |

**Table B.4 Acute risk assessment undertaken using PRIMo revision 3.1**

|                                                                                                           |                                                                                                    |                          |                            |                     |                                                                                                  |                          |                            |                     |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|--------------------------|----------------------------|---------------------|--------------------------------------------------------------------------------------------------|--------------------------|----------------------------|---------------------|
| Unprocessed commodities                                                                                   | <b>Results for children</b><br>No. of commodities for which ARfD/ADI is exceeded (IESTI):          |                          |                            |                     | <b>Results for adults</b><br>No. of commodities for which ARfD/ADI is exceeded (IESTI):          |                          |                            |                     |
|                                                                                                           | ---                                                                                                |                          |                            |                     | ---                                                                                              |                          |                            |                     |
|                                                                                                           | <b>IESTI</b>                                                                                       |                          |                            |                     | <b>IESTI</b>                                                                                     |                          |                            |                     |
|                                                                                                           | Highest % of ARfD/ADI                                                                              | Commodities              | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI                                                                            | Commodities              | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|                                                                                                           | 96.78%                                                                                             | Lettuces                 | 0 / 3.81                   | 145.16              | 48.04%                                                                                           | Chards/beet leaves       | 0 / 3.81                   | 72.06               |
|                                                                                                           | 65.71%                                                                                             | Kales                    | 0 / 2.24                   | 98.56               | 43.09%                                                                                           | Head cabbages            | 0 / 1.54                   | 64.63               |
|                                                                                                           | 57.45%                                                                                             | Spinaches                | 0 / 3.81                   | 86.18               | 37.80%                                                                                           | Chinese cabbages/pe-tsai | 0 / 2.24                   | 56.70               |
|                                                                                                           | 56.48%                                                                                             | Potatoes                 | 0 / 0.55                   | 84.72               | 30.87%                                                                                           | Lettuces                 | 0 / 3.81                   | 46.30               |
|                                                                                                           | 47.99%                                                                                             | Chinese cabbages/pe-tsai | 0 / 2.24                   | 71.98               | 28.75%                                                                                           | Kales                    | 0 / 2.24                   | 43.12               |
|                                                                                                           | 45.33%                                                                                             | Head cabbages            | 0 / 1.54                   | 68.00               | 14.13%                                                                                           | Beans                    | 0 / 3.22                   | 21.19               |
| 39.66%                                                                                                    | Chards/beet leaves                                                                                 | 0 / 3.81                 | 59.50                      | 13.49%              | Red mustards                                                                                     | 0 / 3.81                 | 20.24                      |                     |
| 39.23%                                                                                                    | Beans                                                                                              | 0 / 3.22                 | 58.85                      | 13.09%              | Broccoli                                                                                         | 0 / 0.82                 | 19.64                      |                     |
| 31.82%                                                                                                    | Cauliflowers                                                                                       | 0 / 0.82                 | 47.74                      | 12.74%              | Cauliflowers                                                                                     | 0 / 0.82                 | 19.11                      |                     |
| 22.85%                                                                                                    | Broccoli                                                                                           | 0 / 0.82                 | 34.28                      | 10.96%              | Potatoes                                                                                         | 0 / 0.55                 | 16.44                      |                     |
| 15.77%                                                                                                    | Peas                                                                                               | 0 / 3.61                 | 23.66                      | 10.17%              | Spinaches                                                                                        | 0 / 3.81                 | 15.25                      |                     |
| 14.49%                                                                                                    | Kohlrabies                                                                                         | 0 / 0.42                 | 21.74                      | 9.88%               | Lentils                                                                                          | 0 / 2.41                 | 14.82                      |                     |
| 10.77%                                                                                                    | Milk: Cattle                                                                                       | 0 / 0.13                 | 16.15                      | 8.56%               | Yams                                                                                             | 0 / 0.45                 | 12.84                      |                     |
| 10.76%                                                                                                    | Lentils                                                                                            | 0 / 2.41                 | 16.14                      | 7.98%               | Peas                                                                                             | 0 / 3.61                 | 11.97                      |                     |
| 10.24%                                                                                                    | Strawberries                                                                                       | 0 / 0.94                 | 15.36                      | 6.27%               | Sweet potatoes                                                                                   | 0 / 0.45                 | 9.41                       |                     |
| Expand/collapse list                                                                                      |                                                                                                    |                          |                            |                     |                                                                                                  |                          |                            |                     |
| <b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b> |                                                                                                    |                          |                            |                     |                                                                                                  |                          |                            |                     |
| Processed commodities                                                                                     | <b>Results for children</b><br>No of processed commodities for which ARfD/ADI is exceeded (IESTI): |                          |                            |                     | <b>Results for adults</b><br>No of processed commodities for which ARfD/ADI is exceeded (IESTI): |                          |                            |                     |
|                                                                                                           | ---                                                                                                |                          |                            |                     | ---                                                                                              |                          |                            |                     |
| <b>IESTI</b>                                                                                              |                                                                                                    |                          |                            | <b>IESTI</b>        |                                                                                                  |                          |                            |                     |

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|                                                                                                                                                                                                                                                                                       | MRL /<br>input for<br>RA |                              |           |                        | MRL /<br>input for<br>RA |                                |           |                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------------------------|-----------|------------------------|--------------------------|--------------------------------|-----------|------------------------|
|                                                                                                                                                                                                                                                                                       | Highest % of<br>ARfD/ADI | Processed commodities        | (mg/kg)   | Exposure<br>(µg/kg bw) | Highest % of<br>ARfD/ADI | Processed commodities          | (mg/kg)   | Exposure<br>(µg/kg bw) |
|                                                                                                                                                                                                                                                                                       | 79.1%                    | Chards/beet leaves / boiled  | 0 / 3.81  | 118.66                 | 31.8%                    | Chards/beet leaves /<br>boiled | 0 / 3.81  | 47.72                  |
|                                                                                                                                                                                                                                                                                       | 49.1%                    | Raspberries / juice          | 0 / 6.3   | 73.71                  | 22.89%                   | Cauliflowers / boiled          | 0 / 0.82  | 34.33                  |
|                                                                                                                                                                                                                                                                                       | 43.3%                    | Broccoli / boiled            | 0 / 0.82  | 64.91                  | 21.04%                   | Spinaches / frozen;<br>boiled  | 0 / 3.81  | 31.56                  |
|                                                                                                                                                                                                                                                                                       | 41.2%                    | Kales / boiled               | 0 / 2.24  | 61.78                  | 15.38%                   | Beans / canned                 | 0 / 3.22  | 23.07                  |
|                                                                                                                                                                                                                                                                                       | 38.2%                    | Cauliflowers / boiled        | 0 / 0.82  | 57.36                  | 13.22%                   | Broccoli / boiled              | 0 / 0.82  | 19.84                  |
|                                                                                                                                                                                                                                                                                       | 35.4%                    | Spinaches / frozen; boiled   | 0 / 3.81  | 53.04                  | 10.48%                   | Purslanes / boiled             | 0 / 3.81  | 15.72                  |
|                                                                                                                                                                                                                                                                                       | 34.3%                    | Potatoes / fried             | 0 / 0.55  | 51.49                  | 10.00%                   | Apples / juice                 | 0 / 0.45  | 15.00                  |
|                                                                                                                                                                                                                                                                                       | 18.7%                    | Potatoes / dried (flakes)    | 0 / 2.17  | 28.01                  | 8.74%                    | Wine grapes / juice            | 0 / 0.63  | 13.10                  |
|                                                                                                                                                                                                                                                                                       | 18.3%                    | Wine grapes / juice          | 0 / 0.63  | 27.50                  | 7.70%                    | Maize / oil                    | 0 / 22.75 | 11.56                  |
|                                                                                                                                                                                                                                                                                       | 17.8%                    | Oranges / juice              | 0 / 0.51  | 26.63                  | 6.37%                    | Peas / canned                  | 0 / 1.44  | 9.55                   |
|                                                                                                                                                                                                                                                                                       | 17.2%                    | Peas / canned                | 0 / 1.44  | 25.77                  | 5.93%                    | Kohlrabies / boiled            | 0 / 0.42  | 8.89                   |
|                                                                                                                                                                                                                                                                                       | 16.2%                    | Apples / juice               | 0 / 0.45  | 24.36                  | 5.74%                    | Cassava roots / boiled         | 0 / 0.45  | 8.61                   |
|                                                                                                                                                                                                                                                                                       | 15.2%                    | Sweet potatoes / boiled      | 0 / 0.45  | 22.82                  | 5.72%                    | Coffee beans / extraction      | 0 / 0.36  | 8.58                   |
|                                                                                                                                                                                                                                                                                       | 14.8%                    | Peas (without pods) / canned | 0 / 2.78  | 22.15                  | 5.69%                    | Head cabbages / canned         | 0 / 0.91  | 8.53                   |
|                                                                                                                                                                                                                                                                                       | 14.1%                    | Maize / oil                  | 0 / 22.75 | 21.19                  | 5.09%                    | Oranges / juice                | 0 / 0.51  | 7.64                   |
|                                                                                                                                                                                                                                                                                       | Expand/collapse list     |                              |           |                        |                          |                                |           |                        |
|                                                                                                                                                                                                                                                                                       |                          |                              |           |                        |                          |                                |           |                        |
| <b>Conclusion:</b><br>No exceedance of the toxicological reference value was identified for any unprocessed commodity.<br>A short term intake of residues of is unlikely to present a public health risk.<br>For processed commodities, no exceedance of the ARfD/ADI was identified. |                          |                              |           |                        |                          |                                |           |                        |

## **Appendix C - Detailed evaluation of the additional studies relied on**

### **C.1 Methods of analysis**

No additional studies submitted.



## **C.2 Mammalian toxicology**

No additional studies submitted.

## C.3 Residue data

### C.3.1 Nature and magnitude of residues in primary crops

#### C.3.1.1 Nature of residues

No additional studies submitted.

#### C.3.1.2 Magnitude of residues

##### C.3.1.2.1 Strawberry

###### C.3.1.2.1.1 Study 1

Reference: Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in northern France, Germany, Italy and Spain, [REDACTED] 2013, Study ID: 11-2093, Activity ID: RARVL098

Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991 Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)  
US EPA OCSPG Guideline No. 860.1500

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### Materials and methods

Four trials on strawberry were conducted in greenhouses in France, Germany, Italy and Spain using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2011 growing season.

'BYI 02960 200 SL' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 500 – 1000 L/ha of water with a 10 day RTI, 3 day PHI and final application at BBCH 85-87.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-89).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, fruit samples were taken before the last application (-0) and at 0, 1, 3, 4/5, 7, 9/10 and 13/14 days after the last application. Samples weighing at least 1 kg were collected from treated and untreated plots except two samples from trial 11-2093-01 (France). As these were the 0 day PHI samples and a sufficient quantity was sampled to allow analysis, it is not considered that this deviation impacted the validity of the trial. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 205 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in strawberry.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to strawberries (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 82-93% and 76-86%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

Residues of flupyradifurone in strawberries 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.018 – 0.16 mg/kg.

Residues of DFA in strawberries 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between <0.02 – 0.053 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.1.1-1.

**Table C.3.1.2.1.1-1 Residue trials on strawberry**

Reference: Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in northern France, Germany, Italy and Spain, [REDACTED] 2013, Study ID: 11-2093, Activity ID: RARVL098

GLP: Yes Sample storage conditions: 205 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Strawberry / Fruit Analytical method: Method 01304

Indoor/outdoor: Indoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 SL 200 Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year                       | Commodity<br>Variety                            | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest    | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |       |                                                                          |                             | PHI<br>(days) | Remarks |
|----------------------------------------------------|-------------------------------------------------|-------------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-------|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                                                    |                                                 |                                                                   | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA   | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |
| 11-2093-01<br>F-80700<br>Cremery<br>France<br>2011 | Strawberry<br>Darselect<br>(hanging<br>variety) | 1. 06-04-2010<br>2. 15-04 to 11-05-2011<br>3. 14-06 to 12-07-2011 | 125<br>125                        | 500<br>500      | 25<br>25         | 26-04-2011<br>06-05-2011                                  | 10                                            | BBCH 85                                 | Fruit               | <0.01               | <0.02 | <0.03                                                                    | <0.007                      | -0            |         |
|                                                    |                                                 |                                                                   |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.027               | <0.02 | 0.047                                                                    | <0.007                      | 0             |         |
|                                                    |                                                 |                                                                   |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.017               | <0.02 | 0.037                                                                    | <0.007                      | 1             |         |
|                                                    |                                                 |                                                                   |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | <u>0.018</u>        | <0.02 | <u>0.038</u>                                                             | <u>&lt;0.007</u>            | 3             |         |
|                                                    |                                                 |                                                                   |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.010               | <0.02 | 0.030                                                                    | <0.007                      | 5             |         |
|                                                    |                                                 |                                                                   |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.015               | <0.02 | 0.035                                                                    | <0.007                      | 7             |         |
|                                                    |                                                 |                                                                   |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.013               | <0.02 | 0.033                                                                    | <0.007                      | 10            |         |
|                                                    |                                                 |                                                                   |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.012               | <0.02 | 0.032                                                                    | <0.007                      | 14            |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         |       |              |       |              |                  |    |  |
|----------------------------------------------------------------------------------------|----------------------------------------------------------------|------------------------------------------------------------------------|------------|--------------|--------------|--------------------------|----|---------|-------|--------------|-------|--------------|------------------|----|--|
| 11-2093-02<br>D-53881<br>Dom-Esch<br>Germany<br>2011                                   | Strawberry<br>Elisanta<br>Tray – frigo<br>(hanging<br>variety) | 1. 16-07-2010<br>2. 14-03 to 23-05-2011<br>3. 28-04 to 21-06-2011      | 125<br>125 | 1000<br>1000 | 12.5<br>12.5 | 17-05-2011<br>27-05-2011 | 10 | BBCH 87 | Fruit | 0.017        | <0.02 | 0.037        | <0.007           | -0 |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.067        | <0.02 | 0.087        | <0.007           | 0  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.074        | <0.02 | 0.094        | <0.007           | 1  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.037        | <0.02 | 0.057        | <u>&lt;0.007</u> | 3  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.041        | <0.02 | 0.061        | <0.007           | 5  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | <u>0.046</u> | <0.02 | <u>0.066</u> | <0.007           | 7  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.028        | <0.02 | 0.048        | <0.007           | 10 |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | <0.01        | <0.02 | <0.03        | <0.007           | 13 |  |
| 11-2093-03<br>I-75015<br>Tinchi<br>frazione<br>di<br>Pisticci<br>(MT)<br>Italy<br>2011 | Strawberry<br>Ventana                                          | 1. 30-10-2010<br>2. 28-02 to 31-05-2011<br>3. 01-05 to 30-06-2011      | 125<br>125 | 700<br>700   | 17.9<br>17.9 | 26-04-2011<br>06-05-2011 | 10 | BBCH 85 | Fruit | 0.042        | <0.02 | 0.062        | <0.007           | -0 |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.20         | <0.02 | 0.22         | <0.007           | 0  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.17         | <0.02 | 0.19         | <0.007           | 1  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | <u>0.094</u> | 0.020 | <u>0.114</u> | 0.007            | 3  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.039        | 0.021 | 0.060        | 0.007            | 5  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.036        | 0.028 | 0.064        | 0.009            | 7  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.034        | 0.036 | 0.070        | 0.012            | 10 |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.029        | 0.044 | 0.073        | <u>0.015</u>     | 14 |  |
| 11-2093-04<br>E-21450<br>Cartaya<br>Spain<br>2011                                      | Strawberry<br>Splendor                                         | 1. 20-10-2010<br>2. 10-12-2010 to 16-05-2011<br>3. 07-01 to 31-05-2011 | 125<br>125 | 800<br>800   | 15.6<br>15.6 | 11-03-2011<br>21-03-2011 | 10 | BBCH 87 | Fruit | 0.088        | <0.02 | 0.108        | <0.007           | -0 |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.33         | <0.02 | 0.35         | <0.007           | 0  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.23         | <0.02 | 0.25         | <0.007           | 1  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | <u>0.16</u>  | 0.022 | 0.182        | 0.007            | 3  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.16         | 0.027 | <u>0.187</u> | 0.009            | 4  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.067        | 0.037 | 0.104        | 0.012            | 7  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.036        | 0.044 | 0.080        | 0.015            | 9  |  |
|                                                                                        |                                                                |                                                                        |            |              |              |                          |    |         | Fruit | 0.039        | 0.053 | 0.092        | <u>0.018</u>     | 14 |  |

#### **C.3.1.2.1.2 Study 2**

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in the Netherlands, Belgium, southern France and Germany, [REDACTED] 2013, Study ID: 12-2121, Activity ID: RAAAN121                                                                                                                                                                            |
| Guideline(s):          | REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)<br>OECD 509 Adopted 2009-09-07 OECD GUIDELINE FOR THE TESTING OF CHEMICALS<br>Crop Field Trial US EPA OCSPP Guideline No. 860.1500 |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                       |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                                                                                                               |

#### **Materials and methods**

Four trials on strawberry were conducted in greenhouses in the Netherlands, Belgium, France and Germany using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2012 growing season.

'BYI 02960 200 SL' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 500 – 1000 L/ha of water with a 9/10 day RTI, 3 day PHI and final application at BBCH 85-87.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-89).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, fruit samples were taken before the last application (-0) and at 0, 1, 3, 4/5, 7, 10 and 14/16 days after the last application. Samples weighing at least 1 kg were collected from treated and untreated plots except for 3 samples from trial 12-2121-02 (Belgium) which weighed between 0.61 – 0.81 kg. This was due to the yield being lower than expected for this plot. As a sufficient quantity was sampled to allow analysis, it is not considered that this deviation impacted the validity of the trial. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. Samples from trial 12-2121-04

(Germany) reached a temperature of -10.2°C for a limited time during shipment. As the samples remained frozen, it is not considered that this deviation impacted the validity of the trial. The maximum storage interval between harvest and analysis was 333 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in strawberry.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR, NL, 2015). Therefore, the method is considered applicable to strawberries (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 94-100% and 94-98%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

Residues of flupyradifurone in strawberries 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.079 – 0.20 mg/kg.

Residues of DFA in strawberries 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.03 – 0.044 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.1.2-1.

**Table C.3.1.2.1.2-1 Residue trials on strawberry**

Reference: Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in the Netherlands, Belgium. Southern France and Germany. [REDACTED]  
[REDACTED] 2013, Study ID: 11-2093, Activity ID: RARVL098

GLP: Yes Sample storage conditions: 333 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Strawberry / Fruit Analytical method: Method 01212

Indoor/outdoor: Indoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 SL 200 Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |
|                              |                      |                                                                |                                   |                 |                  |                                                           |                                               |                                         |                     |                     |     |                                                                          |                             |               |         |



The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                              |                                                 |                                                                             |            |              |              |                                  |    |         |                                                                      |                                                                             |                                                                      |                                                                             |                                                                                 |                                         |  |
|--------------------------------------------------------------|-------------------------------------------------|-----------------------------------------------------------------------------|------------|--------------|--------------|----------------------------------|----|---------|----------------------------------------------------------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------|-----------------------------------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------|--|
| 12-2121-01<br>1749 VA<br>Warmenhuizen<br>Netherlands<br>2012 | Strawberry<br>Sonata<br>(hanging<br>variety)    | 1. 30-03-<br>2012<br>2. 01-05 to<br>21-05-2012<br>3. 01-06 to<br>01-07-2012 | 125<br>125 | 1000<br>1000 | 12.5<br>12.5 | 22-05-<br>2012<br>01-06-<br>2012 | 10 | BBCH 85 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 0.032<br>0.17<br>0.15<br><u>0.20</u><br>0.16<br>0.19<br>0.15<br>0.084       | <0.02<br><0.02<br><0.02<br><0.02<br>0.020<br>0.021<br>0.027<br>0.035 | 0.052<br>0.19<br>0.17<br><u>0.22</u><br>0.18<br>0.211<br>0.177<br>0.119     | <0.007<br><0.007<br><0.007<br><0.007<br>0.007<br>0.007<br>0.009<br><u>0.012</u> | -0<br>0<br>1<br>3<br>5<br>7<br>10<br>14 |  |
| 12-2121-02<br>6210 Villers-<br>Perwin<br>Belgium<br>2012     | Strawberry<br>Darselect<br>(hanging<br>variety) | 1. 17-07-<br>2012<br>2. 30-07 to<br>15-08-2012<br>3. 30-08 to<br>15-09-2012 | 125<br>125 | 750<br>750   | 16.7<br>16.7 | 22-08-<br>2012<br>31-08-<br>2012 | 9  | BBCH 87 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 0.069<br>0.19<br>0.19<br><u>0.17</u><br>0.16<br>0.086<br>0.042<br>0.052     | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br>0.024<br>0.035<br>0.041 | 0.089<br>0.21<br>0.21<br><u>0.19</u><br>0.18<br>0.11<br>0.077<br>0.093      | <0.007<br><0.007<br><0.007<br><0.007<br>0.008<br>0.012<br><u>0.014</u>          | -0<br>0<br>1<br>3<br>5<br>7<br>10<br>14 |  |
| 12-2121-03<br>84200<br>Carpentras<br>France<br>2012          | Strawberry<br>Naiade                            | 1. 15-12-<br>2011<br>2. 15-03 to<br>22-03-2012<br>3. 12-04 to<br>22-05-2012 | 125<br>125 | 1000<br>1000 | 12.5<br>12.5 | 06-04-<br>2012<br>16-04-<br>2012 | 10 | BBCH 87 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 0.050<br>0.25<br>0.21<br><u>0.19</u><br>0.13<br>0.11<br>0.079<br>0.051      | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br>0.020<br>0.030 | 0.070<br>0.27<br>0.23<br><u>0.21</u><br>0.15<br>0.13<br>0.099<br>0.081      | <0.007<br><0.007<br><0.007<br><0.007<br><0.007<br>0.007<br><u>0.010</u>         | -0<br>0<br>1<br>3<br>4<br>7<br>10<br>16 |  |
| 12-2121-04<br>49377<br>Calveslage<br>Germany<br>2012         | Strawberry<br>Clery                             | 1. 15-08-<br>2011<br>2. 08-04 to<br>09-05-2012<br>3. 01-05 to<br>12-06-2012 | 125<br>125 | 500<br>500   | 25<br>25     | 02-05-<br>2012<br>12-05-<br>2012 | 10 | BBCH 85 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 0.025<br>0.094<br>0.096<br><u>0.079</u><br>0.054<br>0.050<br>0.033<br>0.019 | <0.02<br><0.02<br><0.02<br>0.023<br>0.025<br>0.029<br>0.035<br>0.044 | 0.045<br>0.114<br>0.116<br><u>0.102</u><br>0.079<br>0.079<br>0.068<br>0.063 | <0.007<br><0.007<br><0.007<br>0.008<br>0.008<br>0.010<br>0.012<br><u>0.015</u>  | -0<br>0<br>1<br>3<br>5<br>7<br>10<br>14 |  |

### C.3.1.2.1.3 Study 3

|                        |                                                                                                                                                                                                                                                                                                                    |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in Germany, Belgium, Northern France, the Netherlands and Italy, [REDACTED] 2022, Study ID: E21RP105                                                                                     |
| Guideline(s):          | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market<br>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)<br>US EPA OCSPP 860.1500, Crop Field Trial |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                 |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                         |

### Materials and methods

Seven trials on strawberry were conducted in greenhouses in Germany, Belgium, northern France and the Netherlands using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2021 growing season.

'BYI 02960 200 SL' was applied as a foliar application at a rate of 1 x 0.124 – 0.130 kg/ha flupyradifurone in 595 – 830 L/ha of water with a 3 day PHI and application at BBCH 73-87.

The applications are underdosed relative to the critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-89).

Weather data were reported for the trials and no exceptional events were noted. All seven of the trials were decline trials, fruit samples were taken at 0, 1, 3, 4/5/6, 7, 9/10/11, 14/15, 21/22 and 28 days after the application. Samples weighing at least 1 kg were collected from treated and untreated plots except two samples from trial E21RP105-01 (Germany). This was due to delayed fruit development resulting from local weather conditions. As sufficient sample was available for analysis, it is not considered that this deviation impacted the validity of the trial. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 396 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in strawberry.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR, NL, 2015). Therefore, the method is considered applicable to strawberries (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 103-108% and 102-110%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

Residues of flupyradifurone in strawberries 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.047 – 0.23 mg/kg.

Residues of DFA in strawberries 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between <0.02 – 0.068 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.1.3-1.

**Table C.3.1.2.1.3-1 Residue trials on strawberry**

Reference: Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in Germany, Belgium, Northern France, the Netherlands and Italy, XXXXXXXXXX 2022, Study ID: E21RP105

GLP: Yes Sample storage conditions: 396 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Strawberry / Fruit Analytical method: Method 01212

Indoor/outdoor: Indoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 SL 200 Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                            |                         |                                                                   |     |     |      |            |     |         |                                                                               |                                                                                  |                                                                               |                                                                                  |                                                                                             |                                               |  |
|----------------------------------------------------------------------------|-------------------------|-------------------------------------------------------------------|-----|-----|------|------------|-----|---------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------------|--|
| E21RP105-01<br>42799<br>Leichlingen<br>Germany<br>2021                     | Strawberry<br>Dahli     | 1. 25-03-2021<br>2. 23-04 to 01-06-2021<br>3. 01-06 to 01-07-2021 | 129 | 620 | 20.8 | 25-05-2021 | n/a | BBCH 85 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 0.14<br>0.15<br><u>0.16</u><br>0.13<br>0.070<br>0.044<br>0.028<br>0.014<br>0.010 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br>0.025<br>0.040<br>0.060<br>0.068 | 0.16<br>0.17<br><u>0.18</u><br>0.15<br>0.090<br>0.069<br>0.068<br>0.074<br>0.078 | <0.007<br><0.007<br><0.007<br><0.007<br><0.007<br>0.008<br>0.013<br>0.020<br><u>0.023</u>   | 0<br>1<br>3<br>5<br>7<br>10<br>14<br>21<br>28 |  |
| E21RP105-02<br>6221<br>Saint-Amand<br>Belgium<br>2021                      | Strawberry<br>Sonsation | 1. 10-06-2020<br>2. 14-05 to 25-06-2021<br>3. 15-06 to 06-07-2021 | 130 | 728 | 17.9 | 15-06-2021 | n/a | BBCH 85 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit          | 0.070<br>0.056<br><u>0.047</u><br>0.045<br>0.043<br>0.031<br>0.027<br>0.021      | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02          | 0.090<br>0.076<br><u>0.067</u><br>0.065<br>0.063<br>0.051<br>0.047<br>0.041      | <0.007<br><0.007<br><u>&lt;0.007</u><br><0.007<br><0.007<br><0.007<br><0.007<br><0.007      | 0<br>1<br>3<br>6<br>7<br>10<br>14<br>21       |  |
| E21RP105-03<br>41230<br>Soings en<br>Sologne<br>Northern<br>France<br>2021 | Strawberry<br>Darselet  | 1. 01-07-2020<br>2. 08-04 to 30-04-2021<br>3. 01-05 to 31-05-2021 | 126 | 603 | 20.9 | 03-05-2021 | n/a | BBCH 73 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit          | 0.20<br>0.16<br>0.16<br><u>0.19</u><br>0.10<br>0.095<br>0.050<br>0.022<br><0.01  | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br>0.030<br>0.043 | 0.22<br>0.18<br>0.18<br><u>0.21</u><br>0.12<br>0.115<br>0.070<br>0.052<br>0.053  | <0.007<br><0.007<br><0.007<br><0.007<br><0.007<br><0.007<br><0.007<br>0.010<br><u>0.014</u> | 0<br>1<br>3<br>4<br>7<br>9<br>14<br>22<br>28  |  |
| E21RP105-04<br>1682<br>NS<br>Zwaagdijk<br>The<br>Netherlands<br>2021       | Strawberry<br>Elsanta   | 1. 10-08-2021<br>2. 15-09 to 15-10-2021<br>3. 05-10 to 05-11-2021 | 130 | 830 | 15.7 | 05-10-2021 | n/a | BBCH 85 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit          | 0.17<br>0.20<br>0.21<br><u>0.23</u><br>0.19<br>0.15<br>0.10<br>0.088<br>0.063    | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br>0.020<br>0.027 | 0.19<br>0.22<br>0.23<br><u>0.25</u><br>0.21<br>0.17<br>0.12<br>0.108<br>0.090    | <0.007<br><0.007<br><0.007<br><0.007<br><0.007<br><0.007<br><0.007<br>0.007<br><u>0.009</u> | 0<br>1<br>3<br>5<br>7<br>10<br>14<br>21<br>28 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                    |                        |                                                                   |     |     |      |            |     |         |       |              |       |              |                  |    |  |
|--------------------------------------------------------------------|------------------------|-------------------------------------------------------------------|-----|-----|------|------------|-----|---------|-------|--------------|-------|--------------|------------------|----|--|
| E21RP105-06<br>49377<br>Vechta OT<br>Calvelsage<br>Germany<br>2021 | Strawberry<br>Clery    | 1. 18-08-2020<br>2. 20-04 to 05-06-2021<br>3. 15-05 to 20-06-2021 | 124 | 595 | 20.8 | 03-06-2021 | n/a | BBCH 87 | Fruit | 0.079        | <0.02 | 0.099        | <0.007           | 0  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.076        | <0.02 | 0.096        | <0.007           | 1  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | <u>0.084</u> | <0.02 | <u>0.104</u> | <u>&lt;0.007</u> | 3  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.052        | <0.02 | 0.072        | <0.007           | 5  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.046        | <0.02 | 0.066        | <0.007           | 7  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.042        | <0.02 | 0.062        | <0.007           | 11 |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.037        | <0.02 | 0.057        | <0.007           | 15 |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.029        | <0.02 | 0.049        | <0.007           | 21 |  |
| E21RP105-07<br>75025<br>Policoro<br>Italy<br>2021                  | Strawberry<br>Candonga | 1. 20-10-2020<br>2. 15-03 to 20-05-2021<br>3. 09-04 to 31-05-2021 | 127 | 810 | 15.7 | 16-04-2021 | n/a | BBCH 81 | Fruit | 0.20         | <0.02 | 0.22         | <0.007           | 0  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.16         | <0.02 | 0.18         | <0.007           | 1  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | <u>0.16</u>  | <0.02 | <u>0.18</u>  | <0.007           | 3  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.14         | <0.02 | 0.16         | <0.007           | 5  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.068        | <0.02 | 0.088        | <0.007           | 7  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.044        | <0.02 | 0.064        | <0.007           | 10 |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.027        | 0.022 | 0.049        | 0.007            | 14 |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.037        | 0.038 | 0.075        | <u>0.013</u>     | 21 |  |
| E21RP105-08<br>75020<br>Scanzano<br>Jonico<br>Italy<br>2021        | Strawberry<br>Marisol  | 1. 31-10-2020<br>2. 30-11 to 15-07-2021<br>3. 26-04 to 31-07-2021 | 127 | 709 | 17.9 | 23-04-2021 | n/a | BBCH 85 | Fruit | 0.15         | <0.02 | 0.17         | <0.007           | 0  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.13         | <0.02 | 0.15         | <0.007           | 1  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | <u>0.088</u> | <0.02 | <u>0.108</u> | <0.007           | 3  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.044        | <0.02 | 0.064        | <0.007           | 5  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.029        | <0.02 | 0.049        | <0.007           | 7  |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.027        | <0.02 | 0.047        | <0.007           | 10 |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.028        | 0.020 | 0.048        | 0.007            | 14 |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | 0.021        | 0.023 | 0.044        | <u>0.008</u>     | 21 |  |
|                                                                    |                        |                                                                   |     |     |      |            |     |         | Fruit | <0.01        | 0.021 | 0.031        | 0.007            | 28 |  |

#### **C.3.1.2.1.4 Study 4**

|                        |                                                                                                                                                                         |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in Spain, [REDACTED] 2023, Study ID: E22RP109 |
| Guideline(s):          | OECD Test Guideline 509 (2009)<br>US EPA OCSPP 860.1500 (1996)                                                                                                          |
| Deviations:            | No                                                                                                                                                                      |
| GLP:                   | Yes                                                                                                                                                                     |
| Validity of the study: | Acceptable                                                                                                                                                              |

#### **Materials and methods**

One trial on strawberry was conducted in the greenhouse in Spain using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2022 growing season.

'BYI 02960 200 SL' was applied as a foliar application at a rate of 1 x 0.129 kg/ha flupyradifurone in 517 L/ha of water with a 3 day PHI and application at BBCH 85.

The application is underdosed relative to the critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-89).

Weather data were reported for the trial and no exceptional events were noted. The trial was a decline trial, fruit samples were taken at 0, 1, 3, 5, 7, 9, 14, 22 and 29 days after the application. Samples weighing at least 1 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 162 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in strawberry.

#### **Results and discussions**

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR, NL, 2015). Therefore, the method is considered applicable to strawberries (high water). Acceptable procedural recoveries were reported in

the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 107-109% and 102%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

Residues of flupyradifurone in strawberries 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were 0.35 mg/kg.

Residues of DFA in strawberries 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were 0.089 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.1.4-1.



**Table C.3.1.2.1.4-1 Residue trials on strawberry**

Reference: Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in Spain, ██████████ 2023, Study ID: E22RP109

GLP: Yes Sample storage conditions: 162 days at ≤-18°C

Crop/crop group: Strawberry / Fruit Analytical method: Method 01212

Indoor/outdoor: Indoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 SL 200 Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year                            | Commodity<br>Variety             | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest                             | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |       |                                                                          |                             | PHI<br>(days) | Remarks |
|---------------------------------------------------------|----------------------------------|--------------------------------------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-------|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                                                         |                                  |                                                                                            | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA   | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |
| E22RP109-01<br>11160 La Muela de Vejer<br>Spain<br>2022 | Strawberry<br>Florida<br>fortuna | 1. 05-10-2022<br>2. 10-11-2022 to 30-05-2023 <sup>(a)</sup><br>3. 07-12-2022 to 30-05-2023 | 129                               | 517             | 25               | 05-12-2022                                                | n/a                                           | BBCH 85                                 | Fruit               | 0.42                | <0.02 | 0.44                                                                     | <0.007                      | 0             |         |
|                                                         |                                  |                                                                                            |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.48                | <0.02 | 0.50                                                                     | <0.007                      | 1             |         |
|                                                         |                                  |                                                                                            |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.31                | <0.02 | 0.33                                                                     | <0.007                      | 3             |         |
|                                                         |                                  |                                                                                            |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | <u>0.35</u>         | <0.02 | <u>0.37</u>                                                              | <0.007                      | 5             |         |
|                                                         |                                  |                                                                                            |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.19                | <0.02 | 0.21                                                                     | <0.007                      | 7             |         |
|                                                         |                                  |                                                                                            |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.18                | 0.032 | 0.21                                                                     | 0.011                       | 9             |         |
|                                                         |                                  |                                                                                            |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.063               | 0.065 | 0.13                                                                     | 0.022                       | 14            |         |
|                                                         |                                  |                                                                                            |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.022               | 0.089 | 0.11                                                                     | <u>0.030</u>                | 22            |         |
|                                                         |                                  |                                                                                            |                                   |                 |                  |                                                           |                                               |                                         | Fruit               | 0.014               | 0.075 | 0.089                                                                    | 0.025                       | 29            |         |

<sup>(a)</sup> The flowering end date is an estimation as the flowering period was not finished at the last sampling date

### **C.3.1.2.2 Potatoes**

#### **C.3.1.2.2.1 Study 1**

Reference: BYI 02960 200 SL – Magnitude of the Residue in Potato – Tuberous and Corm Vegetables (Crop Subgroup 1C),  
[REDACTED] 2012, Activity ID: RARVY015

Guideline(s): EPA Ref.: OPPTS 860.1500, Crop Field Trials  
PMRA Ref.: DACO 7.4.1. Supervised Residue Field Trial Study  
PMRA Ref.: DACO 7.4.2. Residue Decline Study  
OECD Test Guideline 509: Crop Field Trial (Adopted Sept. 7, 2009)

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

Twenty six outdoor trials on potatoes were conducted in the USA and Canada using 'BYI 02960 200 SL', an SL formulation containing 200 g/L flupyradifurone, in the 2010/11 growing season.

'BYI 02960 200 SL' was applied as a foliar application at a rate of 2 x 0.201 – 0.221 kg/ha flupyradifurone in 93 - 467 L/ha of water with a 6-8 day RTI, 7 day PHI and final application at BBCH 43-95.

The applications support the authorised critical GAP on potatoes and tropical root and tuber vegetables (2 x 0.205 kg a.s./ha, 7 day PHI, 7 days RTI, all BBCH growth stages).

Weather data were reported for the trials and no exceptional events were noted. Four of the 26 trials were decline trials, potato tuber samples were taken at 0, 3, 7, 14 and 21 days after the last application. Samples weighing at least 1.5 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 263 days for flupyradifurone and DFA at  $\leq -20^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

It should be noted that in some instances residue trials have been carried out at the same location. Trials RV178-10DA & RV200-10HA (Alton, NY), RV179-10HA, RV182-10HA & RV183-10HA (North Rose, NY), RV186-10HA & RV187-10HA (Clarence, MO), RV193-10HA & RV195-10HA (Payette, ID), RV194-10HA & RV202-10DA (Rupert) and RV196-10HA & RV197-10HA (Ephrata, WA) were carried out at the same locations and with

application within 30 days apart and/or on the same variety of potato. Therefore, these trials cannot be considered independent and are considered replicates. As laid out in the guidance, the mean residue values from these trials are therefore used to calculate MRLs and risk assessment values.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 (also referred to as RV-001-P10-02) with an LOQ of 0.01 mg/kg for flupyradifurone and 0.05 mg/kg parent equivalents for DFA in potato.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to potato (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 88-92% and 86-89%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone except for two samples (RV194-10HA-A001 and RV200-10HA-A001) which had residues of 0.0111 and 0.0100 mg/kg respectively. No residues at or above the LOQ were detected in control samples of the metabolite DFA for all trials.

Residues of flupyradifurone in potatoes 7 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between <0.01 – 0.037 mg/kg.

Residues of DFA in potatoes 7 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between <0.05 – 0.088 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.2.1-1.

**Table C.3.1.2.2.1-1 Residue trials on potatoes**

Reference: BYI 02960 200 SL – Magnitude of the Residue in Potato – Tuberous and Corm Vegetables  
(Crop Subgroup 1C), [REDACTED] 2012, Activity ID: RARVY015

GLP: Yes Sample storage conditions: 263 days at ≤-20°C

Crop/crop group: Potatoes / Root and tuber vegetables Analytical method: Method 01304 (also referred to as RV-001-P10-02) with

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.05 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |
|                              |                      |                                                                |                                   |                 |                  |                                                           |                                               |                                         |                     |                     |     |                                                                          |                             |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                |                               |                                                |            |            |              |                        |   |         |       |                                                 |                    |                                                 |                                                 |    |  |
|------------------------------------------------|-------------------------------|------------------------------------------------|------------|------------|--------------|------------------------|---|---------|-------|-------------------------------------------------|--------------------|-------------------------------------------------|-------------------------------------------------|----|--|
| RV178-10DA<br>Alton, NY,<br>USA<br>2010†       | Potato<br>Superior            | 1. 30-May-10<br>2. –<br>3. 27-Aug to 03-Sep-10 | 208<br>206 | 280<br>280 | 74.3<br>73.6 | 19-Aug-10<br>27-Aug-10 | 8 | BBCH 93 | Tuber | <0.010†<br>0.011†                               | <0.050†<br><0.050† | <0.060†<br>0.061†                               | <0.017†<br><0.017†                              | 0  |  |
|                                                |                               |                                                |            |            |              |                        |   |         | Tuber | <0.010†<br>0.015†                               | <0.050†<br><0.050† | <0.060†<br>0.065†                               | <0.017†<br><0.017†                              | 3  |  |
|                                                |                               |                                                |            |            |              |                        |   |         | Tuber | <0.010†<br><0.010†                              | <0.050†<br><0.050† | <0.060†<br><0.060†                              | <0.017†<br><0.017†<br>Avg:<br><u>&lt;0.017†</u> | 7  |  |
|                                                |                               |                                                |            |            |              |                        |   |         | Tuber | <0.010†<br>0.011†                               | <0.050†<br><0.050† | <0.060†<br>0.061†                               | <0.017†<br><0.017†                              | 14 |  |
|                                                |                               |                                                |            |            |              |                        |   |         | Tuber | 0.012†<br>0.012†<br>Avg:<br><u>0.012†</u>       | <0.050†<br><0.050† | 0.062†<br>0.062†<br>Avg:<br><u>0.062†</u>       | <0.017†<br><0.017†                              | 21 |  |
| RV179-10HA<br>North Rose,<br>NY, USA<br>2010†  | Potato<br>Carola              | 1. 29-May-10<br>2. –<br>3. 08-Sep-10           | 201<br>201 | 280<br>280 | 71.8<br>71.8 | 25-Aug-10<br>02-Sep-10 | 8 | BBCH 91 | Tuber | <0.010†<br><0.010†<br>Avg:<br><u>&lt;0.010†</u> | <0.050†<br><0.050† | <0.060†<br><0.060†<br>Avg:<br><u>&lt;0.060†</u> | <0.017†<br><0.017†<br>Avg:<br><u>&lt;0.017†</u> | 6  |  |
| RV180-10HA<br>Germansville,<br>PA, USA<br>2010 | Potato<br>Dark Red<br>Norland | 1. 19-Apr-10<br>2. –<br>3. 15-Jul-10           | 212<br>205 | 190<br>190 | 112<br>108   | 30-Jun-10<br>07-Jul-10 | 7 | BBCH 89 | Tuber | <0.010<br><0.010<br>Avg:<br><u>&lt;0.010</u>    | 0.087<br>0.085     | 0.097<br>0.095<br>Avg:<br><u>0.096</u>          | 0.029<br>0.028<br>Avg:<br><u>0.029</u>          | 8  |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                            |                               |                                      |            |            |              |                        |   |         |       |                                                                                    |                                            |                                                                                    |                                                                                    |   |  |
|------------------------------------------------------------|-------------------------------|--------------------------------------|------------|------------|--------------|------------------------|---|---------|-------|------------------------------------------------------------------------------------|--------------------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---|--|
| RV181-10HA<br>Frenchtown,<br>NJ, USA<br>2010               | Potato<br>Dark Red<br>Norland | 1. 21-Apr-10<br>2. –<br>3. 23-Jul-10 | 221<br>211 | 300<br>260 | 73.7<br>81.2 | 08-Jul-10<br>16-Jul-10 | 8 | BBCH 91 | Tuber | <0.010<br><0.010<br>Avg:<br><u>&lt;0.010</u>                                       | <0.050<br><0.050                           | <0.060<br><0.060<br>Avg:<br><u>&lt;0.060</u>                                       | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u>                                       | 7 |  |
| RV182-10HA, North<br>Rose, NY,<br>USA<br>2010 <sup>†</sup> | Potato<br>NorDonna            | 1. 02-Jul-10<br>2. –<br>3. 01-Oct-10 | 207<br>208 | 340<br>350 | 60.9<br>59.4 | 17-Sep-10<br>24-Sep-10 | 7 | BBCH 91 | Tuber | <0.010 <sup>†</sup><br><0.010 <sup>†</sup><br>Avg:<br><u>&lt;0.010<sup>†</sup></u> | <0.050 <sup>†</sup><br><0.050 <sup>†</sup> | <0.060 <sup>†</sup><br><0.060 <sup>†</sup><br>Avg:<br><u>&lt;0.060<sup>†</sup></u> | <0.017 <sup>†</sup><br><0.017 <sup>†</sup><br>Avg:<br><u>&lt;0.017<sup>†</sup></u> | 7 |  |
| RV183-10HA<br>North Rose,<br>NY, USA<br>2010 <sup>†</sup>  | Potato<br>NY-129              | 1. 02-Jul-10<br>2. –<br>3. 01-Oct-10 | 205<br>209 | 340<br>350 | 60.3<br>59.7 | 17-Sep-10<br>24-Sep-10 | 7 | BBCH 91 | Tuber | <0.010 <sup>†</sup><br><0.010 <sup>†</sup><br>Avg:<br><u>&lt;0.010<sup>†</sup></u> | <0.050 <sup>†</sup><br><0.050 <sup>†</sup> | <0.060 <sup>†</sup><br><0.060 <sup>†</sup><br>Avg:<br><u>&lt;0.060<sup>†</sup></u> | <0.017 <sup>†</sup><br><0.017 <sup>†</sup><br>Avg:<br><u>&lt;0.017<sup>†</sup></u> | 7 |  |
| RV184-10HA<br>Pikeville, NC,<br>USA<br>2010                | Potato<br>Snowden             | 1. 10-Mar-10<br>2. –<br>3. 03-Jun-10 | 200<br>206 | 260<br>280 | 76.9<br>73.6 | 20-May-10<br>27-May-10 | 7 | BBCH 74 | Tuber | <0.010<br><0.010<br>Avg:<br><u>&lt;0.010</u>                                       | 0.083<br>0.057                             | 0.093<br>0.067<br>Avg:<br><u>0.080</u>                                             | 0.028<br>0.019<br>Avg:<br><u>0.024</u>                                             | 7 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                         |                    |                                      |            |            |              |                        |   |         |       |                                                                                    |                                            |                                                                                    |                                                                                    |   |  |
|---------------------------------------------------------|--------------------|--------------------------------------|------------|------------|--------------|------------------------|---|---------|-------|------------------------------------------------------------------------------------|--------------------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---|--|
| RV185-10HA,<br>Oviedo, FL,<br>USA<br>2010               | Potato<br>Kennebec | 1. 18-Mar-10<br>2. –<br>3. 08-Jun-10 | 205<br>206 | 280<br>280 | 73.2<br>73.6 | 25-May-10<br>01-Jun-10 | 7 | BBCH 93 | Tuber | 0.021<br>0.018<br>Avg:<br><u>0.020</u>                                             | <0.050<br><0.050                           | 0.071<br>0.068<br>Avg:<br><u>0.070</u>                                             | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u>                                       | 7 |  |
| RV186-10HA<br>Clarence,<br>MO, USA<br>2010 <sup>†</sup> | Potato<br>Kennebec | 1. 14-Apr-10<br>2. –<br>3. 05-Aug-10 | 206<br>204 | 180<br>190 | 114<br>107   | 22-Jul-10<br>29-Jul-10 | 7 | BBCH 93 | Tuber | <0.010 <sup>†</sup><br><0.010 <sup>†</sup><br>Avg:<br><u>&lt;0.010<sup>†</sup></u> | <0.050 <sup>†</sup><br><0.050 <sup>†</sup> | <0.060 <sup>†</sup><br><0.060 <sup>†</sup><br>Avg:<br><u>&lt;0.060<sup>†</sup></u> | <0.017 <sup>†</sup><br><0.017 <sup>†</sup><br>Avg:<br><u>&lt;0.017<sup>†</sup></u> | 7 |  |
| RV187-10HA<br>Clarence,<br>MO, USA<br>2010 <sup>†</sup> | Potato<br>Kennebec | 1. 27-May-10<br>2. –<br>3. 20-Oct-10 | 204<br>204 | 190<br>190 | 107<br>107   | 06-Oct-10<br>13-Oct-10 | 7 | BBCH 45 | Tuber | <0.010 <sup>†</sup><br><0.010 <sup>†</sup><br>Avg:<br><u>&lt;0.010<sup>†</sup></u> | <0.050 <sup>†</sup><br><0.050 <sup>†</sup> | <0.060 <sup>†</sup><br><0.060 <sup>†</sup><br>Avg:<br><u>&lt;0.060<sup>†</sup></u> | <0.017 <sup>†</sup><br><0.017 <sup>†</sup><br>Avg:<br><u>&lt;0.017<sup>†</sup></u> | 7 |  |
| RV188-10HA<br>Stewardson,<br>IL, USA<br>2010            | Potato<br>Kennebec | 1. 22-Apr-10<br>2. –<br>3. 27-Jul-10 | 200<br>209 | 210<br>240 | 95.2<br>87.1 | 12-Jul-10<br>20-Jul-10 | 8 | BBCH 95 | Tuber | <0.010<br><0.010<br>Avg:<br><u>&lt;0.010</u>                                       | <0.050<br><0.050                           | <0.060<br><0.060<br>Avg:<br><u>&lt;0.060</u>                                       | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u>                                       | 7 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                       |                              |                                      |            |            |              |                        |   |         |       |                                              |                  |                                              |                                              |   |  |
|-------------------------------------------------------|------------------------------|--------------------------------------|------------|------------|--------------|------------------------|---|---------|-------|----------------------------------------------|------------------|----------------------------------------------|----------------------------------------------|---|--|
| RV189-10HA<br>Rockwood,<br>Ontario,<br>Canada<br>2010 | Potato<br>Russett<br>Burbank | 1. 18-May-10<br>2. –<br>3. 14-Sep-10 | 206<br>207 | 120<br>130 | 172<br>159   | 01-Sep-10<br>07-Sep-10 | 6 | BBCH 93 | Tuber | <0.010<br><0.010<br>Avg:<br><u>&lt;0.010</u> | <0.050<br><0.050 | <0.060<br><0.060<br>Avg:<br><u>&lt;0.060</u> | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u> | 7 |  |
| RV190-10HA<br>Taber,<br>Alberta,<br>Canada<br>2010    | Potato<br>Russett<br>Burbank | 1. 24-Jun-10<br>2. –<br>3. 13-Oct-10 | 211<br>203 | 140<br>140 | 151<br>145   | 28-Sep-10<br>06-Oct-10 | 8 | BBCH 49 | Tuber | <0.010<br><0.010<br>Avg:<br><u>&lt;0.010</u> | <0.050<br><0.050 | <0.060<br><0.060<br>Avg: <u>&lt;0.060</u>    | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u> | 7 |  |
| RV191-10HA<br>Jerome, ID,<br>USA<br>2010              | Potato<br>Ranger<br>Russet   | 1. 03-May-10<br>2. –<br>3. 21-Sep-10 | 206<br>201 | 210<br>200 | 98.1<br>101  | 07-Sep-10<br>14-Sep-10 | 7 | BBCH 93 | Tuber | <0.010<br><0.010<br>Avg:<br><u>&lt;0.010</u> | <0.050<br><0.050 | <0.060<br><0.060<br>Avg: <u>&lt;0.060</u>    | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u> | 7 |  |
| RV192-10HA<br>Sanger, CA,<br>USA<br>2010              | Potato<br>Red La<br>Soda     | 1. 26-Apr-10<br>2. –<br>3. 28-Jul-10 | 202<br>201 | 370<br>370 | 54.6<br>54.3 | 14-Jul-10<br>21-Jul-10 | 7 | BBCH 91 | Tuber | <0.010<br>0.034<br>Avg:<br><u>0.022</u>      | <0.050<br><0.050 | <0.060<br>0.084<br>Avg:<br>0.072             | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u> | 7 |  |



The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                            |                               |                                              |            |            |              |                                |   |         |       |                                                 |                    |                                                 |                                                 |   |  |
|--------------------------------------------|-------------------------------|----------------------------------------------|------------|------------|--------------|--------------------------------|---|---------|-------|-------------------------------------------------|--------------------|-------------------------------------------------|-------------------------------------------------|---|--|
| RV193-10HA<br>Payette, ID,<br>USA<br>2010† | Potato<br>Dark Red<br>Norland | 1. 17-May-<br>10<br>2. –<br>3. 17-Aug-<br>10 | 206<br>211 | 280<br>290 | 73.6<br>72.8 | 04-Aug-<br>10<br>10-Aug-<br>10 | 6 | BBCH 91 | Tuber | <0.010†<br><0.010†<br>Avg:<br><u>&lt;0.010†</u> | <0.050†<br><0.050† | <0.060†<br><0.060†<br>Avg:<br><u>&lt;0.060†</u> | <0.017†<br><0.017†<br>Avg:<br><u>&lt;0.017†</u> | 7 |  |
| RV194-10HA<br>Rupert, ID,<br>USA<br>2010†  | Potato<br>Russet<br>Burbank   | 1. 05-May-<br>10<br>2. –<br>3. 03-Sep-<br>10 | 209<br>212 | 160<br>160 | 131<br>133   | 20-Aug-<br>10<br>28-Aug-<br>10 | 8 | BBCH 95 | Tuber | <0.010†<br><0.010†<br>Avg:<br><u>&lt;0.010†</u> | <0.050†<br><0.050† | <0.060†<br><0.060†<br>Avg:<br><u>&lt;0.060†</u> | <0.017†<br><0.017†<br>Avg:<br><u>&lt;0.017†</u> | 6 |  |
| RV195-10HA<br>Payette, ID,<br>USA<br>2010† | Potato<br>Russet<br>Norkotah  | 1. 01-May-<br>10<br>2. –<br>3. 27-Aug-<br>10 | 206<br>207 | 280<br>280 | 73.6<br>73.9 | 13-Aug-<br>10<br>20-Aug-<br>10 | 7 | BBCH 95 | Tuber | <0.010†<br><0.010†<br>Avg:<br><u>&lt;0.010†</u> | <0.050†<br><0.050† | <0.060†<br><0.060†<br>Avg:<br><u>&lt;0.060†</u> | <0.017†<br><0.017†<br>Avg:<br><u>&lt;0.017†</u> | 7 |  |
| RV196-10HA<br>Ephrata, WA,<br>USA<br>2010† | Potato<br>Umatilla            | 1. 29-Apr-10<br>2. –<br>3. 09-Sep-<br>10     | 204<br>209 | 230<br>240 | 88.7<br>87.1 | 26-Aug-<br>10<br>02-Sep-<br>10 | 7 | BBCH 48 | Tuber | <0.010†<br><0.010†<br>Avg:<br><u>&lt;0.010†</u> | <0.050†<br><0.050† | <0.060†<br><0.060†<br>Avg:<br><u>&lt;0.060†</u> | <0.017†<br><0.017†<br>Avg:<br><u>&lt;0.017†</u> | 7 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                     |                             |                                      |            |            |              |                        |   |         |       |                                              |                    |                                              |                                                 |   |  |
|---------------------------------------------------------------------|-----------------------------|--------------------------------------|------------|------------|--------------|------------------------|---|---------|-------|----------------------------------------------|--------------------|----------------------------------------------|-------------------------------------------------|---|--|
| RV197-10HA<br>Ephrata, WA,<br>USA, 2010†                            | Potato<br>Norkotah          | 1. 04-May-10<br>2. –<br>3. 26-Aug-10 | 208<br>204 | 190<br>190 | 109<br>107   | 12-Aug-10<br>19-Aug-10 | 7 | BBCH 48 | Tuber | 0.057†<br>0.016†<br>Avg:<br><u>0.037†</u>    | <0.050†<br><0.050† | 0.107†<br>0.066†<br>Avg:<br><u>0.087†</u>    | <0.017†<br><0.017†<br>Avg:<br><u>&lt;0.017†</u> | 7 |  |
| RV198-10HA<br>Abbotsford,<br>British<br>Columbia,<br>Canada<br>2010 | Potato<br>Russet<br>Burbank | 1. 07-Jul-10<br>2. –<br>3. 23-Sep-10 | 213<br>206 | 200<br>200 | 107<br>103   | 09-Sep-10<br>16-Sep-10 | 7 | BBCH 43 | Tuber | 0.046<br>0.027<br>Avg:<br><u>0.037</u>       | <0.050<br><0.050   | 0.096<br>0.077<br>Avg:<br><u>0.087</u>       | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u>    | 7 |  |
| RV199-10HA<br>Minto,<br>Manitoba,<br>Canada<br>2010                 | Potato<br>Norland           | 1. 19-May-10<br>2. –<br>3. 01-Sep-10 | 209<br>212 | 160<br>160 | 131<br>133   | 18-Aug-10<br>25-Aug-10 | 7 | BBCH 91 | Tuber | <0.010<br><0.010<br>Avg:<br><u>&lt;0.010</u> | <0.050<br><0.050   | <0.060<br><0.060<br>Avg:<br><u>&lt;0.060</u> | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u>    | 7 |  |
| RV200-10HA<br>Alton, NY,<br>USA<br>2010†                            | Potato<br>Reba              | 1. 28-May-10<br>2. –<br>3. 03-Sep-10 | 205<br>205 | 280<br>280 | 73.2<br>73.2 | 19-Aug-10<br>27-Aug-10 | 8 | BBCH 93 | Tuber | <0.010†<br>0.014†<br>Avg:<br><u>0.012†</u>   | <0.050†<br><0.050† | <0.060†<br>0.064†<br>Avg:<br><u>0.062†</u>   | <0.017†<br><0.017†<br>Avg:<br><u>&lt;0.017†</u> | 7 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                           |                            |                                                   |            |            |            |                                |   |         |       |                                                 |                    |                                           |                                              |    |  |
|-------------------------------------------|----------------------------|---------------------------------------------------|------------|------------|------------|--------------------------------|---|---------|-------|-------------------------------------------------|--------------------|-------------------------------------------|----------------------------------------------|----|--|
| RV201-10DA<br>Gardner, KS,<br>USA<br>2010 | Potato<br>Norland<br>Red   | 1. 13-Apr-10<br>2. –<br>3. 16-Jul to<br>06-Aug-10 | 209<br>211 | 150<br>150 | 139<br>141 | 09-Jul-10<br>16-Jul-10         | 7 | BBCH 93 | Tuber | 0.040<br>0.021                                  | <0.050<br><0.050   | 0.090<br>0.071                            | <0.017<br><0.017                             | 0  |  |
|                                           |                            |                                                   |            |            |            |                                |   |         | Tuber | 0.012<br>0.016                                  | <0.050<br><0.050   | 0.062<br>0.066                            | <0.017<br><0.017                             | 3  |  |
|                                           |                            |                                                   |            |            |            |                                |   |         | Tuber | 0.018<br>0.019                                  | <0.050<br><0.050   | 0.068<br>0.069                            | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u> | 7  |  |
|                                           |                            |                                                   |            |            |            |                                |   |         | Tuber | 0.029<br><0.010<br>Avg:<br><u>0.020</u>         | <0.050<br><0.050   | 0.079<br><0.060<br>Avg:<br><u>0.070</u>   | <0.017<br><0.017                             | 14 |  |
|                                           |                            |                                                   |            |            |            |                                |   |         | Tuber | 0.016<br><0.010                                 | <0.050<br><0.050   | 0.066<br><0.060                           | <0.017<br><0.017                             | 21 |  |
| RV202-10DA<br>Rupert, ID,<br>USA<br>2010† | Potato<br>Ranger<br>Russet | 1. 16-Apr-10<br>2. –<br>3. 18-Aug to<br>08-Sep-10 | 205<br>206 | 110<br>110 | 186<br>187 | 11-Aug-<br>10<br>18-Aug-<br>10 | 7 | BBCH 91 | Tuber | <0.010†<br><0.010†                              | <0.050†<br><0.050† | <0.060†<br><0.060†                        | <0.017†<br><0.017†                           | 0  |  |
|                                           |                            |                                                   |            |            |            |                                |   |         | Tuber | <0.010†<br><0.010†                              | <0.050†<br><0.050† | <0.060†<br><0.060†                        | <0.017†<br><0.017†                           | 3  |  |
|                                           |                            |                                                   |            |            |            |                                |   |         | Tuber | <0.010†<br><0.010†<br>Avg:<br><u>&lt;0.010†</u> | <0.050†<br><0.050† | <0.060†<br><0.060†                        | <0.017†<br><0.017†                           | 7  |  |
|                                           |                            |                                                   |            |            |            |                                |   |         | Tuber | <0.010†<br><0.010†                              | 0.073†<br>0.102†   | 0.083†<br>0.112†<br>Avg:<br><u>0.098†</u> | 0.024†<br>0.034†<br>Avg:<br><u>0.029†</u>    | 14 |  |
|                                           |                            |                                                   |            |            |            |                                |   |         | Tuber | <0.010†<br><0.010†                              | <0.050†<br>0.105†  | <0.060†<br>0.115†                         | <0.017†<br>0.035†                            | 21 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                         |                            |                                                       |            |            |            |                                |   |         |       |                                              |                  |                                              |                                              |    |  |
|---------------------------------------------------------|----------------------------|-------------------------------------------------------|------------|------------|------------|--------------------------------|---|---------|-------|----------------------------------------------|------------------|----------------------------------------------|----------------------------------------------|----|--|
| RV203-10DA<br>Josephburg,<br>Alberta,<br>Canada<br>2012 | Potato<br>Russet<br>Nacota | 1. 13-May-<br>10<br>2. –<br>3. 10-Sep to<br>29-Sep-10 | 209<br>207 | 100<br>100 | 209<br>207 | 03-Sep-<br>10<br>10-Sep-<br>10 | 7 | BBCH 49 | Tuber | <0.010<br><0.010                             | <0.050<br><0.050 | <0.060<br><0.060                             | <0.017<br><0.017                             | 0  |  |
|                                                         |                            |                                                       |            |            |            |                                |   |         | Tuber | <0.010<br><0.010                             | <0.050<br><0.050 | <0.060<br><0.060                             | <0.017<br><0.017                             | 3  |  |
|                                                         |                            |                                                       |            |            |            |                                |   |         | Tuber | <0.010<br><0.010<br>Avg:<br><u>&lt;0.010</u> | <0.050<br><0.050 | <0.060<br><0.060<br>Avg:<br><u>&lt;0.060</u> | <0.017<br><0.017<br>Avg:<br><u>&lt;0.017</u> | 6  |  |
|                                                         |                            |                                                       |            |            |            |                                |   |         | Tuber | <0.010<br><0.010                             | <0.050<br><0.050 | <0.060<br><0.060                             | <0.017<br><0.017                             | 13 |  |
|                                                         |                            |                                                       |            |            |            |                                |   |         | Tuber | <0.010<br><0.010                             | <0.050<br><0.050 | <0.060<br><0.060                             | <0.017<br><0.017                             | 19 |  |
|                                                         |                            |                                                       |            |            |            |                                |   |         |       |                                              |                  |                                              |                                              |    |  |

† Trial not considered independent.

### **C.3.1.2.3 Flowering brassica**

#### **C.3.1.2.3.1 Study 1**

Reference: Determination of the residues of BYI 02960 in/on Broccoli and Cauliflower after Spraying of BYI 02960 SL 200 in the Field in Germany, the Netherlands and United Kingdom, [REDACTED] 2012, Study ID: 10-2221, Activity ID: RARVL026

Guideline(s): EC Guidance working document 7029/VI/95 rev.5 (1997-07-22), EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed

US EPA OCSPP Guideline No. 860.1500.SUPP

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

Four outdoor trials on cauliflower (2 trials) and broccoli (2 trials) were conducted in the Netherlands, Germany and the UK using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2010 growing season.

'BYI 02960 200 SL' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 300 L/ha of water with a 10 day RTI, 3 day PHI and final application at BBCH 46-49. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. Rainfall occurred within 4 hours after application in trial 10-2221-01 but this is not expected to adversely impact the validity of the trial. All four of the trials were decline trials, broccoli and cauliflower curd samples were taken before the last application (-0) and at 0, 1, 3, 5 and 7 days after the last application. Samples weighing at least 1 kg and consisting of at least 12 plants were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 271 days for flupyradifurone and DFA at ≤-

20°C. The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to cauliflower and broccoli (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 105-117% and 81-113%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in broccoli 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.18 – 0.22 mg/kg.

Residues of flupyradifurone in cauliflower 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.04 – 0.19 mg/kg.

Residues of DFA in broccoli 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.13 – 0.34 mg/kg (expressed as flupyradifurone).

Residues of DFA in cauliflower 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.09 – 0.11 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.3.1-1.

**Table C.3.1.2.3.1-1 Residue trials on cauliflower and broccoli**

Reference: Determination of the residues of BYI 02960 in/on Broccoli and Cauliflower after Spraying of BYI 02960 SL 200 in the Field in Germany, the Netherlands and United Kingdom, [REDACTED] 2012, Study ID: 10-2221, Activity ID: RARVL026

GLP: Yes Sample storage conditions: 271 days at  $\leq -20^{\circ}\text{C}$

Crop/crop group: Cauliflower and broccoli / Flowering brassicas Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                         |                        |                                                        |            |            |              |                                  |    |         |                                              |                                                     |                                              |                                                     |                                                           |                             |  |
|-------------------------------------------------------------------------|------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|----------------------------------------------|-----------------------------------------------------|----------------------------------------------|-----------------------------------------------------|-----------------------------------------------------------|-----------------------------|--|
| 10-2221-01<br>50321<br>Brühl-<br>Schwardorf,<br>Germany<br>2010         | Broccoli<br>Barthemon  | 1. 15-07-<br>2010<br>2. –<br>3. 24-09 to<br>30-09-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 10-09-<br>2010<br>20-09-<br>2010 | 10 | BBCH 47 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | 0.02<br>0.42<br>0.26<br><u>0.22</u><br>0.16<br>0.13 | 0.05<br>0.06<br>0.06<br>0.08<br>0.11<br>0.13 | 0.07<br>0.48<br>0.32<br><u>0.30</u><br>0.27<br>0.26 | 0.017<br>0.020<br>0.020<br>0.027<br>0.037<br><u>0.043</u> | -0<br>0<br>1<br>3<br>5<br>7 |  |
| 10-2221-02<br>1744 HK<br>Sint<br>Maarten,<br>The<br>Netherlands<br>2010 | Broccoli<br>Ironman    | 1. 14-05-<br>2010<br>2. –<br>3. 15-07 to<br>15-08-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 16-07-<br>2010<br>26-07-<br>2010 | 10 | BBCH 49 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | 0.01<br>0.22<br>0.25<br><u>0.18</u><br>0.13<br>0.11 | 0.27<br>0.26<br>0.23<br>0.28<br>0.34<br>0.34 | 0.28<br>0.48<br>0.48<br>0.46<br><u>0.47</u><br>0.45 | 0.090<br>0.087<br>0.077<br>0.093<br><u>0.11</u><br>0.11   | -0<br>0<br>1<br>3<br>5<br>7 |  |
| 10-2221-03<br>40764<br>Langenfeld-<br>Reusrath<br>Germany<br>2010       | Cauliflower<br>Fremont | 1. 28-04-<br>2010<br>2. –<br>3. 10-07 to<br>20-07-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 29-06-<br>2010<br>09-07-<br>2010 | 10 | BBCH 48 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | 0.04<br>0.30<br>0.21<br><u>0.19</u><br>0.17<br>0.09 | 0.05<br>0.06<br>0.05<br>0.09<br>0.10<br>0.11 | 0.09<br>0.36<br>0.26<br><u>0.28</u><br>0.27<br>0.20 | 0.017<br>0.020<br>0.017<br>0.030<br>0.033<br><u>0.037</u> | -0<br>0<br>1<br>3<br>5<br>7 |  |
| 10-2221-04<br>IP28 8PA<br>Mildenhall<br>UK<br>2010                      | Cauliflower<br>Freedom | 1. 08-06-<br>2010<br>2. –<br>3. 29-09 to<br>20-10-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 10-09-<br>2010<br>20-09-<br>2010 | 10 | BBCH 46 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | 0.01<br>0.13<br>0.07<br><u>0.04</u><br>0.03<br>0.02 | 0.09<br>0.07<br>0.04<br>0.08<br>0.07<br>0.09 | 0.10<br>0.20<br>0.11<br><u>0.12</u><br>0.10<br>0.11 | 0.030<br>0.023<br>0.013<br>0.027<br>0.023<br><u>0.030</u> | -0<br>0<br>1<br>3<br>5<br>7 |  |



#### **C.3.1.2.3.2 Study 2**

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on cauliflower and broccoli after spray application of BYI 02960 SL 200 in Germany, Belgium and the Netherlands, [REDACTED] 2015, Study ID: 13-2142, Activity ID: RARVN034                                                                                                                                                                                                                      |
| Guideline(s):          | REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<br><br>EC guidance working document 7029/VI/95 rev. 5 (July 22, 1997)<br><br>OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial<br><br>US EPA OCSPG Guideline No. 860.1500 |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                                                                                                                                    |

#### **Materials and methods**

Four outdoor trials on cauliflower (2 trials) and broccoli (2 trials) were conducted in the Netherlands, Germany and Belgium using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2013 growing season.

'BYI 02960 200 SL' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 550 - 600 L/ha of water with a 10-11 day RTI, 3 day PHI and final application at BBCH 45-47. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, broccoli and cauliflower curd samples were taken before the last application (-0) and at 0, 3, 5, 7, 10 and 13/14 days after the last application. Samples weighing at least 1 kg and consisting of at least 12 plants were collected from treated and

untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 446 days for flupyradifurone and DFA at  $\leq -20^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to cauliflower and broccoli (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 105-118% and 99-111%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in broccoli 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.11 – 0.13 mg/kg.

Residues of flupyradifurone in cauliflower 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.071 – 0.15 mg/kg.

Residues of DFA in broccoli 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.17 – 0.81 mg/kg (expressed as flupyradifurone).

Residues of DFA in cauliflower 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.044 – 0.063 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.3.2-1.

**Table C.3.1.2.3.2-1 Residue trials on cauliflower and broccoli**

Reference: Determination of the residues of BYI 02960 in/on cauliflower and broccoli after spray application of BYI 02960 SL 200 in Germany, Belgium and the Netherlands, [REDACTED]  
[REDACTED] 2015, Study ID: 13-2142, Activity ID: RARVN034

GLP: Yes Sample storage conditions: 446 days at  $\leq -20^{\circ}\text{C}$

Crop/crop group: Cauliflower and broccoli / Flowering brassicas Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                  |                                 |                                                        |            |            |              |                                  |    |         |                                                      |                                                                   |                                                             |                                                                   |                                                                      |                                    |  |
|------------------------------------------------------------------|---------------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------------------------------------------------------|-------------------------------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------------|----------------------------------------------------------------------|------------------------------------|--|
| 13-2142-01<br>42799<br>Leichlingen<br>Germany<br>2013            | Cauliflower<br>Freedom          | 1. 25-05-<br>2013<br>2. –<br>3. 01-08 to<br>31-08-2013 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 30-07-<br>2013<br>09-08-<br>2013 | 10 | BBCH 47 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | <0.01<br>0.18<br><u>0.15</u><br>0.14<br>0.11<br>0.046<br>0.036    | <0.02<br><0.02<br>0.023<br>0.033<br>0.043<br>0.044<br>0.063 | <0.03<br>0.20<br><u>0.173</u><br>0.173<br>0.153<br>0.090<br>0.099 | <0.007<br><0.007<br>0.008<br>0.011<br>0.014<br>0.015<br><u>0.021</u> | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |
| 13-2142-02<br>6221 Saint-<br>Amand<br>Belgium<br>2013            | Broccoli<br>Montop F1<br>Hybrid | 1. 27-05-<br>2013<br>2. –<br>3. 22-07 to<br>02-08-2013 | 125<br>125 | 550<br>550 | 22.7<br>22.7 | 09-07-<br>2013<br>19-07-<br>2013 | 10 | BBCH 45 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | 0.016<br>0.43<br><u>0.11</u><br>0.045<br>0.021<br>0.011<br><0.01  | 0.097<br>0.12<br>0.15<br>0.16<br>0.16<br>0.15<br>0.17       | 0.113<br>0.55<br><u>0.26</u><br>0.205<br>0.181<br>0.161<br>0.18   | 0.032<br>0.040<br>0.050<br>0.053<br>0.053<br>0.050<br><u>0.057</u>   | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |
| 13-2142-03<br>59457<br>Werl-<br>Westönnen<br>Germany<br>2013     | Cauliflower<br>Lecanu           | 1. 05-05-<br>2013<br>2. –<br>3. 10-06 to<br>15-10-2013 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 18-06-<br>2013<br>29-06-<br>2013 | 11 | BBCH 47 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | 0.016<br>0.61<br><u>0.071</u><br>0.034<br>0.017<br>0.019<br>0.013 | <0.02<br>0.020<br>0.031<br>0.027<br>0.022<br>0.033<br>0.044 | 0.036<br>0.63<br><u>0.102</u><br>0.061<br>0.039<br>0.052<br>0.057 | <0.007<br>0.007<br>0.010<br>0.009<br>0.007<br>0.011<br><u>0.015</u>  | -0<br>0<br>3<br>5<br>7<br>10<br>13 |  |
| 13-2142-04<br>1681 ND<br>Zwaagdijk<br>The<br>Netherlands<br>2013 | Broccoli<br>Lucky               | 1. 07-05-<br>2013<br>2. –<br>3. 18-07 to<br>27-07-2013 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 09-07-<br>2013<br>19-07-<br>2013 | 10 | BBCH 47 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | <0.01<br>0.36<br><u>0.13</u><br>0.063<br>0.028<br>0.014<br><0.01  | 0.32<br>0.32<br>0.51<br>0.68<br>0.74<br>0.81<br>0.77        | 0.33<br>0.68<br>0.64<br>0.743<br>0.768<br><u>0.824</u><br>0.78    | 0.107<br>0.107<br>0.170<br>0.227<br>0.247<br><u>0.270</u><br>0.257   | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |

### C.3.1.2.3.3 Study 3

Reference: Determination of the residues of BYI 02960 in/on broccoli and cauliflower after spray application of BYI 02960 SL 200 in the field in France (South) and Italy. [REDACTED] 2014, Study ID: 11-2063, Activity ID: RARVL069

Guideline(s): EC Guidance working document 7029/VI/95 rev.5 (1997-07-22), REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial

US EPA OCSPP Guideline No. 860.1500

Deviations: No

GLP: Yes

Validity of the study: Acceptable

### Materials and methods

Two outdoor trials on cauliflower (1 trial) and broccoli (1 trial) were conducted in southern France and Italy using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2011 growing season.

'BYI 02960 200 SL' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 600 - 700 L/ha of water with a 10 day RTI, 3 day PHI and final application at BBCH 47-48. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. Both of the trials were decline trials, broccoli and cauliflower curd samples were taken before the last application (-0) and at 0, 3, 5, 7, 10 and 14 days after the last application. Samples weighing at least 1 kg and consisting of at least 12 plants were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 214 days

for flupyradifurone and DFA at  $\leq -20^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to broccoli and cauliflower (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 80-93% and 80-95%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in broccoli 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were 0.26 mg/kg.

Residues of flupyradifurone in cauliflower 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were 0.052 mg/kg.

Residues of DFA in broccoli 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were 0.27 mg/kg (expressed as flupyradifurone).

Residues of DFA in cauliflower 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were 0.072 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.3.3-1.

**Table C.3.1.2.3.3-1 Residue trials on cauliflower and broccoli**

Reference: Determination of the residues of BYI 02960 in/on broccoli and cauliflower after spray application of BYI 02960 SL 200 in the field in France (South) and Italy, [REDACTED] 2014, Study ID: 11-2063, Activity ID: RARVL069

GLP: Yes Sample storage conditions: 214 days at  $\leq -20^{\circ}\text{C}$

Crop/crop group: Cauliflower and broccoli / Flowering brassicas Analytical method: Method 01304

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                     |                           |                                                 |            |            |              |                          |    |         |      |              |       |              |              |    |  |
|-----------------------------------------------------|---------------------------|-------------------------------------------------|------------|------------|--------------|--------------------------|----|---------|------|--------------|-------|--------------|--------------|----|--|
| 11-2063-01<br>31330<br>Le Burgaud<br>France<br>2011 | Cauliflower<br>Fremont F1 | 1. 22-04-2011<br>2. –<br>3. 10-07 to 25-07-2011 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 28-06-2011<br>08-07-2011 | 10 | BBCH 47 | Curd | 0.020        | 0.020 | 0.040        | 0.007        | -0 |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | 0.10         | 0.022 | 0.122        | 0.007        | 0  |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | 0.030        | 0.038 | 0.068        | 0.013        | 3  |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | <u>0.052</u> | 0.038 | <u>0.090</u> | 0.013        | 5  |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | 0.012        | 0.057 | 0.069        | 0.019        | 7  |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | 0.014        | 0.053 | 0.067        | 0.018        | 10 |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | <0.010       | 0.072 | 0.082        | <u>0.024</u> | 14 |  |
| 11-2063-02<br>95100<br>Catania<br>Italy<br>2011     | Broccoli<br>Maraton       | 1. 05-08-2011<br>2. –<br>3. 01-11 to 15-12-2011 | 125<br>125 | 700<br>700 | 17.9<br>17.9 | 04-11-2011<br>14-11-2011 | 10 | BBCH 48 | Curd | 0.090        | 0.073 | 0.163        | 0.024        | -0 |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | 0.50         | 0.078 | 0.578        | 0.026        | 0  |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | <u>0.26</u>  | 0.11  | 0.37         | 0.037        | 3  |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | 0.23         | 0.15  | <u>0.38</u>  | 0.050        | 5  |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | 0.16         | 0.18  | 0.34         | 0.060        | 7  |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | 0.098        | 0.23  | 0.328        | 0.077        | 10 |  |
|                                                     |                           |                                                 |            |            |              |                          |    |         | Curd | 0.032        | 0.27  | 0.302        | <u>0.090</u> | 14 |  |



#### **C.3.1.2.3.4 Study 4**

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on cauliflower and broccoli after spray application of BYI 02960 SL 200 in Spain and Italy, [REDACTED] 2015, Study ID: 13-2140, Activity ID: RARVN035                                                                                                                                                                                                                                       |
| Guideline(s):          | REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<br><br>EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)<br><br>OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial<br><br>US EPA OCSPP Guideline No. 860.1500 |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                                                                                                                                |

#### **Materials and methods**

Two outdoor trials on cauliflower (1 trial) and broccoli (1 trial) were conducted in Spain and Italy using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2013 growing season.

'BYI 02960 200 SL' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 800 - 1000 L/ha of water with a 10/12 day RTI, 3 day PHI and final application at BBCH 47-48. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. Both of the trials were decline trials, broccoli and cauliflower curd samples were taken before the last application (-0) and at 0, 3, 5, 7, 10 and 14 days after the last application. Samples weighing at least 1 kg and/or consisting of at least 12 plants were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep

frozen until analysis. The maximum storage interval between harvest and analysis was 226 days for flupyradifurone and DFA at  $\leq -20^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to broccoli and cauliflower (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 104-109% and 81-114%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in broccoli 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were 0.27 mg/kg.

Residues of flupyradifurone in cauliflower 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were 0.018 mg/kg.

Residues of DFA in broccoli 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were 0.28 mg/kg (expressed as flupyradifurone).

Residues of DFA in cauliflower 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were 0.096 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.3.4-1.

**Table C.3.1.2.3.4-1 Residue trials on cauliflower and broccoli**

Reference: Determination of the residues of BYI 02960 in/on cauliflower and broccoli after spray application of BYI 02960 SL 200 in Spain and Italy, [REDACTED] 2015, Study ID: 13-2140, Activity ID: RARVN035

GLP: Yes Sample storage conditions: 226 days at  $\leq -20^{\circ}\text{C}$

Crop/crop group: Cauliflower and broccoli / Flowering brassicas Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or<br>planting<br>2.Flowering<br>g<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or number<br>and last<br>date | Interval<br>between<br>applicati<br>ons<br>(days) | Growth<br>stage at<br>last<br>treatmen<br>t | Portion<br>analyse<br>d | Residues (mg/kg) |     |                                                                       |                          | PHI<br>(days<br>) | Remarks |
|------------------------------|----------------------|------------------------------------------------------------------------|-----------------------------------|-----------------|------------------|--------------------------------------------------------|---------------------------------------------------|---------------------------------------------|-------------------------|------------------|-----|-----------------------------------------------------------------------|--------------------------|-------------------|---------|
|                              |                      |                                                                        | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                        |                                                   |                                             |                         | Flupyradifurone  | DFA | Sum of<br>flupyradifurone and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed as DFA |                   |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         |      |              |       |             |              |    |  |
|------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------------|------------|--------------|--------------|----------------------------------|----|---------|------|--------------|-------|-------------|--------------|----|--|
| 13-2140-01<br>41310<br>Brenes<br>Spain<br>2013                               | Cauliflower<br>Sirente            | 1. 26-10-<br>2013<br>2. –<br>3. 01-11-<br>2013 to 28-<br>01-2014 | 125<br>125 | 1000<br>1000 | 12.5<br>12.5 | 28-01-<br>2014<br>07-02-<br>2014 | 10 | BBCH 48 | Curd | <0.010       | 0.034 | 0.044       | 0.011        | -0 |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | 0.040        | 0.029 | 0.069       | 0.010        | 0  |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | 0.013        | 0.034 | 0.047       | 0.011        | 3  |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | <u>0.018</u> | 0.046 | 0.064       | 0.015        | 5  |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | 0.015        | 0.050 | 0.065       | 0.017        | 7  |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | 0.016        | 0.061 | 0.077       | 0.020        | 10 |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | 0.014        | 0.096 | <u>0.11</u> | <u>0.032</u> | 14 |  |
| 13-2140-02<br>95100<br>Catania (CT)<br>C.da Gelso<br>Bianco<br>Italy<br>2013 | Broccoli<br>Cataneese<br>(locale) | 1. 26-08-<br>2013<br>2. –<br>3. 15-11 to<br>15-12-<br>2013       | 125<br>125 | 800<br>800   | 15.6<br>15.6 | 06-11-<br>2013<br>18-11-<br>2013 | 12 | BBCH 47 | Curd | 0.077        | 0.14  | 0.217       | 0.047        | -0 |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | 0.52         | 0.13  | 0.65        | 0.043        | 0  |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | <u>0.27</u>  | 0.15  | 0.42        | 0.050        | 3  |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | 0.27         | 0.19  | 0.46        | 0.063        | 5  |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | 0.25         | 0.22  | <u>0.47</u> | 0.073        | 7  |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | 0.20         | 0.27  | 0.47        | 0.090        | 10 |  |
|                                                                              |                                   |                                                                  |            |              |              |                                  |    |         | Curd | 0.071        | 0.28  | 0.35        | <u>0.093</u> | 14 |  |

#### **C.3.1.2.3.5 Study 5**

Reference: Determination of the residues of BYI 02960 in/on broccoli and cauliflower after spray application of BYI 02960 SL 200 in Portugal, southern France and Italy, [REDACTED] 2018, Study ID: 16-2147, Activity ID: RARV0054

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)

US EPA OCSPP 860.1500, Crop Field Trial

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

Four outdoor trials on cauliflower (2 trials) and broccoli (2 trials) were conducted in Portugal, southern France and Italy using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2013 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 500 - 800 L/ha of water with a 10/11 day RTI, 3 day PHI and final application at BBCH 47-49. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. All of the trials were decline trials, broccoli and cauliflower curd samples were taken before the last application (-0) and at 0, 3, 4/5, 7, 10 and 14/15 days after the last application. Samples weighing at least 1 kg and/or consisting of at least 12 plants were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 337 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to broccoli and cauliflower (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 84-93% and 84-100%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in broccoli 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.19 – 0.23 mg/kg.

Residues of flupyradifurone in cauliflower 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.015 – 0.019 mg/kg.

Residues of DFA in broccoli 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.093 – 0.28 mg/kg (expressed as flupyradifurone).

Residues of DFA in cauliflower 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.053 – 0.073 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.3.5-1.

**Table C.3.1.2.3.5-1 Residue trials on cauliflower and broccoli**

Reference: Determination of the residues of BYI 02960 in/on broccoli and cauliflower after spray application of BYI 02960 SL 200 in Portugal, southern France and Italy, ██████████ 2018, Study ID: 16-2147, Activity ID: RARV0054

GLP: Yes Sample storage conditions: 337 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Cauliflower and broccoli / Flowering brassicas Analytical method: Method 01304

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or<br>planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or number<br>and last<br>date | Interval<br>between<br>applicati<br>ons<br>(days) | Growth<br>stage at<br>last<br>treatmen<br>t | Portion<br>analyse<br>d | Residues (mg/kg) |     |                                                                       |                          | PHI<br>(days<br>) | Remarks |
|------------------------------|----------------------|-------------------------------------------------------------------|-----------------------------------|-----------------|------------------|--------------------------------------------------------|---------------------------------------------------|---------------------------------------------|-------------------------|------------------|-----|-----------------------------------------------------------------------|--------------------------|-------------------|---------|
|                              |                      |                                                                   | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                        |                                                   |                                             |                         | Flupyradifurone  | DFA | Sum of<br>flupyradifurone and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed as DFA |                   |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                      |                         |                                                                  |            |            |              |                                  |    |         |                                                      |                                                                        |                                                             |                                                                     |                                                                      |                                    |  |
|----------------------------------------------------------------------|-------------------------|------------------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------------------------------------------------------|------------------------------------------------------------------------|-------------------------------------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------|------------------------------------|--|
| 16-2147-01<br>2530-462<br>Moita dos<br>Ferreiros<br>Portugal<br>2016 | Cauliflower<br>Concept  | 1. 15-07-<br>2016<br>2. –<br>3. 23-09-<br>to 03-10-<br>2016      | 125<br>125 | 800<br>800 | 15.6<br>15.6 | 12-09-<br>2016<br>22-09-<br>2016 | 10 | BBCH 47 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | <0.010<br>0.053<br><u>0.015</u><br>0.013<br>0.014<br><0.010<br>0.010   | 0.034<br>0.035<br>0.063<br>0.048<br>0.069<br>0.058<br>0.073 | 0.044<br>0.088<br>0.078<br>0.061<br><u>0.083</u><br>0.068<br>0.083  | 0.011<br>0.012<br>0.021<br>0.016<br>0.023<br>0.019<br><u>0.024</u>   | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |
| 16-2147-02<br>13630<br>Eyragues<br>France<br>2016                    | Cauliflower<br>Thalassa | 1. 03-08-<br>2016<br>2. –<br>3. 25-10 to<br>25-11-<br>2016       | 125<br>125 | 500<br>500 | 25<br>25     | 21-10-<br>2016<br>31-10-<br>2016 | 10 | BBCH 49 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | <0.010<br>0.017<br><u>0.019</u><br>0.011<br><0.010<br><0.010<br><0.010 | <0.02<br><0.02<br>0.023<br>0.026<br>0.033<br>0.041<br>0.053 | <0.030<br>0.037<br>0.042<br>0.037<br>0.043<br>0.051<br><u>0.063</u> | <0.007<br><0.007<br>0.008<br>0.009<br>0.011<br>0.014<br><u>0.018</u> | -0<br>0<br>3<br>4<br>7<br>10<br>14 |  |
| 16-2147-03<br>95100<br>Catania<br>Italy<br>2016                      | Broccoli<br>Marathon    | 1. 12-09-<br>2016<br>2. –<br>3. 09-12-<br>2016 to 31-<br>01-2017 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 02-12-<br>2016<br>12-12-<br>2016 | 10 | BBCH 47 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | 0.069<br>0.57<br><u>0.23</u><br>0.21<br>0.11<br>0.11<br>0.068          | 0.094<br>0.10<br>0.13<br>0.15<br>0.17<br>0.23<br>0.28       | 0.163<br>0.67<br><u>0.36</u><br>0.36<br>0.28<br>0.34<br>0.348       | 0.031<br>0.033<br>0.043<br>0.050<br>0.057<br>0.077<br><u>0.093</u>   | -0<br>0<br>3<br>5<br>7<br>10<br>15 |  |
| 16-2147-04<br>31200<br>Toulouse<br>France<br>2016                    | Broccoli<br>Chevalier   | 1. 27-07-<br>2016<br>2. –<br>3. 01-11 to<br>30-11-<br>2016       | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 24-10-<br>2016<br>04-11-<br>2016 | 11 | BBCH 48 | Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd<br>Curd | 0.035<br>0.63<br><u>0.19</u><br>0.17<br>0.14<br>0.089<br>0.078         | 0.035<br>0.036<br>0.044<br>0.044<br>0.056<br>0.074<br>0.093 | 0.070<br>0.666<br><u>0.234</u><br>0.214<br>0.196<br>0.163<br>0.171  | 0.012<br>0.012<br>0.015<br>0.015<br>0.019<br>0.025<br><u>0.031</u>   | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |



#### **C.3.1.2.4 Head brassica**

##### **C.3.1.2.4.1 Study 1**

|                        |                                                                                                                                                                                                                                                                                                                             |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on savoy, red and white cabbage after spray application of BYI 02960 SL 200 in the field in Germany, northern France and the Netherlands, [REDACTED] 2013, Study ID: 10-2183, Activity ID: RARVL009                                                                           |
| Guideline(s):          | EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8<br>Residues in or on Treated Products, Food and Feed EC guidance working document 7029A/I/95 rev. 5 (July 22, 1997) US EPA OCSPG Guideline No. 860.1500.SUPPUS<br>EPA OCSPG Guideline No. 860.1500.SUPP |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                          |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                         |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                  |

#### **Materials and methods**

Four outdoor trials on savoy, red and white cabbage were conducted in Germany, northern France and the Netherlands using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2010 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 300 - 400 L/ha of water with a 10/11 day RTI, 3 day PHI and final application at BBCH 48-49. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, cabbage head samples were taken before the last application (-0) and at 0, 1, 3, 5 and 7 days after the last application. Samples weighing at least 1 kg and consisting of at least 12 plants were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 146 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to cabbage (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 94-101% and 89-93%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in cabbage 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.02 – 0.07 mg/kg.

Residues of DFA in cabbage 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between <0.02 – 0.28 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.4.1-1.

**Table C.3.1.2.4.1-1 Residue trials on cabbage**

Reference: Determination of the residues of BYI 02960 in/on savoy, red and white cabbage after spray application of BYI 02960 SL 200 in the field in Germany, northern France and the Netherlands, [REDACTED] 2013, Study ID: 10-2183, Activity ID: RARVL009

GLP: Yes Sample storage conditions: 146 days at  $\leq -20^{\circ}\text{C}$

Crop/crop group: Cabbages / Head brassicas Analytical method: Method 01304

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                           |                              |                                                        |            |            |              |                                  |    |         |                                              |                                                             |                                                          |                                                          |                                                                    |                             |  |
|---------------------------------------------------------------------------|------------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|----------------------------------------------|-------------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|--------------------------------------------------------------------|-----------------------------|--|
| 10-2183-01<br>D-42799<br>Leichlingen<br>Germany<br>2010                   | Red<br>cabbage<br>Rovit      | 1. 10-05-<br>2010<br>2. –<br>3. 01-09 to<br>30-09-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 24-08-<br>2010<br>03-09-<br>2010 | 10 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | <0.010<br>0.090<br>0.030<br><u>0.020</u><br>0.020<br><0.010 | 0.030<br>0.020<br>0.030<br>0.040<br>0.050<br>0.060       | 0.040<br>0.11<br>0.060<br>0.060<br><u>0.070</u><br>0.070 | 0.010<br>0.007<br>0.010<br>0.013<br>0.017<br><u>0.020</u>          | -0<br>0<br>1<br>3<br>5<br>7 |  |
| 10-2183-02<br>F-27340<br>Criquebeuf<br>sur Seine<br>France<br>2010        | White<br>cabbage<br>Elton    | 1. 23-06-<br>2010<br>2. –<br>3. 11-10 to<br>12-11-2010 | 125<br>125 | 400<br>400 | 31.3<br>31.3 | 30-09-<br>2010<br>11-10-<br>2010 | 11 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | <0.010<br>0.10<br>0.10<br><u>0.070</u><br>0.020<br>0.030    | <0.020<br><0.020<br><0.020<br><0.020<br><0.020<br><0.020 | <0.030<br>0.12<br>0.12<br><u>0.090</u><br>0.040<br>0.050 | <0.007<br><0.007<br><0.007<br><u>&lt;0.007</u><br><0.007<br><0.007 | -0<br>0<br>1<br>3<br>5<br>7 |  |
| 10-2183-03<br>D-59457<br>Werl-<br>Westoennen<br>Germany<br>2010           | Savoy<br>cabbage<br>Milwakee | 1. 03-05-<br>2010<br>2. –<br>3. 16-07 to<br>01-11-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 17-07-<br>2010<br>27-07-<br>2010 | 10 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | 0.010<br>0.36<br>0.070<br><u>0.020</u><br><0.010<br><0.010  | 0.21<br>0.23<br>0.23<br>0.23<br>0.28<br>0.24             | 0.22<br>0.59<br>0.30<br>0.25<br><u>0.29</u><br>0.25      | 0.070<br>0.077<br>0.077<br>0.077<br><u>0.093</u><br>0.080          | -0<br>0<br>1<br>3<br>5<br>7 |  |
| 10-2183-04<br>NL-1744 HK<br>Sint<br>Maarten<br>The<br>Netherlands<br>2010 | Savoy<br>cabbage<br>Exelvooy | 1. 14-05-<br>2010<br>2. –<br>3. 01-09 to<br>30-09-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 31-08-<br>2010<br>10-09-<br>2010 | 10 | BBCH 49 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | 0.020<br>0.10<br>0.040<br><u>0.020</u><br>0.010<br>0.010    | 0.040<br>0.040<br>0.040<br>0.060<br>0.070<br>0.090       | 0.060<br>0.14<br>0.080<br>0.080<br>0.080<br><u>0.10</u>  | 0.013<br>0.013<br>0.013<br>0.020<br>0.023<br><u>0.030</u>          | -0<br>0<br>1<br>3<br>5<br>7 |  |

#### **C.3.1.2.4.2 Study 2**

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on cabbage after spray application of BYI 02960 SL 200 in Germany, Belgium and the Netherlands, [REDACTED] 2015, Study ID: 13-2144, Activity ID: RARVN032                                                                                                                                                                                                                                       |
| Guideline(s):          | REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<br><br>EC guidance working document 7029/VI/95 rev. 5 (July 22, 1997)<br><br>OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial<br><br>US EPA OCSPP Guideline No. 860.1500 |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                                                                                                                                    |

#### **Materials and methods**

Four outdoor trials on head cabbage were conducted in Germany, Belgium and the Netherlands using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2013 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 550 - 800 L/ha of water with a 10/11 day RTI, 3 day PHI and final application at BBCH 43-49. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, cabbage head samples were taken before the last application (-0) and at 0, 3, 5, 7, 10 and 13/14 days after the last application. Samples weighing at least 1 kg and consisting of at least 12 plants were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until

analysis. The maximum storage interval between harvest and analysis was 466 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to cabbage (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 108-109% and 101-102%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in cabbage 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between  $<0.01 - 0.054$  mg/kg.

Residues of DFA in cabbage 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between  $0.06 - 0.26$  mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.4.2-1.

**Table C.3.1.2.4.2-1 Residue trials on cabbage**

Reference: Determination of the residues of BYI 02960 in/on cabbage after spray application of BYI 02960 SL 200 in Germany, Belgium and the Netherlands, [REDACTED] 2015, Study ID: 13-2144, Activity ID: RARVN032

GLP: Yes Sample storage conditions: 466 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Cabbages / Head brassicas Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                  |                             |                                                        |            |            |              |                                  |    |         |                                                      |                                                                                       |                                                             |                                                                    |                                                                    |                                    |  |
|------------------------------------------------------------------|-----------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------------------------------------------------------|---------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------------------------------------------------------|--------------------------------------------------------------------|------------------------------------|--|
| 13-2144-01<br>42799<br>Leichlingen<br>Germany<br>2013            | Head<br>cabbage<br>Lennox   | 1. 25-05-<br>2013<br>2. –<br>3. 15-08 to<br>30-09-2013 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 13-08-<br>2013<br>23-08-<br>2013 | 10 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head | <0.010<br>0.020<br><0.010<br><u>0.011</u><br><0.010<br><0.010<br><0.010               | 0.050<br>0.047<br>0.071<br>0.087<br>0.095<br>0.14<br>0.15   | 0.060<br>0.067<br>0.081<br>0.098<br>0.105<br>0.15<br><u>0.16</u>   | 0.017<br>0.016<br>0.024<br>0.029<br>0.032<br>0.047<br><u>0.050</u> | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |
| 13-2144-02<br>59457<br>Werl-<br>Westönnen<br>Germany<br>2013     | Head<br>cabbage<br>Perfecta | 1. 20-04-<br>2013<br>2. –<br>3. 10-06 to<br>31-10-2013 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 18-06-<br>2013<br>29-06-<br>2013 | 11 | BBCH 43 | Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head | <0.010<br>0.61 <sup>(a)</sup><br><u>0.012</u><br><0.010<br><0.010<br><0.010<br><0.010 | 0.10<br>0.089<br>0.12<br>0.16<br>0.12<br>0.25<br>0.26       | 0.11<br>0.699<br>0.132<br>0.17<br>0.13<br>0.26<br><u>0.27</u>      | 0.033<br>0.030<br>0.040<br>0.053<br>0.040<br>0.083<br><u>0.087</u> | -0<br>0<br>3<br>5<br>7<br>10<br>13 |  |
| 13-2144-03<br>6221 Saint-<br>Amand<br>Belgium<br>2013            | Head<br>cabbage<br>Robustor | 1. 27-05-<br>2013<br>2. –<br>3. 04-10 to<br>25-10-2013 | 125<br>125 | 550<br>550 | 22.7<br>22.7 | 24-09-<br>2013<br>04-10-<br>2013 | 10 | BBCH 49 | Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head | <0.010<br><0.010<br><u>&lt;0.010</u><br><0.010<br><0.010<br><0.010<br><0.010          | 0.021<br>0.020<br>0.027<br>0.035<br>0.041<br>0.051<br>0.060 | 0.031<br>0.030<br>0.037<br>0.045<br>0.051<br>0.061<br><u>0.070</u> | 0.007<br>0.007<br>0.009<br>0.012<br>0.014<br>0.017<br><u>0.020</u> | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |
| 13-2144-04<br>1681 ND<br>Zwaagdijk<br>The<br>Netherlands<br>2013 | Head<br>cabbage<br>Colmar   | 1. 07-05-<br>2013<br>2. –<br>3. 01-10 to<br>01-11-2013 | 125<br>125 | 800<br>800 | 15.6<br>15.6 | 24-09-<br>2013<br>04-10-<br>2013 | 10 | BBCH 49 | Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head | 0.024<br>0.076<br>0.052<br><u>0.054</u><br>0.034<br>0.025<br>0.017                    | 0.031<br>0.027<br>0.036<br>0.053<br>0.055<br>0.065<br>0.080 | 0.055<br>0.103<br>0.088<br><u>0.107</u><br>0.089<br>0.090<br>0.097 | 0.010<br>0.009<br>0.012<br>0.018<br>0.018<br>0.022<br><u>0.027</u> | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |

(a) The mean value of three individual values (0.59 mg/kg, 0.61 mg/kg, 0.62 mg/kg)



#### **C.3.1.2.4.3 Study 3**

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on cabbage after spray application of BYI 02960 SL 200 in the field in France (South) and Spain, [REDACTED] 2014, Study ID: 11-2062, Activity ID: RARVL068                                                                                                                                                                                                                  |
| Guideline(s):          | REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC EC guidance working document 7029/VI/95 rev. 5 (July 22, 1997) OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial, US EPA OCSPP Guideline No. 860.1500 |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                                                                                                                |

#### **Materials and methods**

Two outdoor trials on head cabbage were conducted in southern France and Spain using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2011 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 500 - 700 L/ha of water with a 9/10 day RTI, 3 day PHI and final application at BBCH 48. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. Both of the trials were decline trials, cabbage head samples were taken before the last application (-0) and at 0, 3, 5, 7, 10/12 and 13/14 days after the last application. Samples weighing at least 1 kg and consisting of at least 12 plants were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 115 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to cabbage (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 89-91% and 94-95%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in cabbage 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.049 – 0.059 mg/kg.

Residues of DFA in cabbage 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.12 – 0.26 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.4.3-1.

**Table C.3.1.2.4.3-1 Residue trials on cabbage**

Reference: Determination of the residues of BYI 02960 in/on cabbage after spray application of BYI 02960 SL 200 in the field in France (South) and Spain, [REDACTED] 2014, Study ID: 11-2062, Activity ID: RARVL068

GLP: Yes Sample storage conditions: 115 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Cabbages / Head brassicas Analytical method: Method 01304

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or number<br>and last<br>date | Interval<br>between<br>applications (days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg) |     |                                                                             |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|--------------------------------------------------------|--------------------------------------------|-----------------------------------------|---------------------|------------------|-----|-----------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                        |                                            |                                         |                     | Flupyradifurone  | DFA | Sum of<br>flupyradifurone and<br>DFA,<br>expressed<br>as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                   |                               |                                                            |            |            |              |                                  |    |         |      |              |       |              |              |    |  |
|---------------------------------------------------|-------------------------------|------------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------|--------------|-------|--------------|--------------|----|--|
| 11-2062-01<br>13630<br>Eyragues<br>France<br>2011 | Savoy<br>cabbage<br>Capriccio | 1. 05-08-<br>2011<br>2. –<br>3. 20-10<br>to 15-11-<br>2011 | 125<br>125 | 500<br>500 | 25<br>25     | 11-10-<br>2011<br>21-10-<br>2011 | 10 | BBCH 48 | Head | <0.010       | 0.060 | 0.070        | 0.020        | -0 |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | 0.16         | 0.067 | 0.227        | 0.022        | 0  |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | <u>0.049</u> | 0.078 | 0.127        | 0.026        | 3  |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | 0.021        | 0.095 | 0.116        | 0.032        | 5  |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | 0.016        | 0.15  | 0.166        | 0.050        | 7  |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | <0.010       | 0.23  | 0.240        | 0.077        | 12 |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | <0.010       | 0.26  | <u>0.270</u> | <u>0.087</u> | 14 |  |
| 11-2062-02<br>08850 Gava<br>Spain<br>2011         | White<br>cabbage<br>Megaton   | 1. 30-07-<br>2011<br>2. –<br>3. 01-12<br>to 30-12-<br>2011 | 125<br>125 | 700<br>700 | 17.9<br>17.9 | 23-11-<br>2011<br>02-12-<br>2011 | 9  | BBCH 48 | Head | 0.013        | 0.028 | 0.041        | 0.009        | -0 |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | 0.078        | 0.027 | 0.105        | 0.009        | 0  |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | <u>0.059</u> | 0.039 | 0.098        | 0.013        | 3  |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | 0.035        | 0.044 | 0.079        | 0.015        | 5  |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | 0.025        | 0.055 | 0.080        | 0.018        | 7  |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | 0.023        | 0.12  | <u>0.143</u> | <u>0.040</u> | 10 |  |
|                                                   |                               |                                                            |            |            |              |                                  |    |         | Head | 0.013        | 0.079 | 0.092        | 0.026        | 13 |  |

#### **C.3.1.2.4.4 Study 4**

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on cabbage after spray application of BYI 02960 SL 200 in Spain and Italy, [REDACTED] 2015, Study ID: 13-2143, Activity ID: RARVN033                                                                                                                                                                                                                                                            |
| Guideline(s):          | REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<br><br>EC guidance working document 7029/VI/95 rev. 5 (July 22, 1997)<br><br>OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial<br><br>US EPA OCSPP Guideline No. 860.1500 |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                                                                                                                                    |

#### **Materials and methods**

Two outdoor trials on head cabbage were conducted in Spain and Italy using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2013 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 – 0.135 kg/ha flupyradifurone in 600 - 861 L/ha of water with an 8/12 day RTI, 3 day PHI and final application at BBCH 47. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. Both of the trials were decline trials, cabbage head samples were taken before the last application (-0) and at 0, 3, 5, 7, 10/11 and 14 days after the last application. Samples weighing at least 1 kg and consisting of at least 12 plants were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until

analysis. The maximum storage interval between harvest and analysis was 502 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to cabbage (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 104-108% and 102-104%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in cabbage 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.03 – 0.13 mg/kg.

Residues of DFA in cabbage 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.097 – 0.16 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.4.4-1.

**Table C.3.1.2.4.4-1 Residue trials on cabbage**

Reference: Determination of the residues of BYI 02960 in/on cabbage after spray application of BYI 02960 SL 200 in Spain and Italy, [REDACTED] 2015, Study ID: 13-2143, Activity ID: RARVN033

GLP: Yes Sample storage conditions: 502 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Cabbages / Head brassicas Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or number<br>and last<br>date | Interval<br>between<br>applications (days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg) |     |                                                                             |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|--------------------------------------------------------|--------------------------------------------|-----------------------------------------|---------------------|------------------|-----|-----------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                        |                                            |                                         |                     | Flupyradifurone  | DFA | Sum of<br>flupyradifurone and<br>DFA,<br>expressed<br>as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |
|                              |                      |                                                                |                                   |                 |                  |                                                        |                                            |                                         |                     |                  |     |                                                                             |                             |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                                |                                   |                                                            |            |            |              |                                  |    |         |      |              |        |              |              |    |  |
|--------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------|--------------|--------|--------------|--------------|----|--|
| 13-2143-01<br>08850 Gava<br>Spain<br>2013                                      | White<br>cabbage<br>Extremo       | 1. 20-12-<br>2012<br>2. –<br>3. 10-04<br>to 30-04-<br>2013 | 135<br>125 | 861<br>800 | 15.7<br>15.6 | 04-04-<br>2013<br>12-04-<br>2013 | 8  | BBCH 47 | Head | <0.010       | <0.020 | <0.030       | <0.007       | -0 |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | 0.12         | <0.020 | 0.14         | <0.007       | 0  |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | 0.027        | 0.035  | 0.062        | 0.012        | 3  |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | <u>0.030</u> | 0.057  | 0.087        | 0.019        | 5  |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | 0.022        | 0.064  | 0.086        | 0.021        | 7  |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | <0.010       | 0.092  | 0.102        | 0.031        | 11 |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | <0.010       | 0.097  | <u>0.107</u> | <u>0.032</u> | 14 |  |
| 13-2143-02<br>97012<br>Chiaromonte<br>Gulfi (RG)<br>C.da Lago<br>Italy<br>2013 | Head<br>cabbage<br>Green<br>lunar | 1. 30-07-<br>2013<br>2. –<br>3. 15-11<br>to 10-12-<br>2013 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 06-11-<br>2013<br>18-11-<br>2013 | 12 | BBCH 47 | Head | 0.038        | 0.090  | 0.128        | 0.030        | -0 |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | 0.32         | 0.096  | 0.416        | 0.032        | 0  |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | <u>0.13</u>  | 0.13   | 0.26         | 0.043        | 3  |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | 0.11         | 0.16   | <u>0.27</u>  | <u>0.053</u> | 5  |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | 0.073        | 0.14   | 0.213        | 0.047        | 7  |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | 0.067        | 0.15   | 0.217        | 0.050        | 10 |  |
|                                                                                |                                   |                                                            |            |            |              |                                  |    |         | Head | 0.029        | 0.15   | 0.179        | 0.050        | 14 |  |



### **C.3.1.2.5 Brussels sprouts**

#### **C.3.1.2.5.1 Study 1**

Reference: Determination of the residues of BYI 02960 in/on Brussels sprouts after spray application of BYI 02960 SL 200 in the field in Germany, France (North) and the Netherlands, [REDACTED] 2012, Study ID: 10-2222, Activity ID: RARVL027

Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029A/I/95 rev. 5 (July 22, 1997) US EPA OCSPG Guideline No. 860.1500.SUPPUS EPA OCSPG Guideline No. 860.1500.SUPP

Deviations: No

GLP: Yes

Validity of the study: Acceptable

### **Materials and methods**

Four outdoor trials on Brussels sprouts were conducted in Germany, northern France and the Netherlands using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2010 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 – 0.1369 kg/ha flupyradifurone in 300 - 500 L/ha of water with a 9/10 day RTI, 3/4 day PHI and final application at BBCH 48-49. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, sprout samples were taken before the last application (-0) and at 0, 1, 3/4, 5 and 7 days after the last application. Samples weighing at least 1 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 126 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to Brussels sprouts (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 101-102% and 92-97%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in Brussels sprouts 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.01 – 0.04 mg/kg.

Residues of DFA in Brussels sprouts 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.06 – 0.18 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.5.1-1.

# **Table C.3.1.2.5.1-1 Residue trials on Brussels sprouts**

Reference: Determination of the residues of BYI 02960 in/on Brussels sprouts after spray application of BYI 02960 SL 200 in the field in Germany, France (North) and the Netherlands, [REDACTED] 2012, Study ID: 10-2222, Activity ID: RARVL027

GLP: Yes Sample storage conditions: 126 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Brussels sprouts / Head Analytical method: Method 01304  
brassicac

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                           |                                |                                                        |            |            |              |                                  |    |         |                                                          |                                                            |                                                    |                                                          |                                                           |                             |  |
|---------------------------------------------------------------------------|--------------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|----------------------------------------------------------|------------------------------------------------------------|----------------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------|-----------------------------|--|
| 10-2222-01<br>D-51399<br>Burscheid<br>Germany<br>2010                     | Brussels<br>sprouts<br>Nautic  | 1. 28-04-<br>2010<br>2. –<br>3. 15-09 to<br>15-10-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 13-09-<br>2010<br>23-09-<br>2010 | 10 | BBCH 49 | Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout | 0.020<br>0.070<br>0.020<br><u>0.010</u><br>0.010<br><0.010 | 0.060<br>0.060<br>0.070<br>0.080<br>0.080<br>0.070 | 0.080<br>0.13<br>0.090<br><u>0.090</u><br>0.090<br>0.080 | 0.020<br>0.020<br>0.023<br><u>0.027</u><br>0.027<br>0.023 | -0<br>0<br>1<br>3<br>5<br>7 |  |
| 10-2222-02<br>F-27340<br>Criquebeuf<br>sur Seine<br>France<br>2010        | Brussels<br>sprouts<br>Syrius  | 1. 23-06-<br>2010<br>2. –<br>3. 05-10 to<br>29-10-2010 | 125<br>125 | 500<br>500 | 25<br>25     | 28-09-<br>2010<br>08-10-<br>2010 | 10 | BBCH 48 | Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout | 0.010<br>0.10<br>0.090<br><u>0.040</u><br>0.030<br>0.020   | 0.030<br>0.030<br>0.040<br>0.070<br>0.060<br>0.11  | 0.040<br>0.13<br>0.13<br>0.11<br>0.090<br><u>0.13</u>    | 0.010<br>0.010<br>0.013<br>0.023<br>0.020<br><u>0.037</u> | -0<br>0<br>1<br>3<br>5<br>7 |  |
| 10-2222-03<br>D-53332<br>Bornheim-<br>Sechtem<br>Germany<br>2010          | Brussels<br>sprouts<br>Maximus | 1. 18-05-<br>2010<br>2. –<br>3. 01-10 to<br>03-11-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 20-09-<br>2010<br>29-09-<br>2010 | 9  | BBCH 48 | Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout | <0.010<br>0.060<br>0.060<br><u>0.020</u><br>0.020<br>0.010 | 0.050<br>0.080<br>0.070<br>0.12<br>0.12<br>0.18    | 0.060<br>0.14<br>0.13<br>0.14<br>0.14<br><u>0.19</u>     | 0.017<br>0.027<br>0.023<br>0.040<br>0.040<br><u>0.060</u> | -0<br>0<br>1<br>4<br>5<br>7 |  |
| 10-2222-04<br>NL-1744<br>HK Sint<br>Maarten<br>The<br>Netherlands<br>2010 | Brussels<br>sprouts<br>Maximus | 1. 14-05-<br>2010<br>2. –<br>3. 01-10 to<br>31-10-2010 | 137<br>125 | 328<br>300 | 41.8<br>41.7 | 12-10-<br>2010<br>22-10-<br>2010 | 10 | BBCH 49 | Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout | 0.030<br>0.060<br>0.070<br><u>0.040</u><br>0.030<br>0.030  | 0.030<br>0.040<br>0.030<br>0.040<br>0.050<br>0.060 | 0.060<br>0.10<br>0.10<br>0.080<br>0.080<br><u>0.090</u>  | 0.010<br>0.013<br>0.010<br>0.013<br>0.017<br><u>0.020</u> | -0<br>0<br>1<br>3<br>5<br>7 |  |

#### **C.3.1.2.5.2 Study 2**

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on Brussels sprouts after spray application of BYI 02960 SL 200 in Germany, Belgium and the Netherlands, [REDACTED] 2015, Study ID: 13-2145, Activity ID: RARVN031                                                                                                                                                                                                                              |
| Guideline(s):          | REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<br><br>EC guidance working document 7029/VI/95 rev. 5 (July 22, 1997)<br><br>OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial<br><br>US EPA OCSPG Guideline No. 860.1500 |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                                                                                                                                    |

#### **Materials and methods**

Four outdoor trials on Brussels sprouts were conducted in Germany, Belgium and the Netherlands using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2013 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 300 - 600 L/ha of water with a 10 day RTI, 3 day PHI and final application at BBCH 48-49. The surfactant adjuvant 'Trend 90' was added to the test item at a dose rate of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, sprout samples were taken before the last application (-0) and at 0, 3, 5, 7, 10 and 14 days after the last application. Samples weighing at least 1 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of

sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 330 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to Brussels sprouts (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 104-109% and 94-100%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in Brussels sprouts 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.015 – 0.055 mg/kg.

Residues of DFA in Brussels sprouts 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.081 – 0.30 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.5.2-1.

**Table C.3.1.2.5.2-1 Residue trials on Brussels sprouts**

Reference: Determination of the residues of BYI 02960 in/on Brussels sprouts after spray application of BYI 02960 SL 200 in Germany, Belgium and the Netherlands, [REDACTED] 2015, Study ID: 13-2145, Activity ID: RARVN031

GLP: Yes Sample storage conditions: 330 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Brussels sprouts / Head Analytical method: Method 01212  
brassicac

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                  |                                |                                                        |            |            |              |                                  |    |         |                                                                    |                                                                        |                                                             |                                                                    |                                                                    |                                    |  |
|------------------------------------------------------------------|--------------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|--------------------------------------------------------------------|------------------------------------------------------------------------|-------------------------------------------------------------|--------------------------------------------------------------------|--------------------------------------------------------------------|------------------------------------|--|
| 13-2145-01<br>42799<br>Leichlingen<br>Germany<br>2013            | Brussels<br>sprouts<br>Clodius | 1. 01-06-<br>2013<br>2. –<br>3. 15-09 to<br>15-12-2013 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 21-10-<br>2013<br>31-10-<br>2013 | 10 | BBCH 49 | Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout | 0.015<br>0.12<br><u>0.055</u><br>0.048<br>0.051<br>0.030<br>0.030      | 0.12<br>0.10<br>0.12<br>0.16<br>0.20<br>0.20<br>0.25        | 0.135<br>0.22<br>0.175<br>0.208<br>0.251<br>0.230<br><u>0.280</u>  | 0.040<br>0.033<br>0.040<br>0.053<br>0.067<br>0.067<br><u>0.083</u> | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |
| 13-2145-02<br>59457<br>Werl-<br>Mawicke<br>Germany<br>2013       | Brussels<br>sprouts<br>Genius  | 1. 14-05-<br>2013<br>2. –<br>3. 01-10 to<br>30-11-2013 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 27-09-<br>2013<br>07-10-<br>2013 | 10 | BBCH 48 | Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout | <0.010<br>0.027<br><u>0.015</u><br><0.010<br><0.010<br><0.010<br>0.013 | 0.024<br>0.024<br>0.027<br>0.037<br>0.046<br>0.081<br>0.065 | 0.034<br>0.051<br>0.042<br>0.047<br>0.056<br><u>0.091</u><br>0.078 | 0.008<br>0.008<br>0.009<br>0.012<br>0.015<br><u>0.027</u><br>0.022 | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |
| 13-2145-03<br>6221 Saint-<br>Amand<br>Belgium<br>2013            | Brussels<br>sprouts<br>Crispus | 1. 27-05-<br>2013<br>2. –<br>3. 10-10 to<br>25-10-2013 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 01-10-<br>2013<br>11-10-<br>2013 | 10 | BBCH 49 | Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout | 0.010<br>0.090<br><u>0.032</u><br>0.017<br>0.020<br>0.016<br><0.010    | 0.074<br>0.077<br>0.091<br>0.10<br>0.15<br>0.20<br>0.24     | 0.084<br>0.167<br>0.123<br>0.117<br>0.170<br>0.216<br><u>0.250</u> | 0.025<br>0.026<br>0.030<br>0.033<br>0.050<br>0.067<br><u>0.080</u> | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |
| 13-2145-04<br>1681 ND<br>Zwaagdijk<br>The<br>Netherlands<br>2013 | Brussels<br>sprouts<br>Nautic  | 1. 07-05-<br>2013<br>2. –<br>3. 15-10 to<br>15-11-2013 | 125<br>125 | 500<br>500 | 25<br>25     | 08-10-<br>2013<br>18-10-<br>2013 | 10 | BBCH 49 | Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout<br>Sprout | <0.010<br>0.056<br><u>0.022</u><br>0.012<br>0.011<br><0.010<br><0.010  | 0.050<br>0.043<br>0.090<br>0.13<br>0.18<br>0.25<br>0.30     | 0.060<br>0.099<br>0.112<br>0.142<br>0.191<br>0.260<br><u>0.310</u> | 0.017<br>0.014<br>0.030<br>0.043<br>0.060<br>0.083<br><u>0.10</u>  | -0<br>0<br>3<br>5<br>7<br>10<br>14 |  |



### **C.3.1.2.6 Kale**

#### **C.3.1.2.6.1 Study 1**

Reference: Determination of the residues of BYI 02960 in/on Kale, curly after Spraying of BYI 02960 SL 200 in the Field in Germany and United Kingdom, [REDACTED]  
[REDACTED] 2012, Study ID: 10-2182, Activity ID: RARVL008

Guideline(s): EC Guidedance working document 7029/VI/95 rev.5 (1997-07-22), EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8

Residues in or on Treated Products, Food and Feed

US EPA OCSPP Guideline No. 860.1500.SUPP

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

Two outdoor trials on curly kale were conducted in Germany and the United Kingdom using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2010 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 300 - 600 L/ha of water with a 10/11 day RTI, 3 day PHI and final application at BBCH 48-49. The surfactant adjuvant 'Trend 90' was added to the test item.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted, except rainfall occurred within 6 hours of the first application in trial 10-2182-02 (UK). As this was the first application of two and the residues reported in this trial for both parent and metabolite are higher than in trial 10-2182-01 (Germany), where no rainfall occurred within 24 hours of both applications, this deviation is not considered to have adversely impacted the validity of the trial. Both of the trials were decline trials, leaf samples were taken before the last application (-0) and at 0, 1, 3, 5 and 7 days after the last application. Samples weighing at least 2 kg and consisting of 12 plants were collected from treated and untreated plots (except for control plots where fewer plants were available but >2 kg was still sampled). Samples were frozen within 24 hours of sampling and stored deep frozen

until analysis. The maximum storage interval between harvest and analysis was 199 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to kale (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 107-110% and 91-101%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in kale 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.09 – 1.1 mg/kg.

Residues of DFA in kale 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.17 – 0.33 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.6.1-1.

**Table C.3.1.2.6.1-1 Residue trials on kale**

Reference: Determination of the residues of BYI 02960 in/on Kale, curly after Spraying of BYI 02960 SL 200 in the Field in Germany and United Kingdom, [REDACTED] 2012, Study ID: 10-2182, Activity ID: RARVL008

GLP: Yes Sample storage conditions: 199 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Kale / Leafy brassicas Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                      |                                 |                                                        |            |            |              |                                  |    |         |      |              |       |             |              |    |  |
|------------------------------------------------------|---------------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------|--------------|-------|-------------|--------------|----|--|
| 10-2182-01<br>40764<br>Landenfeld<br>Germany<br>2010 | Curly kale<br>Winterbor         | 1. 28-04-<br>2010<br>2. –<br>3. 01-08 to<br>01-11-2010 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 16-07-<br>2010<br>27-07-<br>2010 | 11 | BBCH 48 | Leaf | <0.010       | 0.070 | 0.080       | 0.023        | -0 |  |
|                                                      |                                 |                                                        |            |            |              |                                  |    |         | Leaf | 2.6          | 0.10  | 2.7         | 0.033        | 0  |  |
|                                                      |                                 |                                                        |            |            |              |                                  |    |         | Leaf | 0.41         | 0.080 | 0.49        | 0.027        | 1  |  |
|                                                      |                                 |                                                        |            |            |              |                                  |    |         | Leaf | <u>0.090</u> | 0.10  | 0.19        | 0.033        | 3  |  |
|                                                      |                                 |                                                        |            |            |              |                                  |    |         | Leaf | 0.050        | 0.14  | 0.19        | 0.047        | 5  |  |
|                                                      |                                 |                                                        |            |            |              |                                  |    |         | Leaf | 0.030        | 0.17  | <u>0.20</u> | <u>0.057</u> | 7  |  |
| 10-2182-02<br>CB22 5EU<br>Cambridge<br>UK<br>2010    | Curly kale<br>Darkibor<br>Green | 1. 03-06-<br>2010<br>2. –<br>3. 15-10 to<br>15-11-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 15-10-<br>2010<br>25-10-<br>2010 | 10 | BBCH 49 | Leaf | 0.45         | 0.18  | 0.63        | 0.060        | -0 |  |
|                                                      |                                 |                                                        |            |            |              |                                  |    |         | Leaf | 4.6          | 0.19  | 4.79        | 0.063        | 0  |  |
|                                                      |                                 |                                                        |            |            |              |                                  |    |         | Leaf | 3.1          | 0.16  | 3.26        | 0.053        | 1  |  |
|                                                      |                                 |                                                        |            |            |              |                                  |    |         | Leaf | <u>1.1</u>   | 0.25  | <u>1.35</u> | 0.083        | 3  |  |
|                                                      |                                 |                                                        |            |            |              |                                  |    |         | Leaf | 0.61         | 0.33  | 0.94        | <u>0.11</u>  | 5  |  |
|                                                      |                                 |                                                        |            |            |              |                                  |    |         | Leaf | 0.25         | 0.32  | 0.57        | 0.107        | 7  |  |

#### **C.3.1.2.6.2 Study 2**

Reference: Determination of the residues of BYI 02960 in/on curly kale after spray application of BYI 02960 SL 200 in the Netherlands and Belgium, [REDACTED] 2015, Study ID: 13-2147, Activity ID: RARVN029

Guideline(s): REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)

OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial

US EPA OCSPP Guideline No. 860.1500

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

Two outdoor trials on curly kale were conducted in the Netherlands and Belgium using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2013 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 500 - 600 L/ha of water with a 10 day RTI, 3 day PHI and final application at BBCH 49. The surfactant adjuvant 'Trend 90' was added to the test item at a concentration of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. Both of the trials were decline trials, leaf samples were taken before the last application and at 0, 1, 3, 4/5, 7, 10 and 14 days after the last application. Samples weighing at least 2 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between

harvest and analysis was 346 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to kale (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 107-110% and 91-101%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone for all trials. No residues at or above the LOQ were detected in control sample of DFA for trial 13-2147-01 (the Netherlands), residues between 0.028 – 0.032 mg/kg were detected for trial 13-2147-02 (Belgium).

Residues of flupyradifurone in kale 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.22 – 1.9 mg/kg.

Residues of DFA in kale 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.41 – 0.60 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.6.2-1.

**Table C.3.1.2.6.2-1 Residue trials on kale**

Reference: Determination of the residues of BYI 02960 in/on curly kale after spray application of BYI 02960 SL 200 in the Netherlands and Belgium, [REDACTED] 2015, Study ID: 13-2147, Activity ID: RARVN029

GLP: Yes Sample storage conditions: 346 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Kale / Leafy brassicas Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                               |                        |                                                        |            |            |              |                                  |    |         |      |             |      |             |              |    |  |
|---------------------------------------------------------------|------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------|-------------|------|-------------|--------------|----|--|
| 13-2147-01<br>1681 ND<br>Zwaagdijk<br>The Netherlands<br>2013 | Curly kale<br>Reflex   | 1. 03-07-<br>2013<br>2. –<br>3. 22-09 to<br>10-10-2013 | 125<br>125 | 500<br>500 | 25<br>25     | 13-09-<br>2013<br>23-09-<br>2013 | 10 | BBCH 49 | Leaf | 0.019       | 0.10 | 0.119       | 0.033        | -0 |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 2.9         | 0.12 | 3.02        | 0.040        | 0  |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 2.9         | 0.17 | 3.07        | 0.057        | 1  |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | <u>1.9</u>  | 0.34 | <u>2.24</u> | 0.113        | 3  |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 1.3         | 0.37 | 1.67        | 0.123        | 5  |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 0.85        | 0.50 | 1.35        | 0.167        | 7  |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 0.60        | 0.60 | 1.2         | <u>0.20</u>  | 10 |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 0.081       | 0.55 | 0.631       | 0.183        | 14 |  |
| 13-2147-02<br>6221 Saint-<br>Amand<br>Belgium<br>2013         | Curly kale<br>Winnetou | 1. 27-05-<br>2013<br>2. –<br>3. 22-09 to<br>10-10-2013 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 19-07-<br>2013<br>29-07-<br>2013 | 10 | BBCH 49 | Leaf | 0.019       | 0.20 | 0.219       | 0.067        | -0 |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 3.8         | 0.24 | 4.04        | 0.080        | 0  |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 0.43        | 0.21 | 0.64        | 0.070        | 1  |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | <u>0.22</u> | 0.32 | <u>0.54</u> | 0.107        | 3  |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 0.11        | 0.28 | 0.39        | 0.093        | 4  |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 0.055       | 0.33 | 0.385       | 0.11         | 7  |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 0.021       | 0.31 | 0.331       | 0.103        | 10 |  |
|                                                               |                        |                                                        |            |            |              |                                  |    |         | Leaf | 0.034       | 0.41 | 0.444       | <u>0.137</u> | 14 |  |



### C.3.1.2.6.3 Study 3

|                        |                                                                                                                                                                                                                                                                                                                            |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on curly kale after spray application of BYI 02960 SL 200 in Germany, [REDACTED] 2019, Study ID: 18-2102, Activity ID: RARV0266                                                                                                                                              |
| Guideline(s):          | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market<br><br>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)<br><br>US EPA OCSPP 860.1500, Crop Field Trial |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                         |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                        |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                 |

### Materials and methods

Two outdoor trials on curly kale were conducted in Germany using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2018 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.119 – 0.127 kg/ha flupyradifurone in 302 - 408 L/ha of water with a 10/13 day RTI, 3 day PHI and final application at BBCH 48-49. The surfactant adjuvant 'Trend 90' was added to the test item at a concentration of 0.05%. In one of the trials, a 13 day RTI was used. As the residue data show that it is the second application that drives the residues, and as the residues from this trial are similar or higher than the trial undertaken with a 10 day RTI, this deviation is not considered to adversely impact the validity of the trial.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. Both of the trials were decline trials, leaf samples were taken before the last application (0) and at 0, 1, 3, 7, 10, 14 and 20/21 days after the last application. Samples weighing at least 2 kg and consisting of 12 plants were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 202 days for flupyradifurone and DFA

at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to kale (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 100-102% and 74-94%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in kale 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.76 – 0.87 mg/kg.

Residues of DFA in kale 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.45 – 0.90 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.6.3-1.

**Table C.3.1.2.6.3-1 Residue trials on kale**

Reference: Determination of the residues of BYI 02960 in/on curly kale after spray application of BYI 02960 SL 200 in Germany, [REDACTED] 2019, Study ID: 18-2102, Activity ID: RARV0266

GLP: Yes Sample storage conditions: 202 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Kale / Leafy brassicas Analytical method: Method 01304

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                   |                        |                                                      |            |            |              |                          |    |         |      |             |        |             |              |    |  |
|-------------------------------------------------------------------|------------------------|------------------------------------------------------|------------|------------|--------------|--------------------------|----|---------|------|-------------|--------|-------------|--------------|----|--|
| 18-2102-01<br>49377<br>Vechta OT<br>Calveslage<br>Germany<br>2018 | Curly kale<br>Winnetou | 1. 12-08-2018<br>2. –<br>3. 15-10-2018 to 15-02-2019 | 119<br>127 | 380<br>408 | 31.3<br>31.1 | 25-10-2018<br>07-11-2018 | 13 | BBCH 48 | Leaf | 0.34        | 0.19   | 0.53        | 0.063        | -0 |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 4.4         | <0.020 | 4.42        | <0.007       | 0  |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 3.1         | <0.020 | 3.12        | <0.007       | 1  |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | <u>0.87</u> | 0.28   | <u>1.15</u> | 0.093        | 3  |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 0.33        | 0.41   | 0.74        | 0.137        | 7  |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 0.32        | 0.45   | 0.77        | <u>0.150</u> | 10 |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 0.32        | 0.43   | 0.75        | 0.143        | 14 |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 0.19        | 0.36   | 0.55        | 0.12         | 21 |  |
| 18-2102-02<br>42799<br>Leichlingen<br>Germany<br>2018             | Curly kale<br>Winnetou | 1. 28-05-2018<br>2. –<br>3. 01-09 to 31-10-2018      | 127<br>126 | 305<br>302 | 41.6<br>41.7 | 01-09-2018<br>11-09-2018 | 10 | BBCH 49 | Leaf | 0.018       | 0.47   | 0.488       | 0.157        | -0 |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 4.9         | <0.020 | 4.92        | <0.007       | 0  |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 2.1         | <0.020 | 2.12        | <0.007       | 1  |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | <u>0.76</u> | 0.74   | <u>1.50</u> | 0.247        | 3  |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 0.29        | 0.76   | 1.05        | 0.253        | 7  |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 0.11        | 0.90   | 1.01        | <u>0.30</u>  | 10 |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 0.038       | 0.69   | 0.728       | 0.23         | 14 |  |
|                                                                   |                        |                                                      |            |            |              |                          |    |         | Leaf | 0.017       | 0.69   | 0.707       | 0.23         | 20 |  |

### **C.3.1.2.7 Kohlrabi**

#### **C.3.1.2.7.1 Study 1**

|                        |                                                                                                                                                                                                                                                                                            |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on kohlrabi after spraying of BYI 02960 SL 200 in the field in Germany and the Netherlands, [REDACTED] 2013, Study ID: 10-2220, Activity ID: RARVL025                                                                                        |
| Guideline(s):          | EC Guidedance working document 7029/VI/95 rev.5 (1997-07-22), EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8<br><br>Residues in or on Treated Products, Food and Feed<br><br>US EPA OCSPP Guideline No. 860.1500.SUPP |
| Deviations:            | No                                                                                                                                                                                                                                                                                         |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                        |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                 |

#### **Materials and methods**

Two outdoor trials on kohlrabi were conducted in Germany and the Netherlands using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2010 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 300 - 400 L/ha of water with a 10 day RTI, 3 day PHI and final application at BBCH 44-48. The surfactant adjuvant 'Trend 90' was added to the test item at a concentration of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. Both of the trials were decline trials, corm samples were taken before the last application (-0) and at 0, 1, 3, 5 and 7 days after the last application. Samples consisting of 12 plants (weighing between 1 to 12 kg) were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 223 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to kohlrabi (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 93-98% and 91-95%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in kohlrabi 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.02 – 0.03 mg/kg.

Residues of DFA in kohlrabi 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.13 – 0.15 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.7.1-1.

**Table C.3.1.2.7.1-1 Residue trials on kohlrabi**

Reference: Determination of the residues of BYI 02960 in/on kohlrabi after spraying of BYI 02960 SL 200 in the field in Germany and the Netherlands, [REDACTED] 2013, Study ID: 10-2220, Activity ID: RARVL025

GLP: Yes Sample storage conditions: 223 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Kohlrabi / Brassica vegetables Analytical method: Method 01304

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                           |                    |                                                        |            |            |              |                                  |    |         |      |              |       |             |              |    |  |
|---------------------------------------------------------------------------|--------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------|--------------|-------|-------------|--------------|----|--|
| 10-2220-01<br>50321<br>Bruehl-<br>Schwardorf<br>Germany<br>2010           | Kohlrabi<br>Korist | 1. 16-04-<br>2010<br>2. –<br>3. 04-06 to<br>15-06-2010 | 125<br>125 | 300<br>300 | 41.7<br>41.7 | 25-05-<br>2010<br>04-06-<br>2010 | 10 | BBCH 44 | Corm | <0.010       | 0.030 | 0.040       | 0.010        | -0 |  |
|                                                                           |                    |                                                        |            |            |              |                                  |    |         | Corm | 0.060        | 0.030 | 0.090       | 0.010        | 0  |  |
|                                                                           |                    |                                                        |            |            |              |                                  |    |         | Corm | 0.050        | 0.030 | 0.080       | 0.010        | 1  |  |
|                                                                           |                    |                                                        |            |            |              |                                  |    |         | Corm | <u>0.020</u> | 0.080 | 0.10        | 0.027        | 3  |  |
|                                                                           |                    |                                                        |            |            |              |                                  |    |         | Corm | <0.010       | 0.11  | 0.12        | 0.037        | 5  |  |
|                                                                           |                    |                                                        |            |            |              |                                  |    |         | Corm | <0.010       | 0.15  | <u>0.16</u> | <u>0.050</u> | 7  |  |
| 10-2220-02<br>1681 ND<br>Zwaagdijk-<br>Oost<br>The<br>Netherlands<br>2010 | Kohlrabi<br>Korist | 1. 04-06-<br>2010<br>2. –<br>3. 25-07 to<br>10-08-2010 | 125<br>125 | 400<br>400 | 31.3<br>31.3 | 16-07-<br>2010<br>26-07-<br>2010 | 10 | BBCH 48 | Corm | <0.010       | 0.090 | 0.10        | 0.030        | -0 |  |
|                                                                           |                    |                                                        |            |            |              |                                  |    |         | Corm | 0.050        | 0.080 | 0.13        | 0.027        | 0  |  |
|                                                                           |                    |                                                        |            |            |              |                                  |    |         | Corm | 0.050        | 0.080 | 0.13        | 0.027        | 1  |  |
|                                                                           |                    |                                                        |            |            |              |                                  |    |         | Corm | <u>0.030</u> | 0.11  | 0.14        | 0.037        | 3  |  |
|                                                                           |                    |                                                        |            |            |              |                                  |    |         | Corm | 0.020        | 0.12  | 0.14        | 0.040        | 5  |  |
|                                                                           |                    |                                                        |            |            |              |                                  |    |         | Corm | 0.020        | 0.13  | <u>0.15</u> | <u>0.043</u> | 7  |  |



#### **C.3.1.2.7.2 Study 2**

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on kohlrabi after spray application of BYI 02960 SL 200 in the Netherlands and Belgium, [REDACTED] 2015, Study ID: 13-2148, Activity ID: RARVN028                                                                                                                                                                                                                                               |
| Guideline(s):          | REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<br><br>EC guidance working document 7029/VI/95 rev. 5 (July 22, 1997)<br><br>OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial<br><br>US EPA OCSPP Guideline No. 860.1500 |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                                                                                                                                    |

#### **Materials and methods**

Two outdoor trials on kohlrabi were conducted in the Netherlands and Belgium using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2013 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 350 - 600 L/ha of water with a 10 day RTI, 3 day PHI and final application at BBCH 47-49. The surfactant adjuvant 'Trend 90' was added to the test item at a concentration of 0.05%.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, BBCH 12-49).

Weather data were reported for the trials and no exceptional events were noted. Both of the trials were decline trials, corm samples were taken before the last application (-0) and at 0, 1, 3, 5, 7 and 14 days after the last application. Samples consisting of at least 12 plants and weighing at least 2 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The

maximum storage interval between harvest and analysis was 376 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to kohlrabi (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 97-101% and 93-100%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in kohlrabi 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.026 – 0.041 mg/kg.

Residues of DFA in kohlrabi 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.21 – 0.24 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.7.2-1.

**Table C.3.1.2.7.2-1 Residue trials on kohlrabi**

Reference: Determination of the residues of BYI 02960 in/on kohlrabi after spray application of BYI 02960 SL 200 in the Netherlands and Belgium, [REDACTED] 2015, Study ID: 13-2148, Activity ID: RARVN028

GLP: Yes Sample storage conditions: 376 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Kohlrabi / Brassica vegetables Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                  |                       |                                                        |            |            |              |                                  |    |         |      |              |       |             |              |    |  |
|------------------------------------------------------------------|-----------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------|--------------|-------|-------------|--------------|----|--|
| 13-2148-01<br>1681 ND<br>Zwaagdijk<br>The<br>Netherlands<br>2013 | Kohlrabi<br>Vikora    | 1. 07-05-<br>2013<br>2. –<br>3. 06-07 to<br>20-07-2013 | 125<br>125 | 350<br>350 | 35.7<br>35.7 | 25-06-<br>2013<br>05-07-<br>2013 | 10 | BBCH 47 | Corm | 0.014        | 0.054 | 0.068       | 0.018        | -0 |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | 0.10         | 0.061 | 0.161       | 0.020        | 0  |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | 0.091        | 0.056 | 0.147       | 0.019        | 1  |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | <u>0.041</u> | 0.10  | 0.141       | 0.033        | 3  |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | 0.037        | 0.18  | 0.217       | 0.060        | 5  |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | 0.021        | 0.20  | 0.221       | 0.067        | 7  |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | <0.010       | 0.24  | <u>0.25</u> | <u>0.080</u> | 14 |  |
| 13-2148-02<br>6221 Saint-<br>Amand<br>Belgium<br>2013            | Kohlrabi<br>Korist F1 | 1. 27-05-<br>2013<br>2. –<br>3. 01-07 to<br>20-07-2013 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 24-06-<br>2013<br>04-07-<br>2013 | 10 | BBCH 49 | Corm | 0.020        | 0.065 | 0.085       | 0.022        | -0 |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | 0.027        | 0.055 | 0.082       | 0.018        | 0  |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | 0.032        | 0.082 | 0.114       | 0.027        | 1  |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | <u>0.026</u> | 0.092 | 0.118       | 0.031        | 3  |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | 0.020        | 0.16  | 0.18        | 0.053        | 5  |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | 0.015        | 0.20  | 0.215       | 0.067        | 7  |  |
|                                                                  |                       |                                                        |            |            |              |                                  |    |         | Corm | <0.010       | 0.21  | <u>0.22</u> | <u>0.070</u> | 14 |  |

### C.3.1.2.8 Leafy vegetables and herbs

#### C.3.1.2.8.1 Study 1

|                        |                                                                                                                                                                                                                                   |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on lettuce after spraying of BYI 02960 SL 200 in the field in the Netherlands, Belgium, France (North) and Germany, [REDACTED] 2013, Study ID: 10-2223, Activity ID: RARVL028       |
| Guideline(s):          | EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22) |
| Deviations:            | No                                                                                                                                                                                                                                |
| GLP:                   | Yes                                                                                                                                                                                                                               |
| Validity of the study: | Acceptable                                                                                                                                                                                                                        |

#### Materials and methods

Five outdoor trials on lettuce were conducted in the Netherlands, Belgium, northern France and Germany using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2010 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 300 - 600 L/ha of water with a 9/10 day RTI, 3 day PHI and final application at BBCH 48. Normal commercial harvest of lettuce takes place at approximately BBCH 49, therefore as the last application was undertaken at BBCH 48 and as the PHIs and RTIs used match the notified cGAP, this is considered acceptable.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, all growth stages).

Weather data were reported for the trials and no exceptional events were noted. All five of the trials were decline trials, head samples were taken before the last application (-0) and at 0, 1, 3, 5 and 7 days after the last application. Samples consisting of 12 plants (weighing between 1.5 to 7.6 kg) were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 202 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to lettuce (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 91-105% and 90-98%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in head lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.37 – 0.68 mg/kg.

Residues of flupyradifurone in leaf lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.83 – 1.0 mg/kg.

Residues of DFA in head lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between <0.02 – 0.03 mg/kg (expressed as flupyradifurone).

Residues of DFA in leaf lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were <0.02 (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.8.1-1.

**Table C.3.1.2.8.1-1 Residue trials on lettuce**

Reference: Determination of the residues of BYI 02960 in/on lettuce after spraying of BYI 02960 SL 200 in the field in the Netherlands, Belgium, France (North) and Germany, [REDACTED] 2013, Study ID: 10-2223, Activity ID: RARVL028

|                              |                            |                                  |                                                                     |
|------------------------------|----------------------------|----------------------------------|---------------------------------------------------------------------|
| GLP:                         | Yes                        | Sample storage conditions:       | 202 days at ≤-18°C                                                  |
| Crop/crop group:             | Lettuce / Leafy vegetables | Analytical method:               | Method 01304                                                        |
| Indoor/outdoor:              | Outdoor                    | Limit of Quantification (mg/kg): | Flupyradifurone: 0.01 mg/kg<br>DFA: 0.02 mg/kg (parent equivalents) |
| Formulation:                 | BYI 02960 200 SL           | Residues calculated as:          | Flupyradifurone                                                     |
| Content of active substance: | 200 g/L                    |                                  |                                                                     |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                                  | Commodity<br>Variety   | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or number<br>and last<br>date | Interval<br>between<br>applicati<br>ons<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |        |                                                                                      |                             | PHI<br>(days<br>) | Remarks |
|-------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|--------------------------------------------------------|---------------------------------------------------|-----------------------------------------|---------------------|---------------------|--------|--------------------------------------------------------------------------------------|-----------------------------|-------------------|---------|
|                                                                               |                        |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                        |                                                   |                                         |                     | Flupyra<br>difurone | DFA    | Sum of<br>flupyradif<br>urone<br>and DFA,<br>expresse<br>d as<br>flupyradif<br>urone | DFA,<br>expressed<br>as DFA |                   |         |
| 10-2223-01<br>1681 ND<br>Zwaagdijk-<br>Oost<br>The<br>Netherland<br>s<br>2010 | Head lettuce<br>Gisela | 1. 01-07-<br>2010<br>2. –<br>3. 04-08 to<br>10-08-2010         | 125<br>125                        | 300<br>300      | 41.7<br>41.7     | 23-07-<br>2010<br>02-08-<br>2010                       | 10                                                | BBCH 48                                 | Head                | 0.20                | <0.020 | 0.22                                                                                 | <0.007                      | -0                |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 1.9                 | <0.020 | 1.92                                                                                 | <0.007                      | 0                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 1.8                 | <0.020 | 1.82                                                                                 | <0.007                      | 1                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | <u>0.58</u>         | <0.020 | <u>0.60</u>                                                                          | <0.007                      | 3                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.34                | <0.020 | 0.36                                                                                 | <0.007                      | 5                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.22                | <0.020 | 0.24                                                                                 | <0.007                      | 7                 |         |
| 10-2223-02<br>6210<br>Villers-<br>Perwin<br>Belgium<br>2010                   | Head lettuce<br>Lucan  | 1. 13-04-<br>2010<br>2. –<br>3. 29-05 to<br>23-06-2010         | 125<br>125                        | 500<br>500      | 25<br>25         | 04-06-<br>2010<br>14-06-<br>2010                       | 10                                                | BBCH 48                                 | Head                | 0.080               | <0.020 | 0.10                                                                                 | <0.007                      | -0                |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 1.7                 | <0.020 | 1.72                                                                                 | <0.007                      | 0                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.43                | <0.020 | 0.45                                                                                 | <0.007                      | 1                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | <u>0.37</u>         | <0.020 | <u>0.39</u>                                                                          | <0.007                      | 3                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.34                | <0.020 | 0.36                                                                                 | <0.007                      | 5                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.21                | <0.020 | 0.23                                                                                 | <0.007                      | 7                 |         |
| 10-2223-03<br>95000<br>Cergy<br>France<br>2010                                | Head lettuce<br>Abago  | 1. 24-03-<br>2010<br>2. –<br>3. 29-05 to<br>08-06-2010         | 125<br>125                        | 600<br>600      | 20.8<br>20.8     | 18-05-<br>2010<br>28-05-<br>2010                       | 10                                                | BBCH 48                                 | Head                | 0.13                | <0.020 | 0.15                                                                                 | <0.007                      | -0                |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 1.5                 | <0.020 | 1.52                                                                                 | <0.007                      | 0                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 1.3                 | <0.020 | 1.32                                                                                 | <0.007                      | 1                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | <u>0.68</u>         | <0.020 | <u>0.70</u>                                                                          | <0.007                      | 3                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.52                | 0.020  | 0.54                                                                                 | 0.007                       | 5                 |         |
|                                                                               |                        |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.46                | 0.030  | 0.49                                                                                 | <u>0.010</u>                | 7                 |         |



The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                          | Commodity<br>Variety                    | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or number<br>and last<br>date | Interval<br>between<br>applicati<br>ons<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |        |                                                                                      |                             | PHI<br>(days<br>) | Remarks |
|-----------------------------------------------------------------------|-----------------------------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|--------------------------------------------------------|---------------------------------------------------|-----------------------------------------|---------------------|---------------------|--------|--------------------------------------------------------------------------------------|-----------------------------|-------------------|---------|
|                                                                       |                                         |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                        |                                                   |                                         |                     | Flupyra<br>difurone | DFA    | Sum of<br>flupyradif<br>urone<br>and DFA,<br>expresse<br>d as<br>flupyradif<br>urone | DFA,<br>expressed<br>as DFA |                   |         |
| 10-2223-<br>04<br>40764<br>Langenfeld<br>-Reusrath<br>Germany<br>2010 | Leaf lettuce<br>Cavernet<br>Lollo rosso | 1. 28-04-<br>2010<br>2. –<br>3. 14-06 to<br>20-07-2010         | 125<br>125                        | 300<br>300      | 41.7<br>41.7     | 01-06-<br>2010<br>11-06-<br>2010                       | 10                                                | BBCH 48                                 | Head                | 0.37                | <0.020 | 0.39                                                                                 | <0.007                      | -0                |         |
|                                                                       |                                         |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 1.7                 | <0.020 | 1.72                                                                                 | <0.007                      | 0                 |         |
|                                                                       |                                         |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 1.1                 | <0.020 | 1.12                                                                                 | <0.007                      | 1                 |         |
|                                                                       |                                         |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | <u>1.0</u>          | <0.020 | <u>1.02</u>                                                                          | <u>&lt;0.007</u>            | 3                 |         |
|                                                                       |                                         |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.87                | <0.020 | 0.89                                                                                 | <0.007                      | 5                 |         |
|                                                                       |                                         |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.66                | <0.020 | 0.68                                                                                 | <0.007                      | 7                 |         |
| 10-2223-<br>05<br>67125<br>Schauernh<br>eim<br>Germany<br>2010        | Leaf lettuce<br>Chloe Lollo<br>Rosso    | 1. 07-09-<br>2010<br>2. –<br>3. 16-10 to<br>22-10-2010         | 125<br>125                        | 400<br>400      | 31.3<br>31.3     | 06-10-<br>2010<br>15-10-<br>2010                       | 9                                                 | BBCH 48                                 | Head                | 0.80                | <0.020 | 0.82                                                                                 | <0.007                      | -0                |         |
|                                                                       |                                         |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 4.1                 | <0.020 | 4.12                                                                                 | <0.007                      | 0                 |         |
|                                                                       |                                         |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 1.0                 | <0.020 | 1.02                                                                                 | <0.007                      | 1                 |         |
|                                                                       |                                         |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | <u>0.83</u>         | <0.020 | <u>0.85</u>                                                                          | <u>&lt;0.007</u>            | 3                 |         |
|                                                                       |                                         |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.83                | <0.020 | 0.85                                                                                 | <0.007                      | 5                 |         |
|                                                                       |                                         |                                                                |                                   |                 |                  |                                                        |                                                   |                                         | Head                | 0.65                | <0.020 | 0.67                                                                                 | <0.007                      | 7                 |         |

#### **C.3.1.2.8.2 Study 2**

Reference: Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the field in Germany, northern France and Belgium, [REDACTED] 2012, Study ID: 11-2082, Activity ID: RARVL087

(including Amendment No. 1)

Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

Four outdoor trials on lettuce were conducted in Germany, northern France and Belgium using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2011 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 500 - 750 L/ha of water with a 10 day RTI, 3 day PHI and final application at BBCH 48. Normal commercial harvest of lettuce takes place at approximately BBCH 49, therefore as the last application was undertaken at BBCH 48 and as the PHIs and RTIs used match the notified cGAP, this is considered acceptable.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, all growth stages).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, head samples were taken before the last application (-0) and at 0, 3, 7, 10 and 14 days after the last application. Trials 11-2082-03 and -04 (France and Belgium, respectively) also collected samples at 10, 8, 4/5 and 2 days before the last application. Samples consisting of at least 12 plants and weighing at least 1 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 150 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to lettuce (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 105-109% and 99-102%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in leaf lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.11 – 2.9 mg/kg.

Residues of DFA in leaf lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.027 – 0.20 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.8.2-1.

### Table C.3.1.2.8.2-1 Residue trials on lettuce

Reference: Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the field in Germany, northern France and Belgium, [REDACTED] 2012, Study ID: 11-2082, Activity ID: RARVL087

GLP: Yes Sample storage conditions: 150 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Lettuce / Leafy vegetables Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                              |                                               |                                                 |            |            |              |                          |    |         |                                                                              |                                                                                   |                                                                                          |                                                                                           |                                                                                                 |                                                        |  |
|--------------------------------------------------------------|-----------------------------------------------|-------------------------------------------------|------------|------------|--------------|--------------------------|----|---------|------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------------------------------------------------|--|
| 11-2082-01<br>40764<br>Langenfeld<br>Germany<br>2011         | Leaf lettuce<br>Aleppo<br>Lollo bionda        | 1. 26-04-2011<br>2. –<br>3. 30-05 to 10-06-2011 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 17-05-2011<br>27-05-2011 | 10 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head                                 | 0.19<br>2.7<br><u>1.5</u><br>0.52<br>0.13<br>0.073                                | <0.020<br>0.020<br>0.023<br>0.028<br>0.020<br>0.024                                      | 0.21<br>2.72<br><u>1.523</u><br>0.548<br>0.15<br>0.097                                    | 0.007<br>0.007<br>0.008<br><u>0.009</u><br>0.007<br>0.008                                       | -0<br>0<br>3<br>7<br>10<br>14                          |  |
| 11-2082-02<br>59457<br>Werl-<br>Westönnen<br>Germany<br>2011 | Leaf lettuce<br>Kitara Lollo<br>Biaonda       | 1. 28-04-2011<br>2. –<br>3. 26-05 to 15-06-2011 | 125<br>125 | 500<br>500 | 25<br>25     | 21-05-2011<br>31-05-2011 | 10 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head                                 | 0.11<br>2.6<br><u>0.11</u><br>0.033<br>0.023<br>0.011                             | <0.020<br><0.020<br><0.020<br>0.022<br>0.027<br>0.027                                    | 0.13<br>2.62<br><u>0.13</u><br>0.055<br>0.050<br>0.038                                    | <0.007<br><0.007<br><0.007<br>0.007<br><u>0.009</u><br>0.009                                    | -0<br>0<br>3<br>7<br>10<br>14                          |  |
| 11-2082-03<br>37230<br>Fondettes<br>France<br>2011           | Leaf lettuce<br>Quenty<br>Feuille de<br>chene | 1. 05-05-2011<br>2. –<br>3. 20-06 to 15-07-2011 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 14-06-2011<br>24-06-2011 | 10 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head | 2.9<br>2.6<br>1.4<br>0.76<br>0.57<br>3.8<br><u>2.9</u><br>1.6<br>0.90<br>0.75     | <0.020<br><0.020<br>0.027<br>0.037<br>0.049<br>0.048<br>0.096<br>0.11<br>0.14<br>0.20    | 2.92<br>2.62<br>1.427<br>0.797<br>0.619<br>3.848<br><u>2.996</u><br>1.71<br>1.04<br>0.95  | <0.007<br><0.007<br>0.009<br>0.012<br>0.016<br>0.016<br>0.032<br>0.037<br>0.047<br><u>0.067</u> | -10<br>-8<br>-5<br>-2<br>-0<br>0<br>3<br>7<br>10<br>14 |  |
| 11-2082-04<br>6210<br>Villers-<br>Perwin<br>Belgium<br>2011  | Leaf lettuce<br>Funnas                        | 1. 22-04-2011<br>2. –<br>3. 30-05 to 20-06-2011 | 125<br>125 | 750<br>750 | 16.7<br>16.7 | 17-05-2011<br>27-05-2011 | 10 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head | 5.6<br>2.0<br>0.63<br>0.35<br>0.25<br>2.8<br><u>0.43</u><br>0.22<br>0.12<br>0.058 | <0.020<br><0.020<br>0.028<br>0.030<br>0.026<br>0.022<br>0.028<br>0.030<br>0.026<br>0.025 | 5.62<br>2.02<br>0.658<br>0.38<br>0.276<br>2.822<br><u>0.458</u><br>0.25<br>0.146<br>0.083 | <0.007<br><0.007<br>0.009<br>0.010<br>0.009<br>0.007<br>0.009<br><u>0.010</u><br>0.009<br>0.008 | -10<br>-8<br>-5<br>-2<br>-0<br>0<br>3<br>7<br>10<br>14 |  |

### C.3.1.2.8.3 Study 3

|                        |                                                                                                                                                                                                                                                                                                                            |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on lettuce (oak leaf variety) after spray application of BYI 02960 SL 200 in northern France, southern France, Italy and the Netherlands, [REDACTED] 2018, Study ID: 16-2006, Activity ID: RARV0044                                                                          |
| Guideline(s):          | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market<br><br>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)<br><br>US EPA OCSPP 860.1500, Crop Field Trial |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                         |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                        |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                 |

### Materials and methods

Four outdoor trials on lettuce were conducted in the Netherlands, northern France, southern France and Italy using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2016 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 400 - 800 L/ha of water with a 9-11 day RTI, 3 day PHI and final application at BBCH 47-49. Normal commercial harvest of lettuce takes place at approximately BBCH 49, therefore as the last application was undertaken at BBCH 49 and as the PHIs and RTIs used match the notified cGAP, this is considered acceptable.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, all growth stages).

Weather data were reported for the trials and no exceptional events were noted, except wind speeds slightly over 3 m/s for trial 16-2006-01 (the Netherlands) which is not expected to have adversely impacted the validity of the trial. All four of the trials were decline trials, head samples were taken before the last application (-0) and at 0, 3, 6/ 7, 10 and 14 days after the last application. Samples consisting of at least 12 plants and weighing at least 1 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum

storage interval between harvest and analysis was 236 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to lettuce (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 94-95% and 97%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in leaf lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.60 – 1.3 mg/kg.

Residues of DFA in leaf lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between  $<0.02$  – 0.10 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.8.3-1.

**Table C.3.1.2.8.3-1 Residue trials on lettuce**

Reference: Determination of the residues of BYI 02960 in/on lettuce (oak leaf variety) after spray application of BYI 02960 SL 200 in northern France, southern France, Italy and the Netherlands, [REDACTED] 2018, Study ID: 16-2006, Activity ID: RARV0044

GLP: Yes Sample storage conditions: 236 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Lettuce / Leafy vegetables Analytical method: Method 01304

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |



The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                               |                                                         |                                                        |            |            |              |                                  |    |         |                                              |                                                        |                                                         |                                                           |                                                                   |                               |  |
|-------------------------------------------------------------------------------|---------------------------------------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|----------------------------------------------|--------------------------------------------------------|---------------------------------------------------------|-----------------------------------------------------------|-------------------------------------------------------------------|-------------------------------|--|
| 16-2006-01<br>1681 ND<br>Zwaagdijk<br>The Netherlands<br>2016                 | Leaf lettuce<br>Red Salad<br>Bowl (oak<br>leaf variety) | 1. 22-06-<br>2016<br>2. –<br>3. 27-07 to<br>01-08-2016 | 125<br>125 | 800<br>800 | 15.6<br>15.6 | 15-07-<br>2016<br>25-07-<br>2016 | 10 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | <0.010<br>3.0<br><u>0.66</u><br>0.19<br>0.086<br>0.017 | <0.020<br>0.020<br><0.020<br><0.020<br><0.020<br><0.020 | <0.030<br>3.02<br><u>0.68</u><br>0.21<br>0.106<br>0.037   | <0.007<br>0.007<br><u>&lt;0.007</u><br><0.007<br><0.007<br><0.007 | -0<br>0<br>3<br>7<br>10<br>14 |  |
| 16-2006-02<br>37130<br>Lignièrès<br>de Touraine<br>Northern<br>France<br>2016 | Leaf lettuce<br>Kiribati (oak<br>leaf variety)          | 1. 09-05-<br>2016<br>2. –<br>3. 15-06 to<br>15-07-2016 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 10-06-<br>2016<br>21-06-<br>2016 | 11 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | 0.017<br>3.6<br><u>1.1</u><br>0.47<br>0.27<br>0.10     | <0.020<br><0.020<br>0.037<br>0.057<br>0.10<br>0.098     | 0.037<br>3.62<br><u>1.137</u><br>0.527<br>0.37<br>0.198   | <0.007<br><0.007<br>0.012<br>0.019<br><u>0.033</u><br>0.033       | -0<br>0<br>3<br>7<br>10<br>14 |  |
| 16-2006-03<br>13103 St<br>Etienne du<br>Gres<br>Southern<br>France<br>2016    | Leaf lettuce<br>Kiribati<br>(loose leaf<br>variety)     | 1. 23-03-<br>2016<br>2. –<br>3. 10-05 to<br>25-05-2016 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 02-05-<br>2016<br>13-05-<br>2016 | 11 | BBCH 49 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | 0.12<br>2.1<br><u>0.60</u><br>0.41<br>0.20<br>0.17     | 0.026<br>0.029<br>0.041<br>0.044<br>0.054<br>0.074      | 0.147<br>2.129<br><u>0.641</u><br>0.454<br>0.254<br>0.244 | 0.009<br>0.010<br>0.014<br>0.015<br>0.018<br><u>0.025</u>         | -0<br>0<br>3<br>6<br>10<br>14 |  |
| 16-2006-04<br>95100 C.da<br>Pigno;<br>Catania<br>Italy<br>2016                | Leaf lettuce<br>Ribai (oak<br>leaf variety)             | 1. 14-04-<br>2016<br>2. –<br>3. 25-05 to<br>03-06-2016 | 125<br>125 | 400<br>600 | 31.3<br>20.8 | 09-05-<br>2016<br>18-05-<br>2016 | 9  | BBCH 47 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | 0.79<br>4.7<br><u>1.3</u><br>0.57<br>0.34<br>0.070     | 0.023<br>0.025<br>0.025<br>0.035<br>0.039<br>0.038      | 0.813<br>4.725<br><u>1.325</u><br>0.605<br>0.379<br>0.108 | 0.008<br>0.008<br>0.008<br>0.012<br><u>0.013</u><br>0.013         | -0<br>0<br>3<br>7<br>10<br>14 |  |

#### **C.3.1.2.8.4 Study 4**

Reference: Determination of the residues of BYI 02960 in/on lettuce, head after spray application of BYI 02960 SL 200 in the field in France (south), Spain and Italy, [REDACTED] 2012, Study ID: 10-2213, Activity ID: RARVL018 (including Amendment 01)

Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

Five outdoor trials on lettuce were conducted in southern France, Spain and Italy using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2010 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 500 - 700 L/ha of water with a 10/11 day RTI, 3/4 day PHI and final application at BBCH 46-49. Normal commercial harvest of lettuce takes place at approximately BBCH 49, therefore as the last application was undertaken at BBCH 46-49 which is the same principal growth stage and as the PHIs and RTIs used match the notified cGAP, this is considered acceptable.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, all growth stages).

Weather data were reported for the trials and no exceptional events were noted. All five of the trials were decline trials, head samples were taken before the last application (-0) and at 0, 1, 3/4, 4/5 and 7 days after the last application. Samples consisting of at least 12 plants and weighing between 1.4 to 6.7 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 151 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to lettuce (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 91-105% and 90-98%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in head lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.40 – 2.7 mg/kg.

Residues of flupyradifurone in leaf lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 1.1 – 2.1 mg/kg.

Residues of DFA in head lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.02 – 0.05 mg/kg (expressed as flupyradifurone).

Residues of DFA in leaf lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.02 – 0.05 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.8.4-1.

**Table C.3.1.2.8.4-1 Residue trials on lettuce**

Reference: Determination of the residues of BYI 02960 in/on lettuce, head after spray application of BYI 02960 SL 200 in the field in France (south), Spain and Italy, [REDACTED] 2012, Study ID: 10-2213, Activity ID: RARVL018

GLP: Yes Sample storage conditions: 151 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Lettuce / Leafy vegetables Analytical method: Method 01304

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                            |                                            |                                                        |            |            |              |                                  |    |         |                                              |                                                     |                                                       |                                                      |                                                              |                             |  |
|------------------------------------------------------------|--------------------------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|----------------------------------------------|-----------------------------------------------------|-------------------------------------------------------|------------------------------------------------------|--------------------------------------------------------------|-----------------------------|--|
| 10-2213-01<br>86380<br>Marigny<br>Brizay<br>France<br>2010 | Head<br>lettuce<br>Madita                  | 1. 14-05-<br>2010<br>2. –<br>3. 14-06 to<br>24-06-2010 | 125<br>125 | 500<br>500 | 25<br>25     | 01-06-<br>2010<br>11-06-<br>2010 | 10 | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | 0.040<br>2.6<br>0.57<br><u>0.40</u><br>0.29<br>0.15 | <0.020<br><0.020<br><0.020<br>0.020<br>0.020<br>0.020 | 0.060<br>2.62<br>0.59<br><u>0.42</u><br>0.31<br>0.17 | <0.007<br><0.007<br><0.007<br><u>0.007</u><br>0.007<br>0.007 | -0<br>0<br>1<br>3<br>5<br>7 |  |
| 10-2213-02<br>46440<br>Almussafes<br>Spain<br>2010         | Head<br>lettuce<br>Dauair<br>Trocadero     | 1. 20-09-<br>2010<br>2. –<br>3. 15-11 to<br>15-12-2010 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 12-11-<br>2010<br>22-11-<br>2010 | 10 | BBCH 49 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | 0.80<br>3.8<br>3.5<br><u>2.7</u><br>2.3<br>1.3      | 0.020<br>0.020<br>0.030<br>0.030<br>0.030<br>0.030    | 0.82<br>3.82<br>3.53<br><u>2.73</u><br>2.33<br>1.33  | 0.007<br>0.007<br>0.010<br><u>0.010</u><br>0.010<br>0.010    | -0<br>0<br>1<br>3<br>4<br>7 |  |
| 10-2213-03<br>45020 Lusia<br>Rovigo<br>Italy<br>2010       | Head<br>lettuce<br>Ballerina<br>butterhead | 1. 11-05-<br>2010<br>2. –<br>3. 01-06 to<br>30-06-2010 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 01-06-<br>2010<br>11-06-<br>2010 | 10 | BBCH 46 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | 0.050<br>2.7<br>2.2<br><u>0.48</u><br>0.21<br>0.090 | 0.030<br>0.040<br>0.040<br>0.050<br>0.050<br>0.050    | 0.080<br>2.74<br>2.24<br><u>0.53</u><br>0.26<br>0.14 | 0.010<br>0.013<br>0.013<br><u>0.017</u><br>0.017<br>0.017    | -0<br>0<br>1<br>3<br>5<br>7 |  |
| 10-2213-04<br>08850 Gava<br>Spain<br>2010                  | Leaf lettuce<br>Muraï Lollo<br>rosso       | 1. 19-05-<br>2010<br>2. –<br>3. 26-06 to<br>10-07-2010 | 125<br>125 | 600<br>600 | 20.8<br>20.8 | 21-06-<br>2010<br>01-07-<br>2010 | 10 | BBCH 49 | Head<br>Head<br>Head<br>Head<br>Head<br>Head | 0.38<br>3.6<br>3.0<br><u>2.1</u><br>2.0<br>1.3      | 0.030<br>0.030<br>0.040<br>0.050<br>0.050<br>0.050    | 0.41<br>3.63<br>3.04<br><u>2.15</u><br>2.05<br>1.35  | 0.010<br>0.010<br>0.013<br><u>0.017</u><br>0.017<br>0.017    | -0<br>0<br>1<br>4<br>5<br>7 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                |                                       |                                                        |            |            |              |                                  |    |         |      |            |        |             |              |    |  |
|------------------------------------------------|---------------------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------|------------|--------|-------------|--------------|----|--|
| 10-2213-05<br>70031<br>Andria<br>Italy<br>2010 | Leaf lettuce<br>Bergamo<br>Blond loll | 1. 01-09-<br>2010<br>2. –<br>3. 15-10 to<br>31-10-2010 | 125<br>125 | 700<br>700 | 17.9<br>17.9 | 04-10-<br>2010<br>15-10-<br>2010 | 11 | BBCH 49 | Head | 0.040      | <0.020 | 0.060       | <0.007       | -0 |  |
|                                                |                                       |                                                        |            |            |              |                                  |    |         | Head | 2.9        | <0.020 | 2.92        | <0.007       | 0  |  |
|                                                |                                       |                                                        |            |            |              |                                  |    |         | Head | 1.9        | <0.020 | 1.92        | <0.007       | 1  |  |
|                                                |                                       |                                                        |            |            |              |                                  |    |         | Head | <u>1.1</u> | <0.020 | <u>1.12</u> | <0.007       | 3  |  |
|                                                |                                       |                                                        |            |            |              |                                  |    |         | Head | 0.21       | <0.020 | 0.23        | <0.007       | 5  |  |
|                                                |                                       |                                                        |            |            |              |                                  |    |         | Head | 0.17       | 0.020  | 0.19        | <u>0.007</u> | 7  |  |

#### **C.3.1.2.8.5 Study 5**

Reference: Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the field in Spain, Italy, southern France and Portugal, [REDACTED] 2012, Study ID: 11-2071, Activity ID: RARVL076

(including Amendment 01)

Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

Four outdoor trials on lettuce were conducted in southern France, Italy, Spain and Portugal using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2010 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 2 x 0.125 kg/ha flupyradifurone in 500 - 800 L/ha of water with a 9/10 day RTI, 3 day PHI and final application at BBCH 46-49. Normal commercial harvest of lettuce takes place at approximately BBCH 49, therefore as the last application was undertaken at BBCH 46-49 which is the same principal growth stage and as the PHIs and RTIs used match the notified cGAP, this is considered acceptable.

The applications support the authorised critical GAP (2 x 0.125 kg a.s./ha, 3 day PHI, 10 days RTI, all growth stages).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, head samples were taken before the last application (-0) and at 0, 3, 7, 10/11 and 14 days after the last application. In trials 11-2070-03 and -04 (southern France and Portugal, respectively) samples were also collected at 9/10, 8/7, 4/5 and 1/2 days before the last application. Samples consisting of at least 12 plants and weighing at least 1 kg were collected from treated and untreated plots, except for trial 11-2071-02 (Italy) where samples weighing at least 0.79 kg were taken. As sufficient material was available for analysis, this deviation is not considered to have adversely impacted the trial. Samples were frozen within 24 hours of sampling and stored deep frozen until

analysis. The maximum storage interval between harvest and analysis was 183 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to lettuce (high water). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 101% and 101%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone for all trials. No residues at or above the LOQ were detected in control samples of DFA for all trials, except the sample at 3 DALT for trial 11-2071-02 (Italy), in which 0.032 mg/kg was reported.

Residues of flupyradifurone in leaf lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.35 – 3.1 mg/kg.

Residues of DFA in leaf lettuce 3 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.038 – 0.15 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.8.5-1.



# **Table C.3.1.2.8.5-1 Residue trials on lettuce**

Reference: Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the field in Spain, Italy, southern France and Portugal, ██████████ 2012, Study ID: 11-2071, Activity ID: RARVL076

GLP: Yes Sample storage conditions: 183 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Lettuce / Leafy vegetables Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg):  
 Flupyradifurone: 0.01 mg/kg  
 DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                    |                             |                                                        |            |            |              |                                  |    |         |                                                                              |                                                                                       |                                                                                             |                                                                                               |                                                                                                    |                                                                       |  |
|--------------------------------------------------------------------|-----------------------------|--------------------------------------------------------|------------|------------|--------------|----------------------------------|----|---------|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|--|
| 11-2071-01<br>46230<br>Alginet<br>Spain<br>2011                    | Leaf lettuce<br>Livigna RZ  | 1. 11-05-<br>2011<br>2. –<br>3. 20-06 to<br>05-07-2011 | 125<br>125 | 500<br>600 | 25<br>20.8   | 14-06-<br>2011<br>24-06-<br>2011 | 10 | BBCH 49 | Head<br>Head<br>Head<br>Head<br>Head<br>Head                                 | 0.43<br>2.6<br><u>1.5</u><br>0.77<br>0.57<br>0.033                                    | 0.046<br>0.062<br>0.077<br>0.097<br>0.11<br>0.15                                            | 0.476<br>2.662<br><u>1.577</u><br>0.867<br>0.68<br>0.183                                      | 0.015<br>0.021<br>0.026<br>0.032<br>0.037<br><u>0.050</u>                                          | -0<br>0<br>3<br>7<br>10<br>14                                         |  |
| 11-2071-02<br>95100<br>Catania<br>Italy<br>2011                    | Leaf lettuce<br>Lollo Rosso | 1. 10-06-<br>2011<br>2. –<br>3. 10-07 to<br>25-07-2011 | 125<br>125 | 700<br>700 | 17.9<br>17.9 | 28-06-<br>2011<br>08-07-<br>2011 | 10 | BBCH 46 | Head<br>Head<br>Head<br>Head<br>Head<br>Head                                 | 0.55<br>7.3<br><u>3.1</u><br>1.4<br>0.24<br>0.17                                      | 0.051<br>0.039<br>0.083<br>0.13<br>0.11<br>0.12                                             | 0.601<br>7.339<br><u>3.183</u><br>1.53<br>0.35<br>0.29                                        | 0.017<br>0.013<br>0.028<br><u>0.043</u><br>0.037<br>0.040                                          | -0<br>0<br>3<br>7<br>10<br>14                                         |  |
| 11-2071-03<br>31200<br>Toulouse –<br>Croix<br>daurade<br>2011      | Leaf lettuce<br>Pitice      | 1. 18-04-<br>2011<br>2. –<br>3. 25-05 to<br>10-06-2011 | 125<br>125 | 800<br>800 | 15.6<br>15.6 | 18-05-<br>2011<br>27-05-<br>2011 | 9  | BBCH 48 | Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head | 5.3<br>3.4<br>0.69<br>0.39<br>0.29<br>3.5<br><u>0.72</u><br>0.25<br>0.20<br>0.094     | <0.020<br><0.020<br><0.020<br><0.020<br><0.020<br>0.020<br>0.035<br>0.032<br>0.047<br>0.046 | 5.32<br>3.42<br>0.71<br>0.41<br>0.31<br>3.52<br><u>0.755</u><br>0.282<br>0.247<br>0.14        | <0.007<br><0.007<br><0.007<br><0.007<br><0.007<br>0.007<br>0.012<br>0.011<br><u>0.016</u><br>0.015 | -9<br>-7<br>-4<br>-1<br>-0<br>0<br>3<br>7<br>11<br>14                 |  |
| 11-2071-04<br>2715-252<br>Almargem<br>do Bispo<br>Portugal<br>2011 | Leaf lettuce<br>Caypira     | 1. 06-04-<br>2011<br>2. –<br>3. 30-04 to<br>15-11-2011 | 125<br>125 | 800<br>800 | 15.6<br>15.6 | 10-05-<br>2011<br>20-05-<br>2011 | 10 | BBCH 49 | Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head<br>Head | <0.010<br>1.8<br>0.92<br>0.27<br>0.11<br>1.9<br><u>0.35</u><br>0.16<br>0.067<br>0.046 | <0.020<br>0.022<br>0.031<br>0.027<br>0.029<br>0.026<br>0.030<br>0.031<br>0.034<br>0.038     | <0.030<br>1.822<br>0.951<br>0.297<br>0.139<br>1.926<br><u>0.38</u><br>0.191<br>0.101<br>0.084 | <0.007<br>0.007<br>0.010<br>0.009<br>0.010<br>0.009<br>0.010<br>0.010<br>0.011<br><u>0.013</u>     | -10 <sup>(a)</sup><br>-8<br>-5<br>-2<br>-0<br>0<br>3<br>7<br>10<br>14 |  |

(a) The samples at -10 days were erroneously collected before the first application instead of after.

### **C.3.1.2.9 Soyabeans**

#### **C.3.1.2.9.1 Study 1**

|                        |                                                                                                                                                                                                                        |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | BYI 02960 200 SL and BYI 02960 480 FS – Magnitude of the Residue in/on Soybeans, [REDACTED] 2012, Report No.: RARVY011                                                                                                 |
| Guideline(s):          | EPA Ref.: OPPTS 860.1500, Crop Field Trials PMRA Ref.: DACO 7.4.1. Supervised Residue Field Trial Study PMRA Ref.: DACO 7.4.2. Residue Decline Study OECD Test Guideline 509: Crop Field Trial (Adopted Sept. 7, 2009) |
| Deviations:            | No                                                                                                                                                                                                                     |
| GLP:                   | Yes                                                                                                                                                                                                                    |
| Validity of the study: | Acceptable                                                                                                                                                                                                             |

#### **Materials and methods**

Twenty outdoor trials on soyabeans were conducted in the USA using 'BYI 02960 200 SL', an SL formulation containing 200 g/L flupyradifurone, in the 2010/11 growing season. Trials were also carried out using a seed treatment, as this is not the application type in the notified cGAP these trials have not been assessed further.

'BYI 02960 200 SL' was applied as a foliar application at a rate of 2 x 0.196 – 0.221 kg/ha flupyradifurone in 93-467 L/ha of water with a 7-10 day RTI. Separate plots were treated for the collection of forage and hay vs seed. Three of the seed trials and two of the forage/hay trials had an RTI of 7 days, all remaining trials used RTIs within  $\pm 25\%$  of the cGAP. The residues reported from the trials with a 7 day RTI are similar or lower than the residues from trials with an RTI within  $\pm 25\%$  of the cGAP. As this is the case, and that 7 days is only slightly outside  $\pm 25\%$  of the cGAP, the RTIs used are considered acceptable. A 5/7 day PHI was used for the forage and hay samples, while a 19-22 day PHI was used for seed. A BBCH of application is not specified in the notified cGAP. Normal commercial harvest of soyabean forage and hay for feeding purposes is up to BBCH 49. For forage and hay, the last application was carried out at BBCH 16-69 (one trial at BBCH 16 and all remaining trials at BBCH 59 or later). Therefore, the trial at BBCH 16 is not considered supportive of the cGAP and has not been used for assessment purposes. As all the other trials had last application after BBCH 49, this is considered acceptable to support the cGAP. Normal commercial harvest of soyabean seed is BBCH 99. For seed, the last application was carried out at BBCH 79-96. As a BBCH is not specified in the cGAP, and as the PHI and RTI used in the trials match the notified cGAP, this is considered sufficient to support the cGAP.

The adjuvant Dyne-Amic was used in all the application at a concentration of 0.25% (v/v) with the exception of trials RV137-10HB and RV139-10HA which used Agral 90 (0.25% v/v) and Unity (0.25% v/v), respectively.

It should be noted that trials RV138-10HA & RV148-10HA and trials RV139-10HA & RV150-10HA were carried out at the same location (Springfield and York, respectively). As the trials were undertaken on different varieties of soyabean and applications in the different trials were made >30 days apart, the trials are considered independent.

The applications support the authorised critical GAP (2 x 0.205 kg a.s./ha, 21 day PHI, 10 days RTI, all growth stages).

Weather data were reported for the trials and no exceptional events were noted. Four of the trials were decline trials, soyabean seed samples were taken at 8-10, 14/15, 21, 28 and 35 days after the last application. Sample of forage and hay were taken at 0, 3, 7, 14 and 21 days after the last application. Samples of soyabean seed and forage weighing at least 1 kg were collected from treated and untreated plots. Samples of soyabean hay weighing at least 0.5 kg were collected from treated and untreated plots. For collection of hay samples, the plants were cut and allowed to dry in the field for 1 to 12 days prior to collection, in line with local agricultural practises. Samples were frozen within 24 hours of sampling (collection for hay) and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 254 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 (also referred to as RV-001-P10-02) with an LOQ of 0.01 mg/kg for flupyradifurone and 0.05 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (RV-001-P10-02) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to soyabean (seed: high oil, forage/hay: high water). Acceptable procedural recoveries were reported for all soyabean matrices in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 79-107% and 75-97%, respectively).

For soyabean seed samples, no residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials. For forage samples, residues above the LOQ were detected in control samples for some trials (flupyradifurone: 0.0102 to 0.0682 mg/kg; DFA: 0.0387 mg/kg). For hay samples, flupyradifurone residues

above the LOQ were detected in control samples for some trials (0.0124 to 0.0311 mg/kg) and no residues at or above LOQ were detected for DFA in all trials.

Residues of flupyradifurone in soyabean seed 21 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between <0.01 – 1.02 mg/kg.

Residues of flupyradifurone in soyabean forage 7 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.94 – 6.77 mg/kg.

Residues of flupyradifurone in soyabean hay 7 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 1.47 – 17.36 mg/kg.

Residues of DFA in soyabean seed 21 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between <0.05 – 1.615 mg/kg (expressed as flupyradifurone).

Residues of DFA in soyabean forage 7 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.26 – 2.40 mg/kg (expressed as flupyradifurone).

Residues of DFA in soyabean hay 7 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 1.03 – 8.19 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.9.1-1.

**Table C.3.1.2.9.1-1 Residue trials on soyabean**

Reference: BYI 02960 200 SL and BYI 02960 480 FS – Magnitude of the Residue in/on Soybeans, XXXXXXXXXX 2012, Report No.: RARVY011

GLP: Yes Sample storage conditions: 254 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Soyabean / Pulses Analytical method: Method 01304 (also referred to as RV-001-P10-02)

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.05 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                         |                    |                                               |            |            |              |                      |    |         |        |                                                |              |                                                   |                                                |    |  |
|---------------------------------------------------------|--------------------|-----------------------------------------------|------------|------------|--------------|----------------------|----|---------|--------|------------------------------------------------|--------------|---------------------------------------------------|------------------------------------------------|----|--|
| RV132-10DA<br>Seven Springs, NC Region 2<br>USA<br>2010 | Soyabean<br>AG5605 | 1. 08-06-10<br>2. –<br>3. 02-08 to 22-11-2010 | 204<br>208 | 211<br>224 | 96.7<br>92.9 | 23-07-10<br>02-08-10 | 10 | BBCH 65 | Forage | 15.2<br>17.4                                   | 0.62<br>0.69 | 15.82<br>18.09                                    | 0.207<br>0.23                                  | 0  |  |
|                                                         |                    |                                               |            |            |              |                      |    |         | Forage | 7.23<br>9.6                                    | 0.94<br>1.20 | 8.17<br>10.8                                      | 0.313<br>0.40                                  | 3  |  |
|                                                         |                    |                                               |            |            |              |                      |    |         | Forage | <u>4.04</u><br><u>3.46</u><br>Avg: <u>3.75</u> | 2.16<br>1.63 | <u>6.20</u><br><u>5.09</u><br>Avg: <u>5.65</u>    | 0.72<br>0.543                                  | 7  |  |
|                                                         |                    |                                               |            |            |              |                      |    |         | Forage | 1.51<br>1.26                                   | 2.40<br>2.40 | 3.91<br>3.66                                      | <u>0.80</u><br><u>0.80</u><br>Avg: <u>0.80</u> | 14 |  |
|                                                         |                    |                                               |            |            |              |                      |    |         | Forage | 0.09<br>0.08                                   | 2.04<br>2.05 | 2.13<br>2.13                                      | 0.68<br>0.68                                   | 21 |  |
|                                                         |                    |                                               |            |            |              |                      |    |         | Hay    | 31.6<br>32.9                                   | 1.34<br>1.47 | 32.94<br>34.37                                    | 0.447<br>0.49                                  | 0  |  |
|                                                         |                    |                                               |            |            |              |                      |    |         | Hay    | 24.5<br>17.1                                   | 4.04<br>3.33 | 28.54<br>20.43                                    | 1.347<br>1.11                                  | 3  |  |
|                                                         |                    |                                               |            |            |              |                      |    |         | Hay    | <u>11.8</u><br><u>10.6</u><br>Avg: <u>11.2</u> | 4.41<br>4.33 | <u>16.21</u><br><u>14.93</u><br>Avg: <u>15.57</u> | 1.47<br>1.443                                  | 7  |  |
|                                                         |                    |                                               |            |            |              |                      |    |         | Hay    | 1.71<br>3.48                                   | 2.92<br>5.53 | 4.63<br>9.01                                      | 0.973<br>1.843                                 | 14 |  |
|                                                         |                    |                                               |            |            |              |                      |    |         | Hay    | 0.22<br>0.14                                   | 6.75<br>4.50 | 6.97<br>4.64                                      | <u>2.25</u><br><u>1.50</u><br>Avg: <u>1.88</u> | 21 |  |



The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                               |                              |                                                  |            |            |              |                      |    |         |        |                                                          |                |                                                   |                                                                         |    |  |
|---------------------------------------------------------------|------------------------------|--------------------------------------------------|------------|------------|--------------|----------------------|----|---------|--------|----------------------------------------------------------|----------------|---------------------------------------------------|-------------------------------------------------------------------------|----|--|
|                                                               |                              |                                                  | 202<br>204 | 192<br>198 | 105<br>103   | 08-10-10<br>18-10-10 | 10 | BBCH 85 | Seed   | 0.02<br>0.02                                             | <0.05<br><0.05 | 0.07<br>0.07                                      | <0.017<br><0.017                                                        | 9  |  |
|                                                               |                              |                                                  |            |            |              |                      |    |         | Seed   | <0.01<br><0.01                                           | <0.05<br><0.05 | <0.06<br><0.06                                    | <0.017<br><0.017                                                        | 14 |  |
|                                                               |                              |                                                  |            |            |              |                      |    |         | Seed   | 0.01<br><0.01                                            | <0.05<br><0.05 | 0.06<br><0.06                                     | <u>&lt;0.017</u><br><u>&lt;0.017</u><br><u>Avg:</u><br><u>&lt;0.017</u> | 21 |  |
|                                                               |                              |                                                  |            |            |              |                      |    |         | Seed   | <u>0.01</u><br><u>0.01</u><br><u>Avg:</u><br><u>0.01</u> | <0.05<br><0.05 | <u>0.06</u><br><u>0.06</u><br><u>Avg: 0.06</u>    | <0.017<br><0.017                                                        | 28 |  |
|                                                               |                              |                                                  |            |            |              |                      |    |         | Seed   | 0.01<br>0.01                                             | <0.05<br><0.05 | 0.06<br>0.06                                      | <0.017<br><0.017                                                        | 35 |  |
| RV133-<br>10HA<br>Tallassee,<br>AL Region<br>2<br>USA<br>2010 | Soyabean<br>Stine 4782-<br>4 | 1. 09-06-10<br>2. –<br>3. 20-08 to<br>18-10-2010 | 204<br>206 | 218<br>237 | 93.6<br>86.9 | 03-08-10<br>13-08-10 | 10 | BBCH 67 | Forage | <u>1.65</u><br><u>2.24</u><br><u>Avg:</u><br>1.95        | 1.51<br>1.81   | <u>3.16</u><br><u>4.05</u><br><u>Avg: 3.61</u>    | <u>0.503</u><br><u>0.603</u><br><u>Avg:</u><br><u>0.553</u>             | 7  |  |
|                                                               |                              |                                                  |            |            |              |                      |    |         | Hay    | <u>6.39</u><br><u>6.49</u><br><u>Avg:</u><br>6.44        | 6.85<br>5.77   | <u>13.24</u><br><u>12.26</u><br><u>Avg: 12.75</u> | <u>2.283</u><br><u>1.923</u><br><u>Avg:</u><br><u>2.103</u>             | 7  |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                          |                        |                                                  |            |            |             |                      |    |         |        |                                                    |              |                                          |                                                      |    |  |
|----------------------------------------------------------|------------------------|--------------------------------------------------|------------|------------|-------------|----------------------|----|---------|--------|----------------------------------------------------|--------------|------------------------------------------|------------------------------------------------------|----|--|
|                                                          |                        |                                                  | 207<br>205 | 167<br>230 | 124<br>89.1 | 17-09-10<br>27-09-10 | 10 | BBCH 81 | Seed   | <u>0.24</u><br><u>0.27</u><br>Avg:<br><u>0.255</u> | 0.07<br>0.07 | <u>0.31</u><br><u>0.34</u><br>Avg: 0.325 | <u>0.023</u><br><u>0.023</u><br>Avg:<br><u>0.023</u> | 21 |  |
| RV134-<br>10DA<br>Proctor, AR<br>Region 4<br>USA<br>2010 | Soyabean<br>Armor 47G7 | 1. 25-05-10<br>2. –<br>3. 05-07 to<br>09-10-2010 | 204<br>205 | 187<br>187 | 109<br>110  | 25-06-10<br>05-07-10 | 10 | BBCH 63 | Forage | 13.2<br>13.3                                       | 0.27<br>0.27 | 13.47<br>13.57                           | 0.09<br>0.09                                         | 0  |  |
|                                                          |                        |                                                  |            |            |             |                      |    |         | Forage | 8.77<br>7.87                                       | 0.50<br>0.50 | 9.27<br>8.37                             | 0.167<br>0.167                                       | 3  |  |
|                                                          |                        |                                                  |            |            |             |                      |    |         | Forage | <u>3.77</u><br><u>4.75</u><br>Avg:<br><u>4.26</u>  | 0.58<br>0.70 | <u>4.35</u><br><u>5.45</u><br>Avg: 4.90  | 0.193<br>0.233                                       | 7  |  |
|                                                          |                        |                                                  |            |            |             |                      |    |         | Forage | 1.40<br>1.28                                       | 0.69<br>0.71 | 2.09<br>1.99                             | 0.23<br>0.237                                        | 14 |  |
|                                                          |                        |                                                  |            |            |             |                      |    |         | Forage | 0.36<br>0.52                                       | 0.87<br>0.87 | 1.23<br>1.39                             | <u>0.29</u><br><u>0.29</u><br>Avg: 0.29              | 21 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|  |  |            |            |            |                      |    |         |      |                                                           |              |                                                  |                                                           |    |  |
|--|--|------------|------------|------------|----------------------|----|---------|------|-----------------------------------------------------------|--------------|--------------------------------------------------|-----------------------------------------------------------|----|--|
|  |  |            |            |            |                      |    |         | Hay  | 34.0<br>35.1                                              | 0.52<br>0.51 | 34.52<br>35.61                                   | 0.173<br>0.17                                             | 0  |  |
|  |  |            |            |            |                      |    |         | Hay  | 17.0<br>14.4                                              | 0.80<br>0.81 | 17.80<br>15.21                                   | 0.267<br>0.27                                             | 3  |  |
|  |  |            |            |            |                      |    |         | Hay  | <u>6.59</u><br><u>10.4</u><br><u>Avg:</u><br><u>8.495</u> | 1.37<br>1.81 | <u>7.96</u><br><u>12.21</u><br><u>Avg: 10.09</u> | 0.457<br>0.603                                            | 7  |  |
|  |  |            |            |            |                      |    |         | Hay  | 3.14<br>3.83                                              | 1.53<br>1.68 | 4.67<br>5.51                                     | <u>0.51</u><br><u>0.56</u><br><u>Avg: 0.54</u>            | 14 |  |
|  |  |            |            |            |                      |    |         | Hay  | 0.50<br>0.67                                              | 1.09<br>1.43 | 1.59<br>2.10                                     | 0.363<br>0.477                                            | 21 |  |
|  |  | 205<br>204 | 188<br>188 | 109<br>109 | 25-08-10<br>04-09-10 | 10 | BBCH 85 | Seed | 0.56<br>0.56                                              | 0.29<br>0.27 | 0.85<br>0.83                                     | 0.097<br>0.090                                            | 10 |  |
|  |  |            |            |            |                      |    |         | Seed | 0.77<br>0.85                                              | 0.38<br>0.36 | 1.15<br>1.21                                     | 0.127<br>0.120                                            | 15 |  |
|  |  |            |            |            |                      |    |         | Seed | <u>0.62</u><br><u>0.60</u><br><u>Avg:</u><br><u>0.61</u>  | 0.30<br>0.39 | <u>0.92</u><br><u>0.99</u><br><u>Avg: 0.955</u>  | <u>0.10</u><br><u>0.13</u><br><u>Avg:</u><br><u>0.115</u> | 21 |  |
|  |  |            |            |            |                      |    |         | Seed | 0.37<br>0.37                                              | 0.26<br>0.28 | 0.63<br>0.65                                     | 0.087<br>0.093                                            | 28 |  |
|  |  |            |            |            |                      |    |         | Seed | 0.48<br>0.40                                              | 0.26<br>0.22 | 0.74<br>0.62                                     | 0.087<br>0.073                                            | 35 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                      |                              |                                                  |            |            |            |                      |    |         |        |                                                                                 |                              |                                                                              |                                                                                      |    |  |
|------------------------------------------------------|------------------------------|--------------------------------------------------|------------|------------|------------|----------------------|----|---------|--------|---------------------------------------------------------------------------------|------------------------------|------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|----|--|
| RV135-10HA<br>Fisk, MO<br>Region 4<br>USA<br>2010    | Soyabean<br>Stine 4782-4     | 1. 16-06-10<br>2. –<br>3. 13-08 to<br>01-11-2010 | 206        | 189        | 111        | 29-07-10             | 9  | BBCH 67 | Forage | <u>0.93</u><br><u>1.08</u><br>Avg:<br><u>1.01</u>                               | 1.21<br>1.07                 | <u>2.14</u><br><u>2.15</u><br>Avg: <u>2.15</u>                               | <u>0.403</u><br><u>0.357</u><br>Avg:<br><u>0.380</u>                                 | 6  |  |
|                                                      |                              |                                                  | 205        | 187        | 110        | 07-08-10             |    |         | Hay    | <u>3.03</u><br><u>4.78</u><br>Avg:<br><u>3.91</u>                               | 6.19<br>7.14                 | <u>9.22</u><br><u>11.92</u><br>Avg: <u>10.57</u>                             | <u>2.063</u><br><u>2.38</u><br>Avg: <u>2.22</u>                                      | 6  |  |
|                                                      |                              |                                                  | 204<br>204 | 187<br>186 | 109<br>110 | 04-10-10<br>12-10-10 | 8  | BBCH 96 | Seed   | <u>&lt;0.01</u><br><u>0.02</u><br>Avg:<br><u>0.015</u>                          | <0.05<br><0.05               | <u>&lt;0.06</u><br><u>0.07</u><br>Avg: <u>0.065</u>                          | <u>&lt;0.017</u><br><u>&lt;0.017</u><br>Avg:<br><u>&lt;0.017</u>                     | 20 |  |
| RV136-10HA<br>Pollard, AR<br>Region 4<br>USA<br>2010 | Soyabean<br>Pioneer<br>94M80 | 1. 03-06-10<br>2. –<br>3. 09-08 to<br>20-10-2010 | 203<br>204 | 186<br>186 | 109<br>110 | 23-07-10<br>01-08-10 | 10 | BBCH 67 | Forage | <u>2.44</u><br><u>2.41</u><br><u>2.85</u><br><u>3.64</u><br>Avg:<br><u>2.84</u> | 1.59<br>1.40<br>1.57<br>1.64 | <u>4.03</u><br><u>3.81</u><br><u>4.42</u><br><u>5.28</u><br>Avg: <u>4.39</u> | <u>0.530</u><br><u>0.467</u><br><u>0.523</u><br><u>0.547</u><br>Avg:<br><u>0.517</u> | 7  |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                               |                                     |                                                  |            |            |              |                      |   |         |        |                                                    |              |                                                   |                                                      |    |  |
|---------------------------------------------------------------|-------------------------------------|--------------------------------------------------|------------|------------|--------------|----------------------|---|---------|--------|----------------------------------------------------|--------------|---------------------------------------------------|------------------------------------------------------|----|--|
|                                                               |                                     |                                                  |            |            |              |                      |   |         | Hay    | <u>7.22</u><br><u>6.58</u><br>Avg:<br><u>6.90</u>  | 4.51<br>4.41 | <u>11.73</u><br><u>10.99</u><br>Avg: <u>11.36</u> | <u>1.503</u><br><u>1.470</u><br>Avg:<br><u>1.487</u> | 7  |  |
|                                                               |                                     |                                                  | 206<br>205 | 188<br>188 | 110<br>109   | 22-09-10<br>30-09-10 | 8 | BBCH 81 | Seed   | <u>0.09</u><br><u>0.08</u><br>Avg:<br><u>0.085</u> | 0.19<br>0.19 | <u>0.28</u><br><u>0.27</u><br>Avg: <u>0.275</u>   | <u>0.063</u><br><u>0.063</u><br>Avg:<br><u>0.063</u> | 20 |  |
| RV137-<br>10DB<br>Branchton,<br>ON Region<br>5<br>USA<br>2010 | Soyabean<br>Secan<br>RCAT<br>Matrix | 1. 26-05-10<br>2. –<br>3. 06-08 to<br>14-10-2010 | 210<br>196 | 310<br>290 | 67.7<br>67.6 | 29-07-10<br>06-08-10 | 8 | BBCH 66 | Forage | 11.4<br>10.9                                       | 0.38<br>0.37 | 11.78<br>11.27                                    | 0.127<br>0.123                                       | 0  |  |
|                                                               |                                     |                                                  |            |            |              |                      |   |         | Forage | 5.31<br>4.48                                       | 0.73<br>0.62 | 6.04<br>5.10                                      | 0.243<br>0.207                                       | 3  |  |
|                                                               |                                     |                                                  |            |            |              |                      |   |         | Forage | <u>1.95</u><br><u>2.48</u><br>Avg:<br><u>2.22</u>  | 0.96<br>1.14 | <u>2.91</u><br><u>3.62</u><br>Avg: <u>3.27</u>    | 0.320<br>0.380                                       | 7  |  |
|                                                               |                                     |                                                  |            |            |              |                      |   |         | Forage | 1.37<br>1.04                                       | 1.42<br>1.24 | 2.79<br>1.28                                      | 0.473<br>0.413                                       | 14 |  |
|                                                               |                                     |                                                  |            |            |              |                      |   |         | Forage | 0.42<br>0.37                                       | 1.41<br>1.56 | 1.83<br>1.93                                      | <u>0.470</u><br><u>0.520</u><br>Avg:<br>0.495        | 21 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|  |  |            |            |              |                      |   |         |      |                                                           |              |                                          |                                                     |    |  |
|--|--|------------|------------|--------------|----------------------|---|---------|------|-----------------------------------------------------------|--------------|------------------------------------------|-----------------------------------------------------|----|--|
|  |  |            |            |              |                      |   |         | Hay  | 26.2<br>25.1                                              | 1.35<br>0.89 | 27.55<br>25.99                           | 0.450<br>0.297                                      | 0  |  |
|  |  |            |            |              |                      |   |         | Hay  | 4.51<br>11.1                                              | 2.18<br>3.08 | 6.69<br>14.18                            | 0.727<br>1.027                                      | 3  |  |
|  |  |            |            |              |                      |   |         | Hay  | <u>9.58</u><br><u>2.85</u><br><u>Avg:</u><br><u>6.22</u>  | 2.88<br>1.46 | <u>12.46</u><br><u>4.31</u><br>Avg: 8.39 | <u>0.960</u><br><u>0.487</u><br>Avg:<br>0.724       | 7  |  |
|  |  |            |            |              |                      |   |         | Hay  | 1.17<br>0.94                                              | 1.85<br>1.49 | 3.02<br>2.43                             | 0.617<br>0.497                                      | 14 |  |
|  |  |            |            |              |                      |   |         | Hay  | 0.43<br>0.38                                              | 1.41<br>1.81 | 1.84<br>2.19                             | 0.470<br>0.603                                      | 21 |  |
|  |  | 207<br>221 | 296<br>336 | 69.9<br>65.8 | 31-08-10<br>09-09-10 | 9 | BBCH 88 | Seed | 0.20<br>0.16                                              | 0.30<br>0.29 | 0.50<br>0.45                             | 0.10<br>0.097                                       | 8  |  |
|  |  |            |            |              |                      |   |         | Seed | 0.21<br>0.22                                              | 0.46<br>0.51 | 0.67<br>0.73                             | 0.153<br>0.17                                       | 14 |  |
|  |  |            |            |              |                      |   |         | Seed | 0.23<br>0.25                                              | 0.54<br>0.49 | 0.77<br>0.74                             | 0.18<br>0.163                                       | 21 |  |
|  |  |            |            |              |                      |   |         | Seed | <u>0.38</u><br><u>0.33</u><br><u>Avg:</u><br><u>0.355</u> | 0.51<br>0.65 | <u>0.89</u><br><u>0.98</u><br>Avg: 0.935 | <u>0.17</u><br><u>0.217</u><br>Avg:<br><u>0.194</u> | 28 |  |
|  |  |            |            |              |                      |   |         | Seed | 0.31<br>0.26                                              | 0.20<br>0.17 | 0.51<br>0.43                             | 0.067<br>0.057                                      | 35 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                       |                      |                                               |            |            |            |                      |    |         |        |                                                |              |                                                   |                                                   |    |  |
|-------------------------------------------------------|----------------------|-----------------------------------------------|------------|------------|------------|----------------------|----|---------|--------|------------------------------------------------|--------------|---------------------------------------------------|---------------------------------------------------|----|--|
| RV138-10HA<br>Springfield, NE Region 5<br>USA<br>2010 | Soyabean<br>NC+3051R | 1. 24-05-10<br>2. –<br>3. 23-07 to 05-10-2010 | 207        | 137        | 151        | 09-07-10             | 9  | BBCH 64 | Forage | <u>2.73</u><br><u>3.04</u><br>Avg: <u>2.89</u> | 0.93<br>0.93 | <u>3.66</u><br><u>3.97</u><br>Avg: <u>3.82</u>    | <u>0.31</u><br><u>0.31</u><br>Avg: <u>0.31</u>    | 5  |  |
|                                                       |                      |                                               | 208        | 132        | 158        | 18-07-10             |    |         | Hay    | <u>7.01</u><br><u>9.09</u><br>Avg: <u>8.05</u> | 3.50<br>3.28 | <u>10.51</u><br><u>12.37</u><br>Avg: <u>11.44</u> | <u>1.17</u><br><u>1.093</u><br>Avg: <u>1.132</u>  | 5  |  |
|                                                       |                      |                                               | 211<br>204 | 149<br>148 | 142<br>138 | 08-09-10<br>16-09-10 | 8  | BBCH 79 | Seed   | <u>0.07</u><br><u>0.07</u><br>Avg: <u>0.07</u> | 0.09<br>0.08 | <u>0.16</u><br><u>0.15</u><br>Avg: <u>0.155</u>   | <u>0.03</u><br><u>0.027</u><br>Avg: <u>0.029</u>  | 19 |  |
| RV139-10HA<br>York, NE Region 5<br>USA<br>2010        | Soyabean<br>NC+2751R | 1. 29-04-10<br>2. –<br>3. 15-07 to 29-09-2010 | 205<br>213 | 140<br>142 | 146<br>150 | 28-06-10<br>08-07-10 | 10 | BBCH 16 | Forage | <u>0.87</u><br><u>1.00</u><br>Avg: <u>0.94</u> | 0.77<br>0.82 | <u>1.64</u><br><u>1.82</u><br>Avg: <u>1.73</u>    | <u>0.257</u><br><u>0.273</u><br>Avg: <u>0.265</u> | 7  |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                              |                   |                                                  |            |            |            |                      |    |         |        |                                                                                        |                              |                                                                                   |                                                                                           |    |  |
|--------------------------------------------------------------|-------------------|--------------------------------------------------|------------|------------|------------|----------------------|----|---------|--------|----------------------------------------------------------------------------------------|------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|----|--|
|                                                              |                   |                                                  |            |            |            |                      |    |         | Hay    | <u>3.23</u><br><u>2.86</u><br><u>2.25</u><br><u>1.90</u><br><u>Avg:</u><br><u>2.56</u> | 4.74<br>3.81<br>4.27<br>3.56 | <u>7.97</u><br><u>6.67</u><br><u>6.52</u><br><u>5.46</u><br><u>Avg: 6.66</u>      | <u>1.58</u><br><u>1.27</u><br><u>1.423</u><br><u>1.187</u><br><u>Avg:</u><br><u>1.365</u> | 7  |  |
|                                                              |                   |                                                  | 198<br>205 | 172<br>191 | 115<br>107 | 01-09-10<br>09-09-10 | 8  | BBCH 89 | Seed   | <u>0.03</u><br><u>0.04</u><br><u>Avg:</u><br><u>0.035</u>                              | 0.10<br>0.11                 | <u>0.13</u><br><u>0.15</u><br><u>Avg: 0.14</u>                                    | <u>0.033</u><br><u>0.037</u><br><u>Avg:</u><br><u>0.035</u>                               | 20 |  |
| RV140-<br>10HA<br>Rockwood,<br>ON Region<br>5<br>USA<br>2010 | Soyabean<br>90M01 | 1. 17-05-10<br>2. –<br>3. 26-06 to<br>07-10-2010 | 207<br>205 | 119<br>113 | 174<br>181 | 09-07-10<br>19-07-10 | 10 | BBCH 65 | Forage | <u>3.32</u><br><u>2.72</u><br><u>Avg:</u><br><u>3.02</u>                               | 1.60<br>1.41                 | <u>4.92</u><br><u>4.13</u><br><u>Avg: 4.53</u>                                    | <u>0.533</u><br><u>0.470</u><br><u>Avg:</u><br><u>0.502</u>                               | 7  |  |
|                                                              |                   |                                                  |            |            |            |                      |    |         | Hay    | <u>7.71</u><br><u>9.12</u><br><u>8.01</u><br><u>9.31</u><br><u>Avg:</u><br><u>8.54</u> | 4.44<br>3.66<br>4.79<br>4.38 | <u>12.15</u><br><u>12.78</u><br><u>12.80</u><br><u>13.69</u><br><u>Avg: 12.86</u> | <u>1.48</u><br><u>1.22</u><br><u>1.597</u><br><u>1.46</u><br><u>Avg: 1.44</u>             | 7  |  |



The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                          |                     |                                                  |            |            |            |                      |   |         |        |                                                                                 |                              |                                                                            |                                                                          |    |  |
|----------------------------------------------------------|---------------------|--------------------------------------------------|------------|------------|------------|----------------------|---|---------|--------|---------------------------------------------------------------------------------|------------------------------|----------------------------------------------------------------------------|--------------------------------------------------------------------------|----|--|
|                                                          |                     |                                                  | 206<br>209 | 130<br>132 | 158<br>158 | 10-09-10<br>17-09-10 | 7 | BBCH 85 | Seed   | <u>&lt;0.01</u><br><u>&lt;0.01</u><br>Avg:<br><u>&lt;0.01</u>                   | <0.05<br><0.05               | <u>&lt;0.06</u><br><u>&lt;0.06</u><br>Avg: <0.06                           | <u>&lt;0.017</u><br><u>&lt;0.017</u><br>Avg:<br><u>&lt;0.017</u>         | 20 |  |
| RV141-10HA<br>Campbell,<br>MN Region<br>5<br>USA<br>2010 | Soyabean<br>AG 0808 | 1. 25-05-10<br>2. –<br>3. 28-07 to<br>27-09-2010 | 205<br>206 | 187<br>188 | 110<br>110 | 12-07-10<br>21-07-10 | 9 | BBCH 69 | Forage | <u>2.25</u><br><u>2.79</u><br>Avg:<br><u>2.52</u>                               | 1.44<br>1.66                 | <u>3.69</u><br><u>4.45</u><br>Avg: 4.07                                    | <u>0.48</u><br><u>0.553</u><br>Avg:<br><u>0.517</u>                      | 7  |  |
|                                                          |                     |                                                  |            |            |            |                      |   |         | Hay    | <u>6.90</u><br><u>6.48</u><br><u>6.35</u><br><u>6.51</u><br>Avg:<br><u>6.56</u> | 4.49<br>3.57<br>3.89<br>3.61 | <u>11.39</u><br><u>10.05</u><br><u>10.24</u><br><u>10.12</u><br>Avg: 10.45 | <u>1.497</u><br><u>1.19</u><br><u>1.297</u><br><u>1.203</u><br>Avg: 1.30 | 7  |  |
|                                                          |                     |                                                  | 206<br>205 | 188<br>187 | 110<br>110 | 28-08-10<br>05-09-10 | 8 | BBCH 92 | Seed   | <u>0.16</u><br><u>0.15</u><br>Avg:<br><u>0.155</u>                              | 0.49<br>0.52                 | <u>0.65</u><br><u>0.67</u><br>Avg: 0.66                                    | <u>0.163</u><br><u>0.173</u><br>Avg:<br><u>0.168</u>                     | 22 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                          |                        |                                                  |            |            |            |                      |    |         |        |                                                                                  |                              |                                                                                   |                                                                                      |    |  |
|----------------------------------------------------------|------------------------|--------------------------------------------------|------------|------------|------------|----------------------|----|---------|--------|----------------------------------------------------------------------------------|------------------------------|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|----|--|
| RV142-10HA<br>Clarence,<br>MO Region<br>5<br>USA<br>2010 | Soyabean<br>Asgrow3803 | 1. 29-05-10<br>2. –<br>3. 23-07 to<br>11-10-2010 | 206        | 171        | 120        | 09-07-10             | 7  | BBCH 66 | Forage | <u>4.23</u><br><u>4.72</u><br>Avg:<br><u>4.48</u>                                | 0.52<br>0.56                 | <u>4.75</u><br><u>5.28</u><br>Avg: <u>5.02</u>                                    | <u>0.173</u><br><u>0.187</u><br>Avg:<br><u>0.180</u>                                 | 7  |  |
|                                                          |                        |                                                  | 209        | 190        | 110        | 16-07-10             |    |         | Hay    | <u>15.4</u><br><u>12.2</u><br><u>11.5</u><br><u>11.3</u><br>Avg:<br><u>12.60</u> | 1.49<br>1.15<br>1.30<br>1.09 | <u>16.89</u><br><u>13.35</u><br><u>12.80</u><br><u>12.39</u><br>Avg: <u>13.86</u> | <u>0.497</u><br><u>0.383</u><br><u>0.433</u><br><u>0.363</u><br>Avg:<br><u>0.419</u> | 7  |  |
|                                                          |                        |                                                  | 202<br>207 | 180<br>195 | 112<br>106 | 10-09-10<br>20-09-10 | 10 | BBCH 79 | Seed   | <u>0.19</u><br><u>0.24</u><br>Avg:<br><u>0.215</u>                               | 0.11<br>0.10                 | <u>0.30</u><br><u>0.34</u><br>Avg: <u>0.32</u>                                    | <u>0.037</u><br><u>0.033</u><br>Avg:<br><u>0.035</u>                                 | 21 |  |
| RV143-10HA<br>Breslau,<br>ON Region<br>5<br>USA<br>2010  | Soyabean<br>DKBOO-99   | 1. 17-05-10<br>2. –<br>3. 26-07 to<br>04-10-2010 | 211<br>204 | 118<br>119 | 179<br>171 | 09-07-10<br>19-07-10 | 10 | BBCH 66 | Forage | <u>4.47</u><br><u>3.66</u><br>Avg:<br><u>4.07</u>                                | 1.07<br>1.00                 | <u>5.54</u><br><u>4.66</u><br>Avg: <u>5.10</u>                                    | <u>0.357</u><br><u>0.333</u><br>Avg:<br><u>0.345</u>                                 | 7  |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                           |                              |                                                  |            |            |            |                      |    |         |        |                                                                                        |                              |                                                                               |                                                                                             |    |  |
|-----------------------------------------------------------|------------------------------|--------------------------------------------------|------------|------------|------------|----------------------|----|---------|--------|----------------------------------------------------------------------------------------|------------------------------|-------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|----|--|
|                                                           |                              |                                                  |            |            |            |                      |    |         | Hay    | <u>7.54</u><br><u>6.48</u><br><u>6.63</u><br><u>6.33</u><br><u>Avg:</u><br><u>6.75</u> | 3.07<br>2.32<br>3.01<br>2.78 | <u>10.61</u><br><u>8.80</u><br><u>9.64</u><br><u>9.11</u><br><u>Avg: 9.54</u> | <u>1.023</u><br><u>0.773</u><br><u>1.003</u><br><u>0.927</u><br><u>Avg:</u><br><u>0.932</u> | 7  |  |
|                                                           |                              |                                                  | 207<br>204 | 145<br>127 | 143<br>161 | 07-09-10<br>14-09-10 | 7  | BBCH 85 | Seed   | <u>0.02</u><br><u>0.02</u><br><u>Avg:</u><br><u>0.02</u>                               | <0.05<br><0.05               | <u>0.07</u><br><u>0.07</u><br><u>Avg: 0.07</u>                                | <u>&lt;0.017</u><br><u>&lt;0.017</u><br><u>Avg:</u><br><u>&lt;0.017</u>                     | 20 |  |
| RV144-<br>10HA<br>Richland,<br>IA Region 5<br>USA<br>2010 | Soyabean<br>Pioneer<br>92Y80 | 1. 05-05-10<br>2. –<br>3. 02-08 to<br>11-10-2010 | 207<br>207 | 185<br>185 | 112<br>112 | 16-07-10<br>26-07-10 | 10 | BBCH 69 | Forage | <u>1.18</u><br><u>1.03</u><br><u>Avg:</u><br><u>1.11</u>                               | 1.47<br>1.23                 | <u>2.65</u><br><u>2.26</u><br><u>Avg: 2.46</u>                                | <u>0.49</u><br><u>0.41</u><br><u>Avg: 0.45</u>                                              | 7  |  |
|                                                           |                              |                                                  |            |            |            |                      |    |         | Hay    | <u>4.50</u><br><u>3.88</u><br><u>Avg:</u><br><u>4.19</u>                               | 5.09<br>5.24                 | <u>9.59</u><br><u>9.12</u><br><u>Avg: 9.36</u>                                | <u>1.697</u><br><u>1.747</u><br><u>Avg:</u><br><u>1.722</u>                                 | 7  |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                           |                   |                                                  |            |            |            |                      |    |         |        |                                                               |                |                                                            |                                                                  |    |  |
|-----------------------------------------------------------|-------------------|--------------------------------------------------|------------|------------|------------|----------------------|----|---------|--------|---------------------------------------------------------------|----------------|------------------------------------------------------------|------------------------------------------------------------------|----|--|
|                                                           |                   |                                                  | 203<br>206 | 163<br>154 | 125<br>134 | 10-09-10<br>20-09-10 | 10 | BBCH 88 | Seed   | <u>0.02</u><br><u>0.01</u><br>Avg:<br><u>0.015</u>            | <0.05<br><0.05 | <u>0.07</u><br><u>0.06</u><br>Avg: <u>0.065</u>            | <u>&lt;0.017</u><br><u>&lt;0.017</u><br>Avg:<br><u>&lt;0.017</u> | 21 |  |
| RV145-10HA<br>Cambridge,<br>ON Region<br>5<br>USA<br>2010 | Soyabean<br>90M40 | 1. 27-05-10<br>2. –<br>3. 12-08 to<br>29-09-2010 | 205<br>205 | 109<br>110 | 188<br>186 | 27-07-10<br>05-08-10 | 9  | BBCH 65 | Forage | <u>2.75</u><br><u>2.81</u><br>Avg:<br><u>2.78</u>             | 1.61<br>1.56   | <u>4.36</u><br><u>4.37</u><br>Avg: <u>4.37</u>             | <u>0.537</u><br><u>0.52</u><br>Avg:<br><u>0.529</u>              | 7  |  |
|                                                           |                   |                                                  |            |            |            |                      |    |         | Hay    | <u>1.70</u><br><u>1.23</u><br>Avg:<br><u>1.47</u>             | 2.16<br>1.69   | <u>3.86</u><br><u>2.92</u><br>Avg: <u>3.39</u>             | <u>0.72</u><br><u>0.563</u><br>Avg:<br><u>0.642</u>              | 7  |  |
|                                                           |                   |                                                  | 205<br>204 | 129<br>131 | 159<br>156 | 02-09-10<br>09-09-10 | 7  | BBCH 85 | Seed   | <u>&lt;0.01</u><br><u>&lt;0.01</u><br>Avg:<br><u>&lt;0.01</u> | <0.05<br><0.05 | <u>&lt;0.06</u><br><u>&lt;0.06</u><br>Avg: <u>&lt;0.06</u> | <u>&lt;0.017</u><br><u>&lt;0.017</u><br>Avg:<br><u>&lt;0.017</u> | 20 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                           |                               |                                                  |            |            |             |                      |    |         |        |                                                   |              |                                           |                                                      |    |  |
|-----------------------------------------------------------|-------------------------------|--------------------------------------------------|------------|------------|-------------|----------------------|----|---------|--------|---------------------------------------------------|--------------|-------------------------------------------|------------------------------------------------------|----|--|
| RV146-10DA<br>Northwood,<br>ND Region<br>5<br>USA<br>2010 | Soyabean<br>Asgrow<br>AG00901 | 1. 01-06-10<br>2. –<br>3. 29-06 to<br>29-10-2010 | 206<br>202 | 189<br>256 | 109<br>78.9 | 19-06-10<br>29-06-10 | 10 | BBCH 59 | Forage | 22.1<br>19.1                                      | 0.13<br>0.09 | 22.23<br>19.19                            | 0.043<br>0.030                                       | 0  |  |
|                                                           |                               |                                                  |            |            |             |                      |    |         | Forage | 12.3<br>10.1                                      | 0.28<br>0.23 | 12.58<br>10.33                            | 0.093<br>0.077                                       | 3  |  |
|                                                           |                               |                                                  |            |            |             |                      |    |         | Forage | <u>5.21</u><br><u>5.39</u><br>Avg:<br><u>5.30</u> | 0.25<br>0.26 | <u>5.46</u><br><u>5.65</u><br>Avg: 5.56   | <u>0.083</u><br><u>0.087</u><br>Avg:<br><u>0.085</u> | 7  |  |
|                                                           |                               |                                                  |            |            |             |                      |    |         | Forage | 1.40<br>0.77                                      | 0.23<br>0.19 | 1.63<br>0.96                              | 0.077<br>0.063                                       | 14 |  |
|                                                           |                               |                                                  |            |            |             |                      |    |         | Forage | 0.09<br>0.12                                      | 0.14<br>0.16 | 0.23<br>0.28                              | 0.047<br>0.053                                       | 21 |  |
|                                                           |                               |                                                  |            |            |             |                      |    |         | Hay    | 38.1<br>30.7                                      | 0.29<br>0.24 | 38.39<br>30.94                            | 0.097<br>0.080                                       | 0  |  |
|                                                           |                               |                                                  |            |            |             |                      |    |         | Hay    | 34.5<br>32.8                                      | 0.92<br>0.67 | 35.42<br>33.47                            | 0.307<br>0.223                                       | 3  |  |
|                                                           |                               |                                                  |            |            |             |                      |    |         | Hay    | <u>13.5</u><br><u>5.19</u><br>Avg:<br><u>9.35</u> | 0.65<br>1.41 | <u>14.15</u><br><u>6.60</u><br>Avg: 10.38 | <u>0.217</u><br><u>0.47</u><br>Avg:<br><u>0.344</u>  | 7  |  |
|                                                           |                               |                                                  |            |            |             |                      |    |         | Hay    | 7.56<br>2.75                                      | 0.30<br>1.07 | 7.86<br>3.82                              | 0.10<br>0.357                                        | 14 |  |
|                                                           |                               |                                                  |            |            |             |                      |    |         | Hay    | 0.51<br>0.32                                      | 0.59<br>0.54 | 1.10<br>0.86                              | 0.197<br>0.18                                        | 21 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                              |                              |                                                  |            |            |            |                      |    |         |        |                                                               |                |                                                  |                                                                  |    |  |
|--------------------------------------------------------------|------------------------------|--------------------------------------------------|------------|------------|------------|----------------------|----|---------|--------|---------------------------------------------------------------|----------------|--------------------------------------------------|------------------------------------------------------------------|----|--|
|                                                              |                              |                                                  | 203<br>208 | 183<br>190 | 111<br>109 | 14-09-10<br>24-09-10 | 10 | BBCH 79 | Seed   | <0.01<br><0.01                                                | <0.05<br><0.05 | <0.06<br><0.06                                   | <0.017<br><0.017                                                 | 10 |  |
|                                                              |                              |                                                  |            |            |            |                      |    |         | Seed   | <0.01<br><0.01                                                | <0.05<br><0.05 | <0.06<br><0.06                                   | <0.017<br><0.017                                                 | 15 |  |
|                                                              |                              |                                                  |            |            |            |                      |    |         | Seed   | <u>&lt;0.01</u><br><u>&lt;0.01</u><br>Avg:<br><u>&lt;0.01</u> | <0.05<br><0.05 | <u>&lt;0.06</u><br><u>&lt;0.06</u><br>Avg: <0.06 | <u>&lt;0.017</u><br><u>&lt;0.017</u><br>Avg:<br><u>&lt;0.017</u> | 21 |  |
|                                                              |                              |                                                  |            |            |            |                      |    |         | Seed   | <0.01<br><0.01                                                | <0.05<br><0.05 | <0.06<br><0.06                                   | <0.017<br><0.017                                                 | 28 |  |
|                                                              |                              |                                                  |            |            |            |                      |    |         | Seed   | <0.01<br><0.01                                                | <0.05<br><0.05 | <0.06<br><0.06                                   | <0.017<br><0.017                                                 | 35 |  |
| RV147-<br>10HA<br>Stafford,<br>KS Region<br>5<br>USA<br>2011 | Soyabean<br>Pioneer<br>93Y70 | 1. 24-05-11<br>2. –<br>3. 25-07 to<br>27-09-2011 | 203<br>205 | 187<br>188 | 109<br>109 | 11-07-11<br>18-07-11 | 7  | BBCH 65 | Forage | <u>5.88</u><br><u>7.65</u><br>Avg:<br><u>6.77</u>             | 1.46<br>1.51   | <u>7.34</u><br><u>9.16</u><br>Avg: 8.25          | <u>0.487</u><br><u>0.503</u><br>Avg:<br><u>0.495</u>             | 7  |  |
|                                                              |                              |                                                  |            |            |            |                      |    |         | Hay    | <u>19.7</u><br><u>15.01</u><br>Avg:<br><u>17.36</u>           | 4.31<br>3.95   | <u>24.01</u><br><u>18.96</u><br>Avg: 21.49       | <u>1.437</u><br><u>1.317</u><br>Avg:<br><u>1.377</u>             | 7  |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                             |                    |                                                  |            |            |            |                      |   |         |        |                                                   |              |                                                   |                                                     |    |  |
|-------------------------------------------------------------|--------------------|--------------------------------------------------|------------|------------|------------|----------------------|---|---------|--------|---------------------------------------------------|--------------|---------------------------------------------------|-----------------------------------------------------|----|--|
|                                                             |                    |                                                  | 204<br>208 | 184<br>193 | 111<br>108 | 29-08-11<br>07-09-11 | 9 | BBCH 79 | Seed   | <u>1.10</u><br><u>0.94</u><br>Avg:<br><u>1.02</u> | 1.71<br>1.52 | <u>2.81</u><br><u>2.46</u><br>Avg: <u>2.64</u>    | <u>0.57</u><br><u>0.507</u><br>Avg:<br><u>0.539</u> | 20 |  |
| RV148-10HA<br>Springfield,<br>NE Region<br>5<br>USA<br>2011 | Soyabean<br>S28-B4 | 1. 10-05-11<br>2. –<br>3. 28-07 to<br>04-10-2011 | 201<br>208 | 137<br>139 | 147<br>150 | 13-07-11<br>22-07-11 | 9 | BBCH 63 | Forage | <u>3.36</u><br><u>4.44</u><br>Avg:<br><u>3.90</u> | 1.38<br>1.52 | <u>4.74</u><br><u>5.96</u><br>Avg: <u>5.35</u>    | <u>0.46</u><br><u>0.507</u><br>Avg:<br><u>0.484</u> | 6  |  |
|                                                             |                    |                                                  |            |            |            |                      |   |         | Hay    | <u>7.20</u><br><u>5.98</u><br>Avg:<br><u>6.59</u> | 4.46<br>4.11 | <u>11.66</u><br><u>10.09</u><br>Avg: <u>10.88</u> | <u>1.487</u><br><u>1.37</u><br>Avg: <u>1.43</u>     | 6  |  |
|                                                             |                    |                                                  | 208<br>206 | 134<br>133 | 155<br>155 | 07-09-11<br>15-09-11 | 8 | BBCH 82 | Seed   | <u>0.08</u><br><u>0.06</u><br>Avg:<br><u>0.07</u> | 0.38<br>0.36 | <u>0.46</u><br><u>0.42</u><br>Avg: <u>0.44</u>    | <u>0.127</u><br><u>0.12</u><br>Avg:<br><u>0.124</u> | 19 |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                     |                                  |                                                  |            |            |            |                      |    |         |        |                                                      |              |                                                   |                                                      |    |  |
|-----------------------------------------------------|----------------------------------|--------------------------------------------------|------------|------------|------------|----------------------|----|---------|--------|------------------------------------------------------|--------------|---------------------------------------------------|------------------------------------------------------|----|--|
| RV149-10HA<br>Lenexa, KS<br>Region 5<br>USA<br>2011 | Soyabean<br>Willcross<br>RR2428N | 1. 01-06-11<br>2. –<br>3. 31-07 to<br>11-10-2011 | 207        | 145        | 143        | 14-07-11             | 10 | BBCH 64 | Forage | <u>3.81</u><br><u>4.34</u><br>Avg:<br><u>4.08</u>    | 1.27<br>1.23 | <u>5.08</u><br><u>5.57</u><br>Avg: <u>5.33</u>    | <u>0.423</u><br><u>0.41</u><br>Avg:<br><u>0.417</u>  | 7  |  |
|                                                     |                                  |                                                  | 209        | 147        | 142        | 24-07-11             |    |         | Hay    | <u>14.14</u><br><u>15.53</u><br>Avg:<br><u>14.84</u> | 3.05<br>2.99 | <u>17.19</u><br><u>18.52</u><br>Avg: <u>17.86</u> | <u>1.017</u><br><u>0.997</u><br>Avg:<br><u>1.007</u> | 7  |  |
|                                                     |                                  |                                                  | 209<br>202 | 148<br>147 | 141<br>137 | 12-09-11<br>22-09-11 | 10 | BBCH 79 | Seed   | <u>0.28</u><br><u>0.27</u><br>Avg:<br><u>0.275</u>   | 0.25<br>0.27 | <u>0.53</u><br><u>0.54</u><br>Avg: <u>0.535</u>   | <u>0.083</u><br><u>0.090</u><br>Avg:<br><u>0.087</u> | 19 |  |
| RV150-10HA<br>York, NE<br>Region 5<br>USA<br>2011   | Soyabean<br>16501RR              | 1. 02-06-11<br>2. –<br>3. 22-07 to<br>14-10-2011 | 204<br>205 | 193<br>188 | 106<br>109 | 07-07-11<br>15-07-11 | 8  | BBCH 66 | Forage | <u>3.06</u><br><u>4.06</u><br>Avg:<br><u>3.56</u>    | 1.72<br>1.71 | <u>4.78</u><br><u>5.77</u><br>Avg: <u>5.28</u>    | <u>0.573</u><br><u>0.57</u><br>Avg:<br><u>0.572</u>  | 7  |  |



The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                        |                          |                                                  |            |            |              |                      |    |         |        |                                                               |                |                                                  |                                                                  |    |  |
|--------------------------------------------------------|--------------------------|--------------------------------------------------|------------|------------|--------------|----------------------|----|---------|--------|---------------------------------------------------------------|----------------|--------------------------------------------------|------------------------------------------------------------------|----|--|
|                                                        |                          |                                                  |            |            |              |                      |    |         | Hay    | <u>11.47</u><br><u>11.82</u><br>Avg:<br><u>11.65</u>          | 7.82<br>8.56   | <u>19.29</u><br><u>20.38</u><br>Avg: 19.84       | <u>2.607</u><br><u>2.853</u><br>Avg: 2.73                        | 7  |  |
|                                                        |                          |                                                  | 205<br>206 | 186<br>191 | 110<br>108   | 15-09-11<br>23-09-11 | 8  | BBCH 93 | Seed   | <u>&lt;0.01</u><br><u>&lt;0.01</u><br>Avg:<br><u>&lt;0.01</u> | <0.05<br><0.05 | <u>&lt;0.06</u><br><u>&lt;0.06</u><br>Avg: <0.06 | <u>&lt;0.017</u><br><u>&lt;0.017</u><br>Avg:<br><u>&lt;0.017</u> | 21 |  |
| RV151-10HA<br>Kimbalton,<br>IA Region 5<br>USA<br>2011 | Soyabean<br>Stine 2862-4 | 1. 18-05-11<br>2. –<br>3. 15-07 to<br>14-10-2011 | 210<br>201 | 219<br>312 | 95.9<br>64.4 | 28-06-11<br>08-07-11 | 10 | BBCH 59 | Forage | <u>5.26</u><br><u>4.70</u><br>Avg:<br><u>4.98</u>             | 0.86<br>0.89   | <u>6.12</u><br><u>5.59</u><br>Avg: 5.89          | <u>0.287</u><br><u>0.297</u><br>Avg:<br><u>0.292</u>             | 7  |  |
|                                                        |                          |                                                  |            |            |              |                      |    |         | Hay    | <u>7.48</u><br><u>9.13</u><br>Avg:<br><u>8.31</u>             | 1.39<br>1.52   | <u>8.87</u><br><u>10.65</u><br>Avg: 9.76         | <u>0.463</u><br><u>0.507</u><br>Avg:<br><u>0.485</u>             | 7  |  |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|  |  |  |            |            |              |                      |    |         |      |                                                    |              |                                                 |                                                |    |  |
|--|--|--|------------|------------|--------------|----------------------|----|---------|------|----------------------------------------------------|--------------|-------------------------------------------------|------------------------------------------------|----|--|
|  |  |  | 208<br>199 | 305<br>293 | 68.2<br>67.9 | 13-09-11<br>23-09-11 | 10 | BBCH 80 | Seed | <u>0.05</u><br><u>0.06</u><br>Avg:<br><u>0.055</u> | 0.09<br>0.09 | <u>0.14</u><br><u>0.15</u><br>Avg: <u>0.145</u> | <u>0.03</u><br><u>0.03</u><br>Avg: <u>0.03</u> | 21 |  |
|--|--|--|------------|------------|--------------|----------------------|----|---------|------|----------------------------------------------------|--------------|-------------------------------------------------|------------------------------------------------|----|--|

### **C.3.1.2.10 Olives for oil production**

#### **C.3.1.2.10.1 Study 1**

|                        |                                                                                                                                                                                                                                                                                                                                         |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on olive after spray application of BYI 02960 SL 200 in Italy and Spain, [REDACTED] 2016, Study ID: 14-2125, Activity ID: RARVN090                                                                                                                                                        |
| Guideline(s):          | REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market<br><br>OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial (TG 509 published in September 2009)<br><br>US EPA OCSPP Guideline No. 860.1500, Crop Field Trials |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                      |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                     |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                              |

#### **Materials and methods**

Four outdoor trials on olives were conducted in Italy and Spain using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2014 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 1 x 0.15 kg/ha flupyradifurone in 1000-1100 L/ha of water with application at BBCH 85-88 and a 14 day PHI.

The applications support the authorised critical GAP (1 x 0.15 kg a.s./ha, 14 day PHI, BBCH 55-85).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, olive fruit samples were taken at 0, 7, 14, 20/21, 28 and 33-35 days after application. Samples of olive fruit weighing at least 1 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling (collection for hay) and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 378 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01212 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01212) was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to olive (high oil). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 105-106% and 86-102%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in olives 14 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.19 – 0.57 mg/kg.

Residues of DFA in olives 14 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.025 – 0.10 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.10.1-1.

**Table C.3.1.2.10.1-1 Residue trials on olives**

Reference: Determination of the residues of BYI 02960 in/on olive after spray application of BYI 02960 SL 200 in Italy and Spain, [REDACTED] 2016, Study ID: 14-2125, Activity ID: RARVN090

GLP: Yes Sample storage conditions: 378 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Olives / Oil fruit Analytical method: Method 01212

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                            |                                      |                                                                  |     |      |      |            |     |         |                                                             |                                                               |                                                             |                                                                  |                                                                        |                                       |  |
|----------------------------------------------------------------------------|--------------------------------------|------------------------------------------------------------------|-----|------|------|------------|-----|---------|-------------------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------------|---------------------------------------|--|
| 14-2125-01<br>95037 San Giovanni La Punta (CT); C.da Fisichella Italy 2014 | Olive Coratina Black fruits, for oil | 1. 1996<br>2. 20-04 to 15-05-2014<br>3. 03-11 to 05-12-2014      | 150 | 1000 | 15   | 21-10-2014 | n/a | BBCH 88 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit          | 0.68<br>0.38<br><u>0.25</u><br>0.24<br>0.23<br>0.18           | <0.02<br>0.024<br>0.030<br>0.033<br>0.047<br>0.047          | 0.70<br>0.404<br><u>0.28</u><br>0.273<br>0.277<br>0.227          | <0.007<br>0.008<br>0.010<br>0.011<br><u>0.016</u><br>0.016             | 0<br>7<br>14<br>21<br>28<br>35        |  |
| 14-2125-02<br>08840 Viladecans Spain 2014                                  | Olive Arbequina oil production       | 1. 2000<br>2. 05-03 to 15-04-2014<br>3. 01-11 to 31-12-2014      | 150 | 1000 | 15   | 29-10-2014 | n/a | BBCH 88 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit          | 0.47<br>0.64<br><u>0.49</u><br>0.49<br>0.38<br>0.33           | <0.02<br>0.032<br>0.046<br>0.066<br>0.074<br>0.076          | 0.49<br>0.672<br>0.536<br><u>0.556</u><br>0.454<br>0.406         | <0.007<br>0.011<br>0.015<br>0.022<br><u>0.025</u><br>0.025             | 0<br>7<br>14<br>21<br>28<br>33        |  |
| 14-2125-03<br>76011 Bisceglie Italy 2014                                   | Olive Coratina Oil                   | 1. 1996<br>2. 02-05 to 12-05-2014<br>3. 05-11-2014 to 20-01-2015 | 150 | 1000 | 15   | 10-11-2014 | n/a | BBCH 85 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 1.05<br>0.83<br>0.37<br>0.42<br><u>0.57</u><br>0.45<br>0.52   | <0.02<br>0.027<br>0.035<br>0.035<br>0.059<br>0.079<br>0.10  | 1.07<br>0.857<br>0.405<br>0.455<br><u>0.629</u><br>0.529<br>0.62 | <0.007<br>0.009<br>0.012<br>0.012<br>0.020<br>0.026<br><u>0.033</u>    | 0<br>7<br>14<br>14*<br>20<br>28<br>35 |  |
| 14-2125-04<br>41310 Brenes Spain 2014                                      | Olive Picual Black variety           | 1. 2007<br>2. 10-04 to 30-04-2014<br>3. 01-11-2014 to 31-01-2015 | 150 | 1100 | 13.6 | 23-10-2014 | n/a | BBCH 85 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 0.33<br>0.18<br>0.17<br><u>0.19</u><br>0.13<br>0.075<br>0.068 | <0.02<br><0.02<br><0.02<br><0.02<br>0.020<br>0.021<br>0.025 | 0.35<br>0.20<br>0.19<br><u>0.21</u><br>0.15<br>0.096<br>0.093    | <0.007<br><0.007<br><0.007<br><0.007<br>0.007<br>0.007<br><u>0.008</u> | 0<br>7<br>14<br>14*<br>21<br>28<br>34 |  |

\* Additional samples collected for processing study.

#### **C.3.1.2.10.2 Study 2**

|                        |                                                                                                                                                                                                                                                                                                                                         |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on olive after spray application of BYI 02960 SL 200 in Italy and Spain, [REDACTED] 2018, Study ID: 15-2103, Activity ID: RARVN117                                                                                                                                                        |
| Guideline(s):          | REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market<br><br>OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial (TG 509 published in September 2009)<br><br>US EPA OCSPP Guideline No. 860.1500, Crop Field Trials |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                      |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                     |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                              |

#### **Materials and methods**

Four outdoor trials on olives were conducted in Italy and Spain using 'BYI 02960 SL 200', an SL formulation containing 200 g/L flupyradifurone, in the 2015 growing season.

'BYI 02960 SL 200' was applied as a foliar application at a rate of 1 x 0.15 kg/ha flupyradifurone in 650-1000 L/ha of water with application at BBCH 79-85 and a 14 day PHI. As the application was made in or very close to the principal growth stage specified in the notified cGAP, and as the PHIs used match the notified cGAP, the applications are considered acceptable to support the authorised critical GAP (1 x 0.15 kg a.s./ha, 14 day PHI, BBCH 55-85).

Weather data were reported for the trials and no exceptional events were noted. All four of the trials were decline trials, olive fruit samples were taken at 0, 7/8, 14, 21, 28/29 and 34/35 days after application. Samples of olive fruit weighing at least 1 kg were collected from treated and untreated plots. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 379 days for flupyradifurone and DFA at  $\leq -18^{\circ}\text{C}$ . The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and its metabolite DFA (method 01304) was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to olive (high oil). Acceptable procedural recoveries were reported in the residue trial report for flupyradifurone and DFA (mean recoveries ranging from 98-101% and 102%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone and its metabolite DFA for all trials.

Residues of flupyradifurone in olives 14 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.30 – 3.2 mg/kg.

Residues of DFA in olives 14 days after last application (when higher residues were detected in specimens samples at a later sampling event then these residue values were taken) were between 0.076 – 0.17 mg/kg (expressed as flupyradifurone).

A summary of the residue trials is given in Table C.3.1.2.10.2-1.



**Table C.3.1.2.10.2-1 Residue trials on olives**

Reference: Determination of the residues of BYI 02960 in/on olive after spray application of BYI 02960 SL 200 in Italy and Spain, [REDACTED] 2018, Study ID: 15-2103, Activity ID: RARVN117

GLP: Yes Sample storage conditions: 379 days at  $\leq -18^{\circ}\text{C}$

Crop/crop group: Olives / Oil fruit Analytical method: Method 01304

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 200 SL Residues calculated as: Flupyradifurone

Content of active substance: 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates of<br>treatment<br>or<br>number<br>and last<br>date | Interval<br>between<br>applications<br>(days) | Growth<br>stage at<br>last<br>treatment | Portion<br>analysed | Residues (mg/kg)    |     |                                                                          |                             | PHI<br>(days) | Remarks |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-----------------------------------------------------------|-----------------------------------------------|-----------------------------------------|---------------------|---------------------|-----|--------------------------------------------------------------------------|-----------------------------|---------------|---------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                           |                                               |                                         |                     | Flupyra<br>difurone | DFA | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |         |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                                              |                    |                                                                             |     |      |      |                |     |         |                                                    |                                                     |                                                    |                                                         |                                                             |                                |  |
|------------------------------------------------------------------------------|--------------------|-----------------------------------------------------------------------------|-----|------|------|----------------|-----|---------|----------------------------------------------------|-----------------------------------------------------|----------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------|--------------------------------|--|
| 15-2103-01<br>76125 Trani<br>Italy<br>2015                                   | Olive<br>Coratina  | 1. 1965<br>2. 02-05 to<br>15-05-2015<br>3. 10-11-<br>2015 to 20-<br>01-2016 | 150 | 800  | 18.8 | 04-11-<br>2015 | n/a | BBCH 79 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 0.59<br>0.77<br><u>0.89</u><br>0.74<br>0.73<br>0.62 | <0.02<br><0.02<br>0.024<br>0.044<br>0.048<br>0.056 | 0.61<br>0.79<br><u>0.914</u><br>0.784<br>0.778<br>0.676 | <0.007<br><0.007<br>0.008<br>0.015<br>0.016<br><u>0.019</u> | 0<br>7<br>14<br>21<br>29<br>35 |  |
| 15-2103-02<br>08670<br>Navàs<br>Spain<br>2015                                | Olive<br>Arbequina | 1. 01-01-<br>2008<br>2. 01-05 to<br>15-05-2015<br>3. 25-10 to<br>10-11-2015 | 150 | 650  | 23.1 | 05-10-<br>2015 | n/a | BBCH 80 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 2.9<br>3.0<br>2.9<br><u>3.2</u><br>2.4<br>2.3       | <0.02<br>0.035<br>0.055<br>0.11<br>0.15<br>0.17    | 2.92<br>3.035<br>2.955<br><u>3.31</u><br>2.55<br>2.47   | <0.007<br>0.012<br>0.018<br>0.037<br>0.050<br><u>0.057</u>  | 0<br>8<br>14<br>21<br>28<br>35 |  |
| 15-2103-03<br>95033 C.da<br>Martina;<br>Biancavilla<br>(CT)<br>Italy<br>2015 | Olive<br>Moresca   | 1. 1996<br>2. 15-05 to<br>10-06-2015<br>3. 20-10 to<br>15-12-2015           | 150 | 800  | 18.8 | 06-10-<br>2015 | n/a | BBCH 79 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 0.80<br>0.54<br><u>0.40</u><br>0.39<br>0.34<br>0.32 | <0.02<br><0.02<br>0.023<br>0.035<br>0.048<br>0.056 | 0.82<br>0.56<br>0.423<br><u>0.425</u><br>0.388<br>0.376 | <0.007<br><0.007<br>0.008<br>0.012<br>0.016<br><u>0.019</u> | 0<br>7<br>14<br>21<br>28<br>34 |  |
| 15-2103-04<br>08840<br>Viladecans<br>Spain<br>2015                           | Olive<br>Arbequina | 1. 01-01-<br>200<br>2. 25-04 to<br>10-05-2015<br>3. 15-10 to<br>15-11-2015  | 150 | 1000 | 15.0 | 01-10-<br>2015 | n/a | BBCH 85 | Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit<br>Fruit | 0.72<br>0.32<br><u>0.30</u><br>0.28<br>0.28<br>0.20 | <0.02<br><0.02<br>0.037<br>0.049<br>0.060<br>0.076 | 0.74<br>0.34<br>0.337<br>0.329<br><u>0.34</u><br>0.276  | <0.007<br><0.007<br>0.012<br>0.016<br>0.020<br><u>0.025</u> | 0<br>7<br>14<br>21<br>28<br>34 |  |

## **C.3.2 Nature and magnitude of residues in processed commodities**

### **C.3.2.1 Nature of residues (Standard hydrolysis study)**

No additional data.

### **C.3.2.2 Magnitude of residues (Processing studies)**

#### **C.3.2.2.1 Processing study on soyabean**

Reference: BYI 02960 200 SL – Magnitude of the Residues in/on Soybean Processed Commodities, [REDACTED] 2012, Report No.: RARVY029

Guideline(s): EPA Ref.: OPPTS 860.1520, Processed Food/Feed

PMRA Ref.: DACO 7.4.5. Processed Food/Feed

OECD Test Guideline 508: Residues in Processed Commodities (Adopted Oct., 3 2008)

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

Field trials for a processing study for soyabeans were conducted at two field trial locations in the USA during the 2010 growing season. Flupyradifurone was applied at 2 x 1.0 kg a.s./ha as an SL formulation containing 200 g a.s./L in 93-467 L/ha of water. An RTI of 8/9 days was used and the last application was made at BBCH 79/89. Samples of soyabean seed were harvested using a 19/21 day PHI. Normal agricultural practices were followed, and no unusual weather events were recorded. Both trials included both a treated and an untreated control plot, as well as a third reserve plot which was not harvested. No further consideration of the reserve plot is made.

The RAC samples of soyabean seed were stored frozen within 4 hours of harvest and shipped overnight to the processing facility. Samples were stored frozen prior to processing for up to 254 days. Sufficient storage stability is available to support frozen storage for this period in high oil content commodities (Section 3.2) to which the RAC and processed fractions belong.

*Processing soyabeans into aspirated grain fraction*

The moisture content of the soyabeans was determined and if greater than 13% the samples were dried until it reached 10-13%. The soyabean grain samples were then split into 2 batches and placed in a dust generation room containing a holding bin, 2 bucket conveyors and a screw conveyor. The samples were moved in the system and aspiration was used to remove the light impurities (grain dust). Each batch was moved for 120 minutes, and the light impurities were classified using the following sieves: 2360 µm, 2000 µm, 1180 µm, 850 µm and 425 µm. After classification of each sample, the material that passed through the 2360 µm sieve was recombined to produced one aspirated grain fraction. A sample was collected for analysis.

#### *Processing soyabeans to soyabean flakes*

The remaining whole soyabeans were fed into a roller mill to crack the hull and liberate the kernel. After hulling, the sample was passed through an aspirator to separate the hull and kernel material. The moisture content of the kernel was determined and adjusted to 13.5%. The kernel was allowed to temper for at least 12 hours at ambient temperature before being heated to approx. 70-80°C in a mixer followed by being flaked in a flaking roll. A portion of the flakes were removed for production of defatted soy flour. A sample of soyabean flakes were collected for analysis.

#### *Processing soyabean flakes to soyabean meal*

The remaining soyabean flakes were extruded and turned into collets by direct steam injection and compression. The collets were dried in an oven for 30-40 minutes, and then extracted with solvent along with the flakes to generate crude oil. The process was repeated two more times. The miscella was drained and the extracted collets were desolventised in a heated paddle mixer. Soyabean meal exited the mixer. The extracted flakes were desolventised in air and ground in a pin mill to produce defatted soya flour.

For alkali refining, the percentage free fatty acid of the crude oil was determined. Based on this value, an amount of crude oil was placed in a water bath with sodium hydroxide and mixed. The neutralised oil was centrifuged and the refined oil was decanted and filtered, producing alkali refined oil and soapstock. The soapstock was discarded.

The alkali refined oil was bleached by addition of activated bleaching earth and the mixture was placed under vacuum. The temperature was increased and held for 10-15 minutes. After reducing the temperature, the bleached oil was filtered, producing bleached oil and spent bleaching earth.

To deodorise the bleached oil, the sample was steam bathed for approx. 30 minutes under vacuum at approx. 220-230°C. As the sample was cooled, a 0.5% citric acid solution was added (1 mL / 100 g of deodorised oil), producing refined-bleached-deodorised oil (RBD oil) and deodoriser distillates.

#### *Processing of soyabean to soyabean milk*

Soyabeans were washed and soaked in water for at least 12 hours, before being ground and filtered to remove solids. The soyamilk was cooked at approx. 90-95°C for 9-11 minutes, before collection for analysis.

All specimens were stored deep-frozen within 2 hours of collection.

Analysis for flupyradifurone and DFA residues was performed using LC-MS/MS method RV-001-P10-01 with updates (RV-001-P10-02 being the updated version which is also referred to as method 01304). The analytical method was satisfactorily validated during active approval on high water (forage), high protein (dried beans), high acid (orange), high oil (soyabean seed) and high starch (wheat grain) commodities (DAR, NL, 2015).

## Results and discussions

Processing factors were calculated as the residue in the processed fraction divided by the residues in the RAC.

**Table C.3.2.2.1-1 Processing study on soyabeans with flupyradifurone**

| Matrix                                 | Residues of flupyradifurone (mg/kg) | Processing factors for flupyradifurone | Median Pf           |
|----------------------------------------|-------------------------------------|----------------------------------------|---------------------|
| <b>RD-Enf 1) Flupyradifurone</b>       |                                     |                                        |                     |
| Soyabean seed (RAC)                    | 0.695, 0.414                        | -                                      | -                   |
| Aspirated grain fraction               | 11.03, 4.84                         | 15.88, 11.69                           | 13.79               |
| Meal                                   | 0.593, 0.519                        | 0.85, 1.25                             | 1.05                |
| Hulls                                  | 0.544, 0.485                        | 0.78, 1.17                             | 0.98                |
| Refined oil                            | <0.01, <0.01                        | <0.01, <0.02                           | <0.02               |
| Milk                                   | 0.029, 0.037                        | 0.04, 0.09                             | 0.07 <sup>(a)</sup> |
| Defatted flour                         | 0.728, 0.494                        | 1.05, 1.19                             | 1.12                |
| <b>RD-Enf 2) DFA, expressed as DFA</b> |                                     |                                        |                     |
| Soyabean seed (RAC)                    | 0.017, 0.102                        | -                                      | -                   |
| Aspirated grain fraction               | 0.143, 0.491                        | 8.18, 4.81                             | 6.50                |
| Meal                                   | 0.021, 0.147                        | 1.19, 1.44                             | 1.32                |
| Hulls                                  | 0.018, 0.080                        | 1.04, 0.78                             | 0.91                |

| Matrix                                                  | Residues of flupyradifurone (mg/kg) | Processing factors for flupyradifurone | Median Pf            |
|---------------------------------------------------------|-------------------------------------|----------------------------------------|----------------------|
| Refined oil                                             | <0.017, <0.017                      | <0.96, <0.16                           | <0.56 <sup>(a)</sup> |
| Milk                                                    | <0.017, <0.017                      | <0.96, <0.16                           | <0.56 <sup>(a)</sup> |
| Defatted flour                                          | 0.025, 0.130                        | 1.44, 1.27                             | 1.36                 |
| <b>RD-RA Sum of flupyradifurone and flupyradifurone</b> |                                     |                                        |                      |
| Soyabean seed (RAC)                                     | 0.747, 0.720                        | -                                      | -                    |
| Aspirated grain fraction                                | 11.46, 6.31                         | 15.34, 8.77                            | 12.06                |
| Meal                                                    | 0.656, 0.961                        | 0.88, 1.34                             | 1.11                 |
| Hulls                                                   | 0.599, 0.724                        | 0.80, 1.01                             | 0.91                 |
| Refined oil                                             | <0.06, <0.06                        | <0.08, <0.08                           | <0.08                |
| Milk                                                    | 0.079, 0.087                        | 0.11, 0.12                             | 0.12                 |
| Defatted flour                                          | 0.803, 0.884                        | 1.07, 1.23                             | 1.15                 |

(a) Tentative Pf as derived from two trials with ≥50% difference between individual Pfs.

The analytical method (RV-001-P10-01 with updates (RV-001-P10-02 being the updated version which is also referred to as method 01304)) was satisfactorily validated in high oil and high water content commodities during approval of flupyradifurone (DAR, NL, 2015).

The LOQs of the method are 0.01 mg/kg for flupyradifurone and 0.05 mg/kg for DFA in parent equivalents in/on soyabean (seeds) RAC and processed commodity samples.

**Table C 3.2.2.1-2 Summary of procedural recoveries for flupyradifurone**

| Processed fraction       | Fortification level (mg/kg) | Recoveries (%)               | Mean (%) |
|--------------------------|-----------------------------|------------------------------|----------|
| Soyabean seed (RAC)      | 0.01                        | 97, 97, 92, 102, 90, 102, 96 | 97       |
|                          | 1.0                         | 95, 87, 96                   | 93       |
| Aspirated grain fraction | 0.25                        | 79, 93, 87                   | 86       |
|                          | 15                          | 98, 91, 86                   | 92       |
| Hulls                    | 0.01                        | 103, 76, 101                 | 93       |
|                          | 1.0                         | 91, 90, 87                   | 89       |
| Meal                     | 0.01                        | 83, 111, 78                  | 91       |
|                          | 1.0                         | 85, 93, 104                  | 94       |

|                |      |               |     |
|----------------|------|---------------|-----|
| Refined oil    | 0.01 | 97, 99, 80    | 92  |
|                | 1.0  | 104, 109, 92  | 102 |
| Milk           | 0.01 | 100, 99, 95   | 98  |
|                | 1.0  | 99, 97, 98    | 98  |
| Defatted flour | 0.01 | 116, 104, 114 | 111 |
|                | 1.0  | 100, 87, 91   | 93  |

**Table C 3.2.2.1-4 Summary of procedural recoveries for DFA**

| Processed fraction       | Fortification level (mg/kg) | Recoveries (%)             | Mean (%) |
|--------------------------|-----------------------------|----------------------------|----------|
| Soyabean seed (RAC)      | 0.05                        | 75, 74, 91, 75, 81, 76, 77 | 78       |
|                          | 1.0                         | 77, 79, 87                 | 81       |
| Aspirated grain fraction | 0.05                        | 98, 100, 104               | 101      |
|                          | 0.25                        | 85, 91, 95                 | 90       |
|                          | 15.0                        | 86, 84, 86                 | 85       |
| Hulls                    | 0.05                        | 84, 84, 83                 | 84       |
|                          | 1.0                         | 81, 76, 78                 | 78       |
| Meal                     | 0.05                        | 75, 71, 74                 | 73       |
|                          | 1.0                         | 71, 70, 92                 | 78       |
| Refined oil              | 0.05                        | 101, 109, 101              | 104      |
|                          | 1.0                         | 108, 114, 97               | 106      |
| Milk                     | 0.05                        | 96, 98, 92                 | 95       |
|                          | 1.0                         | 107, 97, 102               | 102      |
| Defatted flour           | 0.05                        | 88, 78, 81                 | 82       |
|                          | 1.0                         | 76, 72, 69                 | 72       |

Acceptable procedural recoveries were reported for all analytes in soyabean (seeds) RAC and all processed commodities.

## Conclusion

For flupyradifurone and DFA a concentration of residues was seen in aspirated grain fractions, meal and defatted flour, while a reduction in residues was seen in hulls, refined oil and milk.

### C.3.2.2.2 Processing study on olives

Reference: Determination of the residues of BYI 02960 in/on olive and the processed fractions (oil, crude; oil, refined and oil, solv. Extracted refined ) after spray application of BYI 02960 SL

200 in Italy and Spain, [REDACTED] 2016, Study ID: 14-3125, Activity ID: RARVN092

Guideline(s): REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

US EPA OPPTS 860.1520, Processed Food/Feed

OECD Guideline for the Testing of Chemicals, Magnitude of the Pesticide Residues in Processed Commodities, 508 (2008-10-03)

EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)

Deviations: No

GLP: Yes

Validity of the study:

### Materials and methods

Field trials for a processing study for olives were conducted at two field trial locations in southern Europe (Italy and Spain) during the 2014 growing season. Flupyradifurone was applied at 1 x 0.15 kg a.s./ha as an SL formulation containing 200 g a.s./L in 1000-1100 L/ha of water. The application was made at BBCH 85 and samples of olive fruit were harvested using a 14 day PHI. Normal agricultural practices were followed, and no unusual weather events were recorded. Trial 14-3125-01 (Italy) included both a treated and an untreated control plot, while trial 14-3125-02 (Spain) included only treated plots.

The RAC samples of olive fruit were stored frozen within 24 hours of harvest. Samples were stored frozen prior to processing for up to 206 days. Sufficient storage stability is available to support frozen storage for this period in high oil content commodities (Section 3.2) to which the RAC and processed fractions belong.

#### *Processing olives into crude oil*

The olives were washed with water (approx. 1:1), transferred into a mill and milled to a pulp. NaCl was added and the mixture was well mixed for 30 minutes. The pulp was then pressed at 200-260 bar which resulted in a liquid phase (cooking oil and water) and a solid phase (wet pomace). The liquid phase was decanted and centrifuged to separate crude oil from water. Samples of **crude oil** were collected for analysis.



### *Processing olives into dry pomace*

The wet pomace resulting from the production of crude oil was dried by heating up to 60°C in a vacuum drum dryer. A water content of <3.5% was achieved.

### *Processing olives into solvent extracted oil*

Dried pomace was placed in vessels and n-hexane was added to form a press cake. The n-hexane was circulated through the press cake for approx. 2 hours at 60°C. Afterwards, the solvent-oil mixture (miscella) was pumped into a distillation vessel and heated. The extracted oil remaining after the first distillation remained in the distillation vessel while the distilled n-hexane was transferred back to the press cake for the second extraction. Fresh n-hexane was added. A second extraction was carried out in the same manner as the first. After the miscella distillation, a rotary evaporator was used to remove the rest of the solvent out of the extracted oil by heating to approx. 80°C until no solvent remained. The solvent extracted oil was filtered under vacuum.

### *Processing olives into refined oil and refined solvent extracted oil*

#### *Hydration*

The oil (both crude and solvent extracted) was heated up to 85°C with continuous stirring. Water (10% relative to raw oil used) was added and the mixture was held at approx. 85°C for approx. 45 minutes with continuous stirring. After this time, the stirring was stopped and the mixture was allowed to separate into the oil and water phases. The water phase (including mucilage) was removed.

#### *Desliming*

Concentrated phosphorus acid (1% relative to the oil phase used) was added to the oil phase at 85°C with continuous stirring and was held for 45 minutes. Immediately before the stirring was stopped, water (10% relative to the oil phase used) was added and phase separation was allowed to occur at 85°C. The water phase (including flocculated precipitation) was removed.

#### *Neutralisation*

The acid number of the oil phase was determined before heating to approx. 90°C with continuous stirring. Sodium hydroxide (7% solution) was added and the mixture was stirred for approx. 20 minutes. Water (10% relative to the used oil phase) was added and after a further minute the stirring was stopped. Phase separation occurred and the water phase was removed.

#### *Washing*

The oil was heated to approx. 90°C with continuous stirring. Water (10% relative to the oil used) was added and the mixture was stirred for approx. 20 minutes. Phase separation occurred and the water phase was removed. The pH of the washing water was determined, with a target pH of between 7 – 8. A pH of 7 was achieved

for all samples. The soap content of the oil was also determined, with a target content of  $\leq 0.01\%$ . All samples achieved a soap content of  $< 0.01\%$ .

#### *Drying*

The oil was heated to approx.  $95^{\circ}\text{C}$  with continuous stirring. Citric acid (60 mg/kg oil) was added and the mixture was dried under vacuum until no further water escaped from the oil.

#### *Bleaching*

The oil was heated to  $95^{\circ}\text{C}$  with continuous stirring under vacuum. The bleaching agent, podsol (Tonsil Supreme 114 FF) was added (1% relative to the used oil) and the oil was bleached for 35 minutes.

#### *Filtration*

The oil was filtered to remove the podsol.

#### *Deodorisation*

The oil was heated to  $240^{\circ}\text{C}$  under vacuum. After the oil reached  $160^{\circ}\text{C}$  the steam was transferred through the oil to expel fatty acids, odour and taste influencing compounds, as well as other volatile components. The oil was held at  $240^{\circ}\text{C}$  for approx. 20 minutes, after which time the oil was allowed to cool. Once the oil had reached  $160^{\circ}\text{C}$  the steam supply was removed from the oil. Samples of **refined oil** and **refined solvent extracted oil** were collected for analysis.

All specimens were stored deep-frozen within 24 hours of collection.

Analysis for flupyradifurone and DFA residues was performed using LC-MS/MS method 01212. The analytical method was satisfactorily validated during active approval on high water (tomato fruit), high starch (barley grain), high protein (dry kidney bean), high oil (rape seed) and high acid (grape) commodities (DAR. NL, 2015). Therefore, the method is considered applicable to olive and its processed fractions which are all high oil.

Acceptable procedural recoveries were reported for flupyradifurone and DFA in the RAC and all processed fractions.

## **Results and discussions**

Processing factors were calculated as the residue in the processed fraction divided by the residues in the RAC.

### **Table C.3.2.2.1-1 Processing study on olives with flupyradifurone**

| Matrix                                                  | Residues of flupyradifurone (mg/kg) | Processing factors for flupyradifurone | Mean Pf              |
|---------------------------------------------------------|-------------------------------------|----------------------------------------|----------------------|
| <b>RD-Enf 1) Flupyradifurone</b>                        |                                     |                                        |                      |
| Olive fruit (RAC)                                       | 0.40, 0.18                          | -                                      | -                    |
| Crude oil                                               | 0.047, 0.024                        | 0.12, 0.13                             | 0.13                 |
| Refined oil                                             | <0.01, <0.01                        | <0.03, <0.06                           | <0.05 <sup>(a)</sup> |
| Refined solvent extracted oil                           | <0.01, <0.01                        | <0.03, <0.06                           | <0.05 <sup>(a)</sup> |
| <b>RD-Enf 2) DFA, expressed as DFA</b>                  |                                     |                                        |                      |
| Olive fruit (RAC)                                       | 0.012, <0.007                       | -                                      | -                    |
| Crude oil                                               | <0.007, <0.007                      | 0.57                                   | 0.57 <sup>(a)</sup>  |
| Refined oil                                             | <0.007, <0.007                      | 0.57                                   | 0.57 <sup>(a)</sup>  |
| Refined solvent extracted oil                           | <0.007, <0.007                      | 0.57                                   | 0.57 <sup>(a)</sup>  |
| <b>RD-RA Sum of flupyradifurone and flupyradifurone</b> |                                     |                                        |                      |
| Olive fruit (RAC)                                       | 0.435, 0.20                         | -                                      | -                    |
| Crude oil                                               | 0.067, 0.044                        | 0.15, 0.22                             | 0.19                 |
| Refined oil                                             | <0.03, <0.03                        | <0.07, <0.15                           | <0.11 <sup>(a)</sup> |
| Refined solvent extracted oil                           | <0.03, <0.03                        | <0.07, <0.15                           | <0.11 <sup>(a)</sup> |

(a) Tentative Pfs as the processing factor was derived from one individual processing factor or which differ by  $\geq 50\%$ .

The analytical method (01212) was satisfactorily validated in high oil content commodities during approval of flupyradifurone (DAR, NL, 2015).

The LOQs of the method are 0.01 mg/kg for flupyradifurone and 0.02 mg/kg for DFA in parent equivalents in/on olive RAC and processed commodity samples.

**Table C 3.2.2.1-2 Summary of procedural recoveries for flupyradifurone**

| Processed fraction | Fortification level (mg/kg) | Recoveries (%)                                              | Mean (%) |
|--------------------|-----------------------------|-------------------------------------------------------------|----------|
| Crude oil          | 0.01                        | 98 <sup>(a)</sup>                                           | -        |
|                    | 0.10                        | 98 <sup>(b)</sup> , 101 <sup>(c)</sup> , 111 <sup>(d)</sup> | 103      |

|                               |      |                                           |     |
|-------------------------------|------|-------------------------------------------|-----|
| Refined oil                   | 0.01 | 97, 98, 100, 101, 101, 102, 102, 106, 108 | 102 |
|                               | 0.10 | 96, 98, 99, 100, 102, 102, 102, 103       | 100 |
| Refined solvent extracted oil | 0.01 | 95                                        | -   |
|                               | 0.10 | 98, 101                                   | 100 |

(a) Value was corrected to account for residues in the control sample. The uncorrected value was 597%.

(b) Value was corrected to account for residues in the control sample. The uncorrected value was 147%.

(c) Value was corrected to account for residues in the control sample. The uncorrected value was 151%.

(d) Value was corrected to account for residues in the control sample. The uncorrected value was 161%.

**Table C 3.2.2.1-4 Summary of procedural recoveries for DFA**

| Processed fraction            | Fortification level (mg/kg) | Recoveries (%)                          | Mean (%) |
|-------------------------------|-----------------------------|-----------------------------------------|----------|
| Crude oil                     | 0.02                        | 94                                      | -        |
|                               | 0.20                        | 94, 98, 107                             | 100      |
| Refined oil                   | 0.02                        | 95, 96, 99, 99, 100, 101, 102, 104, 104 | 100      |
|                               | 0.20                        | 96, 96, 98, 99, 100, 101, 101, 102      | 99       |
| Refined solvent extracted oil | 0.02                        | 97                                      | -        |
|                               | 0.20                        | 98, 100                                 | 99       |

Acceptable procedural recoveries were reported for all analytes in all processed commodities.

## Conclusion

For flupyradifurone and DFA a dilution of residues was seen in crude olive oil, refined olive oil and refined solvent extracted olive oil.

### **C.3.3 Nature and magnitude of residues in rotational crops**

#### **C.3.3.1 Nature of residues**

No additional studies submitted.

### C.3.3.2 Magnitude of residues (field rotational crop studies)

#### C.3.3.2.1 Potatoes

Reference: Determination of the residues of BYI 02960 in/on potato and soil after Spraying of BYI 02960 SL 200 in the Field in Germany, the Netherlands, Italy and Spain, [REDACTED] 2018, Study ID: 16-2510, Activity ID: RARV0055

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

OECD Guidelines for the Testing of Chemicals. Residues in Rotational Crops (Limited Field Studies). 504. 2007-01-08

OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)

US EPA OCSPG Guideline No. 860.1900, Field Accumulation in Rotational Crops

US EPA OCSPG Guideline No. 860.1500 on Crop Field Trial

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### Materials and methods

During the 2016 and 2017 growing seasons, four trials were conducted in Germany, the Netherlands, Italy and Spain to determine the residue level of flupyradifurone and DFA in potato, grown in soil previously treated with flupyradifurone.

BYI 02960 SL 200, an SL formulation containing 200 g/L flupyradifurone, was applied to bare soil at a rate of 1 x 0.3 kg a.s./ha in 300-400 L/ha water. Potatoes were planted after a period of 138 to 181 days and 295 to 343 days after application. The plant back intervals (PBIs) used simulated the scenario of a following crop after the original crop was harvested, therefore is reflective of non-perennial crops with a defined interval for re-planting. A plant back interval of 30 days was not tested as it was considered a unlikely interval for a crop with such a long vegetation period. All trials included an untreated control plot.

After application, BYI 02960 SL 200 was incorporated into the soil. Before planting of the potatoes, the magnitude of flupyradifurone and DFA residues in the soil was determined (the top 0-20 cm).

Weather data were reported for the trials and no exceptional events were noted. Samples of potatoes planted at 138 to 181 day PBIs were harvested at BBCH 45 and 49 (222 – 287 and 243 – 322 days after application). Samples of potatoes planted at 295 to 343 day PBIs were harvested at BBCH 45 and 49 (289 – 445 and 412 – 488 days after application). Potato samples weighing at least 2 kg and consisting of at least 12 tubers were collected from treated and untreated plots. Samples of soil from the top 0-20 cm were harvested at 181 – 148 and 292 – 349 days after application. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 161 days for potatoes and 239 days for soil at -18°C. The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage in potatoes. Data on the storage stability of flupyradifurone and DFA are not available, therefore the residues in soil reported in Table C.3.3.2.1-2 are not relied upon.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in potato. In soil, residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01074/M001 with an LOQ of 0.005 mg/kg for flupyradifurone and DFA, expressed as DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and DFA (method 01304) in potato was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to potato (high starch). Acceptable procedural recoveries were reported in the trial report for flupyradifurone and DFA (mean recoveries ranging from 96-100% and 93-101%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

A summary of the residue trials is given in Table C.3.3.2.1-1

**Table C.3.3.2.1-1 Rotational crop study (potatoes)**

Reference: Determination of the residues of BYI 02960 in/on potato and soil after Spraying of BYI 02960 SL 200 in the Field in Germany, the Netherlands, Italy and Spain, [REDACTED] 2018, Study ID: 16-2510, Activity ID: RARV0055

GLP: Yes Sample storage conditions: 161 days at -18°C

Primary crop: None, bare soil Analytical method: Method 01304

Succeeding crop: Potatoes / root and tuber vegetable Limit of Quantification (mg/kg): Flupyradifurone: 0.01 mg/kg  
DFA: 0.02 mg/kg (parent equivalents)

Formulation: BYI 02960 SL 200 Residues calculated as: Flupyradifurone

Content of active substance 200 g/L

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates or<br>number<br>of<br>treatmen<br>ts and<br>last date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analys<br>ed | Residues (mg/kg)    |                                                 |                                                                          |                             | PBI<br>(days) | DAT<br>(days) |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-------------------------------------------------------------|-----------------------------------|---------------------------------|---------------------|-------------------------------------------------|--------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                              |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                             |                                   |                                 | Flupyradi<br>furone | DFA,<br>expresse<br>d as<br>flupyradif<br>urone | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifruone | DFA,<br>expressed<br>as DFA |               |               |
| 16-2510-01<br>49377          | Potato<br>Seresta    | 1. 24-04-<br>2017                                              | 300                               | 300             | 100              | 25-10-<br>2016                                              | BBCH 45<br>BBCH 49                | Tuber<br>Tuber                  | <0.01<br><0.01      | 0.036<br>0.034                                  | 0.046<br>0.044                                                           | 0.012<br>0.011              | 181<br>181    | 287<br>322    |



| Trial No<br>Location<br>Year                     | Commodity<br>Variety | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates or<br>number<br>of<br>treatmen<br>ts and<br>last date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analys<br>ed | Residues (mg/kg)    |                                                 |                                                                          |                             | PBI<br>(days) | DAT<br>(days) |
|--------------------------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-------------------------------------------------------------|-----------------------------------|---------------------------------|---------------------|-------------------------------------------------|--------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                                                  |                      |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                             |                                   |                                 | Flupyradi<br>furone | DFA,<br>expresse<br>d as<br>flupyradif<br>urone | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifruone | DFA,<br>expressed<br>as DFA |               |               |
| Vechta-<br>Langförden<br>Germany<br>2017         |                      | 2. 15-06 to<br>05-07-2017<br>3. 01-09 to<br>30-09-2017         |                                   |                 |                  | 09-06-<br>2016                                              | BBCH 45<br>BBCH 49                | Tuber<br>Tuber                  | <0.01<br><0.01      | <0.02<br><0.02                                  | <0.03<br><0.03                                                           | <0.007<br><0.007            | 319<br>319    | 425<br>460    |
| 16-2510-02<br>1681 ND                            | Potato<br>Kennebec   | 1. 12-04-<br>2017                                              | 300                               | 400             | 75               | 25-11-<br>2016                                              | BBCH 45<br>BBCH 49                | Tuber<br>Tuber                  | <0.01<br><0.01      | 0.13<br>0.084                                   | 0.14<br>0.094                                                            | 0.043<br>0.028              | 138<br>138    | 222<br>243    |
| Zwaagdijk<br>The<br>Netherland<br>s<br>2017      |                      | 2. 01-07 to<br>15-07-2017<br>3. 24-07 to<br>01-08-2017         |                                   |                 |                  | 11-05-<br>2016                                              | BBCH 45<br>BBCH 49                | Tuber<br>Tuber                  | <0.01<br><0.01      | 0.054<br>0.042                                  | 0.064<br>0.052                                                           | 0.018<br>0.014              | 336<br>336    | 420<br>441    |
| 16-2510-03<br>37050                              | Potato<br>Kennebec   | 1. 02-03-<br>2017                                              | 300                               | 300             | 100              | 12-10-<br>2016                                              | BBCH 45<br>BBCH 49                | Tuber<br>Tuber                  | <0.01<br><0.01      | 0.26<br>0.21                                    | 0.27<br>0.22                                                             | 0.087<br>0.070              | 141<br>141    | 243<br>286    |
| Albaro di<br>Ronco<br>All'Adige<br>Italy<br>2017 |                      | 2. 19-06 to<br>28-06-2017<br>3. 14-07 to<br>31-07-2017         |                                   |                 |                  | 24-03-<br>2016                                              | BBCH 45<br>BBCH 49                | Tuber<br>Tuber                  | <0.01<br><0.01      | 0.057<br>0.044                                  | 0.067<br>0.054                                                           | 0.019<br>0.015              | 343<br>343    | 445<br>488    |
| 16-2510-04<br>46230                              | Potato<br>Desiree    | 1. 04-02-<br>2017                                              | 300                               | 400             | 75               | 06-09-<br>2016                                              | BBCH 45<br>BBCH 49                | Tuber<br>Tuber                  | <0.01<br><0.01      | 0.049<br>0.069                                  | 0.059<br>0.079                                                           | 0.016<br>0.023              | 151<br>151    | 245<br>268    |
| Alginet<br>Spain<br>2017                         |                      | 2. 15-04 to<br>08-05-2017<br>3. 01-06 to<br>10-06-2017         |                                   |                 |                  | 15-04-<br>2016                                              | BBCH 45<br>BBCH 49                | Tuber<br>Tuber                  | <0.01<br><0.01      | 0.033<br>0.037                                  | 0.043<br>0.047                                                           | 0.011<br>0.012              | 295<br>295    | 389<br>412    |

Table C.3.3.2.1-2 Rotational crop study (soil samples)

Reference: Determination of the residues of BYI 02960 in/on potato and soil after Spraying of BYI 02960 SL 200 in the Field in Germany, the Netherlands, Italy and Spain, [REDACTED] 2018, Study ID: 16-2510, Activity ID: RARV0055

GLP: Yes Sample storage conditions: 239 days at -18°C

Primary crop: None, bare soil Analytical method: Method 01074/M001

Succeeding crop: Potatoes / root and tuber vegetable Limit of Quantification (mg/kg): Flupyradifurone and DFA (expressed as DFA): 0.005 mg/kg

Formulation: BYI 02960 SL 200 Residues calculated as: Flupyradifurone

Content of active substance 200 g/L

| Trial No<br>Location<br>Year                                        | Portion analysed | Application rate per treatment |              |           | DAT (days) | Residues (mg/kg) |                                   |                                                              |                       |
|---------------------------------------------------------------------|------------------|--------------------------------|--------------|-----------|------------|------------------|-----------------------------------|--------------------------------------------------------------|-----------------------|
|                                                                     |                  | g a.s./ha                      | Water (L/ha) | g a.s./hL |            | Flupyradifurone  | DFA, expressed as flupyradifurone | Sum of flupyradifurone and DFA, expressed as flupyradifurone | DFA, expressed as DFA |
| 16-2510-01<br>49377<br><br>Vechta-<br>Langförden<br>Germany<br>2017 | Bare soil        | 300                            | 300          | 100       | 181        | 0.019            | <0.15                             | 0.169                                                        | <0.005                |
|                                                                     |                  |                                |              |           | 319        | 0.014            | <0.15                             | 0.164                                                        | <0.005                |
| 16-2510-02<br>1681 ND                                               | Bare soil        | 300                            | 400          | 75        | 138        | 0.061            | <0.15                             | 0.211                                                        | <0.005                |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                             | Portion analysed | Application rate per treatment |              |           | DAT (days) | Residues (mg/kg) |                                   |                                                              |                       |
|--------------------------------------------------------------------------|------------------|--------------------------------|--------------|-----------|------------|------------------|-----------------------------------|--------------------------------------------------------------|-----------------------|
|                                                                          |                  | g a.s./ha                      | Water (L/ha) | g a.s./hL |            | Flupyradifurone  | DFA, expressed as flupyradifurone | Sum of flupyradifurone and DFA, expressed as flupyradifurone | DFA, expressed as DFA |
| Zwaagdijk<br>The Netherlands<br>2017                                     |                  |                                |              |           | 336        | 0.026            | <0.15                             | 0.176                                                        | <0.005                |
| 16-2510-03<br>37050<br><br>Albaro di Ronco<br>All'Adige<br>Italy<br>2017 | Bare soil        | 300                            | 300          | 100       | 147        | 0.035            | <0.15                             | 0.185                                                        | <0.005                |
|                                                                          |                  |                                |              |           | 349        | 0.007            | <0.15                             | 0.157                                                        | <0.005                |
| 16-2510-04<br>46230<br><br>Alginet<br>Spain<br>2017                      | Bare soil        | 300                            | 400          | 75        | 148        | 0.030            | <0.15                             | 0.180                                                        | <0.005                |
|                                                                          |                  |                                |              |           | 292        | 0.026            | <0.15                             | 0.176                                                        | <0.005                |

#### **C.3.3.2.2 Cauliflower and broccoli**

Reference: Determination of the residues of BYI 02960 in/on the field rotational crop cauliflower, broccoli and soil after application of BYI 02960 SL 200 to bare soil in the field in Belgium, the Netherlands, Italy and Spain, [REDACTED] 2018, Study ID: 16-2516, Activity ID: RARV0047

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

OECD Guidelines for the Testing of Chemicals. Residues in Rotational Crops (Limited Field Studies). 504. 2007-01-08

OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)

US EPA OCSP Guideline No. 860.1900, Field Accumulation in Rotational Crops

US EPA OCSP Guideline No. 860.1500 on Crop Field Trial

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

During the 2016 and 2017 growing seasons, four trials were conducted in the Netherlands, Belgium, Italy and Spain to determine the residue level of flupyradifurone and DFA in cauliflower and broccoli, grown in soil previously treated with flupyradifurone (2 trials on cauliflower, 2 trials on broccoli).

BYI 02960 SL 200, an SL formulation containing 200 g/L flupyradifurone, was applied to bare soil at a rate of 1 x 0.3 kg a.s./ha in 300-400 L/ha water. Cauliflower and broccoli were planted after a period of 21 to 30 days, 129 to 161 days and 295 to 343 days after application. The plant back intervals (PBIs) used simulated the scenario of a following crop in the same season as well as in future seasons, reflecting agronomical practice for non-

perennial crops with a defined interval for re-planting. All trials included an untreated control plot.

After application, BYI 02960 SL 200 was incorporated into the soil. Before planting of the cauliflower and broccoli, the magnitude of flupyradifurone and DFA residues in the soil was determined (the top 0-20 cm).

Weather data were reported for the trials and no exceptional events were noted. Samples of cauliflower and broccoli curds planted at 21 to 30 day PBIs were harvested at BBCH 45/46/48 and 49 (86 – 116 and 100 – 130 days after application). Samples of cauliflower and broccoli curds planted at 129 to 161 day PBIs were harvested at BBCH 45/48 and 49 (221 – 230 and 234 – 244 days after application). Samples of cauliflower and broccoli curds planted at 321 to 339 day PBIs were harvested at BBCH 45/49 and 49 (389 – 428 and 403 – 442 days after application). Cauliflower and broccoli samples weighing at least 2 kg and/or consisting of at least 12 individual units were collected from treated and untreated plots. Samples of soil from the top 0-20 cm were harvested at 22 – 30, 130 – 161 and 321 – 342 days after application. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 462 days for cauliflower and broccoli and 372 days for soil at -18°C. The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage in cauliflower and broccoli. Data on the storage stability of flupyradifurone and DFA are not available, therefore the residues in soil reported in Table C.3.3.2.2-2 are not relied upon.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in cauliflower and broccoli. In soil, residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01074/M001 with an LOQ of 0.005 mg/kg for flupyradifurone and DFA, expressed as DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and DFA (method 01304) in cauliflower and broccoli was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to cauliflower and broccoli (high water). Acceptable procedural recoveries were reported in the trial report for flupyradifurone and DFA (mean recoveries ranging from 96-99% and 96-109%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

A summary of the residue trials is given in Table C.3.3.2.2-1.

**Table C.3.3.2.2-1 Rotational crop study (cauliflower and broccoli)**

|                             |                                                                                                                                                                                                                                                                                   |                                  |                                                                     |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on the field rotational crop cauliflower, broccoli and soil after application of BYI 02960 SL 200 to bare soil in the field in Belgium, the Netherlands, Italy and Spain, [REDACTED] 2018, Study ID: 16-2516, Activity ID: RARV0047 |                                  |                                                                     |
| GLP:                        | Yes                                                                                                                                                                                                                                                                               | Sample storage conditions:       | 462 days at -18°C                                                   |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                                                   | Analytical method:               | Method 01304                                                        |
| Succeeding crop:            | Cauliflower and broccoli / Flowering brassicas                                                                                                                                                                                                                                    | Limit of Quantification (mg/kg): | Flupyradifurone: 0.01 mg/kg<br>DFA: 0.02 mg/kg (parent equivalents) |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                                                  | Residues calculated as:          | Flupyradifurone                                                     |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                                                           |                                  |                                                                     |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                         | Commodity<br>Variety     | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest | Application rate<br>per treatment |                 |                  | Dates or<br>number<br>of<br>treatmen<br>ts and<br>last date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analys<br>ed | Residues (mg/kg)    |                                                |                                                                          |                             | PBI<br>(days) | DAT<br>(days) |
|----------------------------------------------------------------------|--------------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|-------------------------------------------------------------|-----------------------------------|---------------------------------|---------------------|------------------------------------------------|--------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                                                                      |                          |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                             |                                   |                                 | Flupyradi<br>furone | DFA,<br>exprese<br>d as<br>flupyradif<br>urone | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifruone | DFA,<br>expressed<br>as DFA |               |               |
| 16-2516-01<br>1681 ND<br>Zwaagdijk<br>The<br>Netherland<br>s<br>2017 | Cauliflower<br>Clarina   | 1. 01-06-<br>2016<br>2. -<br>3. 12-08 to<br>26-08-2016         | 300                               | 400             | 75               | 11-05-<br>2016                                              | BBCH 45<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.075<br>0.070                                 | 0.085<br>0.080                                                           | 0.025<br>0.023              | 21            | 93<br>107     |
|                                                                      | Cauliflower<br>Aerospace | 1. 12-04-<br>2017<br>2. –<br>3. 15-07 to<br>01-08-2017         | 300                               | 400             | 75               | 25-11-<br>2016                                              | BBCH 45<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.045<br>0.036                                 | 0.055<br>0.046                                                           | 0.015<br>0.012              | 138           | 230<br>244    |
|                                                                      | Cauliflower<br>Aerospace | 1. 12-04-<br>2017<br>2. –<br>3. 15-07 to<br>01-08-2017         | 300                               | 400             | 75               | 11-05-<br>2016                                              | BBCH 45<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.021<br>0.023                                 | 0.031<br>0.033                                                           | 0.007<br>0.008              | 336           | 428<br>442    |
| 16-2516-02<br>6221 Saint-<br>Amand<br>Belgium<br>2016/17             | Cauliflower<br>Korlanu   | 1. 10-06-<br>2016<br>2. –<br>3. 15-08 to<br>19-08-2016         | 300                               | 300             | 100              | 11-05-<br>2016                                              | BBCH 46<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.18<br>0.20                                   | 0.19<br>0.21                                                             | 0.060<br>0.067              | 30            | 86<br>100     |
|                                                                      | Cauliflower<br>Tarifa F1 | 1. 24-05-<br>2017<br>2. –<br>3. 10-08 to<br>22-08-2017         | 300                               | 300             | 100              | 14-12-<br>2016                                              | BBCH 45<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.15<br>0.11                                   | 0.16<br>0.12                                                             | 0.050<br>0.037              | 161           | 229<br>243    |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                       | Commodity<br>Variety                | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest   | Application rate<br>per treatment |                 |                  | Dates or<br>number<br>of<br>treatmen<br>ts and<br>last date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analys<br>ed | Residues (mg/kg)    |                                                 |                                                                          |                             | PBI<br>(days) | DAT<br>(days) |
|----------------------------------------------------|-------------------------------------|------------------------------------------------------------------|-----------------------------------|-----------------|------------------|-------------------------------------------------------------|-----------------------------------|---------------------------------|---------------------|-------------------------------------------------|--------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                                                    |                                     |                                                                  | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                             |                                   |                                 | Flupyradi<br>furone | DFA,<br>expresse<br>d as<br>flupyradif<br>urone | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifruone | DFA,<br>expressed<br>as DFA |               |               |
|                                                    | Cauliflower<br>Tarifa F1            | 1. 24-05-<br>2017<br>2. –<br>3. 10-08 to<br>22-08-2017           | 300                               | 300             | 100              | 07-07-<br>2016                                              | BBCH 45<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.12<br>0.098                                   | 0.13<br>0.108                                                            | 0.040<br>0.033              | 321           | 389<br>403    |
| 16-2516-03<br>70032<br>Bitonto<br>Italy<br>2016/17 | Broccoli<br>Marathon F1<br>– Sakata | 1. 30-09-<br>2016<br>2. –<br>3. 20-12-<br>2016 to 20-<br>02-2017 | 300                               | 300             | 100              | 02-09-<br>2016                                              | BBCH 45<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.13<br>0.062                                   | 0.14<br>0.072                                                            | 0.043<br>0.021              | 28            | 116<br>130    |
|                                                    | Broccoli<br>Marathon F1<br>– Sakata | 1. 29-08-<br>2017<br>2. –<br>3. 03-11-<br>2017 to 31-<br>01-2018 | 300                               | 300             | 100              | 30-03-<br>2017                                              | BBCH 45<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.087<br>0.11                                   | 0.097<br>0.12                                                            | 0.029<br>0.037              | 152           | 222<br>235    |
|                                                    | Broccoli<br>Marathon F1<br>– Sakata | 1. 29-08-<br>2017<br>2. –<br>3. 03-11-<br>2017 to 31-<br>01-2018 | 300                               | 300             | 100              | 30-09-<br>2016                                              | BBCH 45<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.047<br>0.068                                  | 0.057<br>0.078                                                           | 0.016<br>0.023              | 333           | 403<br>416    |
| 16-2516-04<br>46230<br>Alginet<br>Spain<br>2016/17 | Broccoli<br>Principe F1<br>(clause) | 1. 29-09-<br>2016<br>2. –<br>3. 15-12-<br>2016 to 15-<br>01-2017 | 300                               | 400             | 75               | 06-09-<br>2016                                              | BBCH 48<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.17<br>0.16                                    | 0.18<br>0.17                                                             | 0.057<br>0.053              | 23            | 115<br>128    |



The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year | Commodity<br>Variety                | Date of<br>1.Sowing or<br>planting<br>2.Flowering<br>3.Harvest   | Application rate<br>per treatment |                 |                  | Dates or<br>number<br>of<br>treatmen<br>ts and<br>last date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analys<br>ed | Residues (mg/kg)    |                                                 |                                                                          |                             | PBI<br>(days) | DAT<br>(days) |
|------------------------------|-------------------------------------|------------------------------------------------------------------|-----------------------------------|-----------------|------------------|-------------------------------------------------------------|-----------------------------------|---------------------------------|---------------------|-------------------------------------------------|--------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                              |                                     |                                                                  | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                             |                                   |                                 | Flupyradi<br>furone | DFA,<br>expresse<br>d as<br>flupyradif<br>urone | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifruone | DFA,<br>expressed<br>as DFA |               |               |
|                              | Broccoli<br>Principe F1<br>(clause) | 1. 29-09-<br>2016<br>2. –<br>3. 15-12-<br>2016 to 15-<br>01-2017 | 300                               | 400             | 75               | 23-05-<br>2016                                              | BBCH 48<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.18<br>0.17                                    | 0.19<br>0.18                                                             | 0.060<br>0.057              | 129           | 221<br>234    |
|                              | Broccoli<br>Parthenon               | 1. 11-08-<br>2017<br>2. –<br>3. 05-10 to<br>30-10-2017           | 300                               | 400             | 75               | 06-09-<br>2016                                              | BBCH 49<br>BBCH 49                | Curd<br>Curd                    | <0.01<br><0.01      | 0.053<br>0.046                                  | 0.063<br>0.056                                                           | 0.018<br>0.019              | 339           | 400<br>414    |

**Table C.3.3.2.2-2 Rotational crop study (soil samples)**

|                             |                                                                                                                                                                                                                                                                                   |                                  |                                                         |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on the field rotational crop cauliflower, broccoli and soil after application of BYI 02960 SL 200 to bare soil in the field in Belgium, the Netherlands, Italy and Spain, [REDACTED] 2018, Study ID: 16-2516, Activity ID: RARV0047 |                                  |                                                         |
| GLP:                        | Yes                                                                                                                                                                                                                                                                               | Sample storage conditions:       | 372 days at -18°C                                       |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                                                   | Analytical method:               | Method 01074/M001                                       |
| Succeeding crop:            | Cauliflower and broccoli / Flowering brassicas                                                                                                                                                                                                                                    | Limit of Quantification (mg/kg): | Flupyradifurone and DFA (expressed as DFA): 0.005 mg/kg |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                                                  | Residues calculated as:          | Flupyradifurone                                         |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                                                           |                                  |                                                         |

| Trial No<br>Location<br>Year                                  | Portion analysed | Application rate per treatment |              |           | DAT (days) | Residues (mg/kg) |                                   |                                                              |                       |
|---------------------------------------------------------------|------------------|--------------------------------|--------------|-----------|------------|------------------|-----------------------------------|--------------------------------------------------------------|-----------------------|
|                                                               |                  | g a.s./ha                      | Water (L/ha) | g a.s./hL |            | Flupyradifurone  | DFA, expressed as flupyradifurone | Sum of flupyradifurone and DFA, expressed as flupyradifurone | DFA, expressed as DFA |
| 16-2516-01<br>1681 ND<br>Zwaagdijk<br>The Netherlands<br>2017 | Bare soil        | 300                            | 400          | 75        | 22         | 0.10             | <0.15                             | 0.25                                                         | <0.005                |
|                                                               | Bare soil        | 300                            | 400          | 75        | 138        | 0.051            | <0.15                             | 0.201                                                        | <0.005                |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                         | Portion analysed | Application rate per treatment |              |           | DAT (days) | Residues (mg/kg) |                                   |                                                              |                       |
|------------------------------------------------------|------------------|--------------------------------|--------------|-----------|------------|------------------|-----------------------------------|--------------------------------------------------------------|-----------------------|
|                                                      |                  | g a.s./ha                      | Water (L/ha) | g a.s./hL |            | Flupyradifurone  | DFA, expressed as flupyradifurone | Sum of flupyradifurone and DFA, expressed as flupyradifurone | DFA, expressed as DFA |
|                                                      | Bare soil        | 300                            | 400          | 75        | 336        | 0.031            | <0.15                             | 0.181                                                        | <0.005                |
| 16-2516-02<br>6221 Saint-Amand<br>Belgium<br>2016/17 | Bare soil        | 300                            | 300          | 100       | 30         | 0.046            | <0.15                             | 0.196                                                        | <0.005                |
|                                                      | Bare soil        | 300                            | 300          | 100       | 161        | 0.039            | <0.15                             | 0.189                                                        | <0.005                |
|                                                      | Bare soil        | 300                            | 300          | 100       | 321        | 0.024            | <0.15                             | 0.174                                                        | <0.005                |
| 16-2516-03<br>70032 Bitonto<br>Italy<br>2016/17      | Bare soil        | 300                            | 300          | 100       | 28         | 0.079            | <0.15                             | 0.229                                                        | <0.005                |
|                                                      | Bare soil        | 300                            | 300          | 100       | 152        | 0.074            | <0.15                             | 0.224                                                        | <0.005                |
|                                                      | Bare soil        | 300                            | 300          | 100       | 333        | 0.064            | <0.15                             | 0.214                                                        | <0.005                |
| 16-2516-04<br>46230 Alginet<br>Spain<br>2016/17      | Bare soil        | 300                            | 400          | 75        | 24         | 0.069            | <0.15                             | 0.219                                                        | <0.005                |
|                                                      | Bare soil        | 300                            | 400          | 75        | 130        | 0.067            | <0.15                             | 0.217                                                        | <0.005                |
|                                                      | Bare soil        | 300                            | 400          | 75        | 342        | 0.019            | <0.15                             | 0.169                                                        | <0.005                |

### C.3.3.2.3 Cabbage

Reference: Determination of the residues of BYI 02960 in/on soil and the field rotational crop cabbage after spray application of BYI 02960 SL 200 to bare soil in the Netherlands, Belgium, southern France and Italy, [REDACTED] 2022, Study ID: E20RC006, Activity ID: RARV0380

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

OECD Guidelines for the Testing of Chemicals. Residues in Rotational Crops (Limited Field Studies). 504. 2007-01-08

OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)

US EPA OCSPG Guideline No. 860.1900, Field Accumulation in Rotational Crops

US EPA OCSPG Guideline No. 860.1500 on Crop Field Trial

OECD Guidance Document on Residues in Rotational Crops ENV/JM/MONO(2018)9, 22-May-2018

Deviations: No

GLP: Yes

Validity of the study: Acceptable

### Materials and methods

During the 2020 growing season, four trials were conducted in the Netherlands, Belgium, southern France and Italy to determine the residue level of flupyradifurone and DFA in cabbage, grown in soil previously treated with flupyradifurone.

BYI 02960 SL 200, an SL formulation containing 200 g/L flupyradifurone, was applied to bare soil at a rate of 1 x 0.302 – 0.313 kg a.s./ha in 302-384 L/ha water. Cabbage was planted after a period of 26 to 29 days after application. The plant back intervals (PBIs)

used simulated the scenario of a failing crop followed by planting of a subsequent crop shortly afterwards. All trials included an untreated control plot.

After application, BYI 02960 SL 200 was incorporated into the soil. Before planting of the cabbage, the magnitude of flupyradifurone and DFA residues in the soil was determined (the top 0-30 cm).

Weather data were reported for the trials and no exceptional events were noted. Samples of cabbage head planted at 26 to 29 day PBIs were harvested at BBCH 47/48 and 49 (106 – 153 and 102 - 166 days after application). Cabbage samples consisting of at least 12 individual units were collected from treated plots and at least 6 units from untreated plots. Samples of soil from the top 0-30 cm were collected at 26 – 29 days after application. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 364 days for cabbage and 555 days for soil at -18°C. The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage in cabbage. Data on the storage stability of flupyradifurone and DFA are not available, therefore the residues in soil reported in Table C.3.3.2.3-2 are not relied upon.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in cabbage. In soil, residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01074/M001 with an LOQ of 0.005 mg/kg for flupyradifurone and DFA, expressed as DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and DFA (method 01304) in cabbage was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to cabbage (high water). Acceptable procedural recoveries were reported in the trial report for flupyradifurone and DFA (mean recoveries ranging from 81-95% and 87-91%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

A summary of the residue trials is given in Table C.3.3.2.3-1.

**Table C.3.3.2.3-1 Rotational crop study (cabbage)**

|                             |                                                                                                                                                                                                                                                                         |                                  |                                                                     |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on soil and the field rotational crop cabbage after spray application of BYI 02960 SL 200 to bare soil in the Netherlands, Belgium, southern France and Italy, [REDACTED] 2022, Study ID: E20RC006, Activity ID: RARV0380 |                                  |                                                                     |
| GLP:                        | Yes                                                                                                                                                                                                                                                                     | Sample storage conditions:       | 364 days at -18°C                                                   |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                                         | Analytical method:               | Method 01304                                                        |
| Succeeding crop:            | Cabbage / Head brassicas                                                                                                                                                                                                                                                | Limit of Quantification (mg/kg): | Flupyradifurone: 0.01 mg/kg<br>DFA: 0.02 mg/kg (parent equivalents) |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                                        | Residues calculated as:          | Flupyradifurone                                                     |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                                                 |                                  |                                                                     |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                      | Commodity<br>Variety                        | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate per<br>treatment |                 |                  | Dates or<br>number of<br>treatment<br>s and last<br>date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analysed | Residues (mg/kg)    |                                                |                                                                          |                             | PBI<br>(days) | DAT<br>(days) |
|-------------------------------------------------------------------|---------------------------------------------|----------------------------------------------------------------|-----------------------------------|-----------------|------------------|----------------------------------------------------------|-----------------------------------|-----------------------------|---------------------|------------------------------------------------|--------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                                                                   |                                             |                                                                | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                          |                                   |                             | Flupyradi<br>furone | DFA,<br>expressed<br>as<br>flupyradifuro<br>ne | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifruone | DFA,<br>expressed<br>as DFA |               |               |
| E20RC006-01<br>1681 ND<br>Zwaagdijk<br>The<br>Netherlands<br>2020 | Cabbage<br>Klimaro, red<br>variety          | 1. 10-06-2020<br>2. –<br>3. 25-09 to<br>10-10-2020             | 313                               | 313             | 100              | 15-05-2020                                               | BBCH 48<br>BBCH 49                | Head<br>Head                | <0.01<br><0.01      | 0.0556<br>0.0687                               | 0.0656<br>0.0697                                                         | 0.0185<br>0.0229            | 26            | 123<br>137    |
| E20RC006-02<br>6221 Saint-Amand<br>Belgium<br>2020                | Cabbage<br>Perfecta F1,<br>white<br>variety | 1. 27-04-2020<br>2. –<br>3. 27-07 to<br>30-07-2020             | 313                               | 313             | 100              | 31-03-2020                                               | BBCH 47<br>BBCH 49                | Head<br>Head                | <0.01<br><0.01      | 0.130<br>0.124                                 | 0.140<br>0.134                                                           | 0.0433<br>0.0413            | 27            | 108<br>121    |
| E20RC006-03<br>31330 St<br>Caprais<br>Southern<br>France<br>2020  | Cabbage,<br>Cilion, white<br>variety        | 1. 22-07-2020<br>2. –<br>3. 01-12-2020 to 28-02-2021           | 302                               | 302             | 100              | 26-06-2020                                               | BBCH 48<br>BBCH 49                | Head<br>Head                | <0.01<br><0.01      | 0.0951<br>0.0844                               | 0.1051<br>0.0944                                                         | 0.0317<br>0.0281            | 26            | 153<br>166    |
| E20RC006-04<br>40128<br>Bologna<br>Italy<br>2020                  | Cabbage,<br>Velevt,<br>white<br>variety     | 1. 14-04-2020<br>2. –<br>3. 01-07 to<br>15-07-2020             | 302                               | 384             | 78.6             | 16-03-2020                                               | BBCH 48<br>BBCH 49                | Head<br>Head                | <0.01<br><0.01      | 0.140<br>0.0884                                | 0.150<br>0.0984                                                          | 0.0467<br>0.0295            | 29            | 106<br>120    |

**Table C.3.3.2.3-2 Rotational crop study (soil samples)**

|                             |                                                                                                                                                                                                                                                                         |                                  |                                                         |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on soil and the field rotational crop cabbage after spray application of BYI 02960 SL 200 to bare soil in the Netherlands, Belgium, southern France and Italy, ██████████ 2022, Study ID: E20RC006, Activity ID: RARV0380 |                                  |                                                         |
| GLP:                        | Yes                                                                                                                                                                                                                                                                     | Sample storage conditions:       | 555 days at -18°C                                       |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                                         | Analytical method:               | Method 01074/M001                                       |
| Succeeding crop:            | Cabbage / Head brassicas                                                                                                                                                                                                                                                | Limit of Quantification (mg/kg): | Flupyradifurone and DFA (expressed as DFA): 0.005 mg/kg |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                                        | Residues calculated as:          | Flupyradifurone                                         |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                                                 |                                  |                                                         |

| Trial No<br>Location<br>Year                                   | Portion analysed | Application rate per treatment |              |           | DAT (days) | Soil layer (cm) | Residues (mg/kg) |                                   |                                                              |                       |
|----------------------------------------------------------------|------------------|--------------------------------|--------------|-----------|------------|-----------------|------------------|-----------------------------------|--------------------------------------------------------------|-----------------------|
|                                                                |                  | g a.s./ha                      | Water (L/ha) | g a.s./hL |            |                 | Flupyradifurone  | DFA, expressed as flupyradifurone | Sum of flupyradifurone and DFA, expressed as flupyradifurone | DFA, expressed as DFA |
| E20RC006-01<br>1681 ND<br>Zwaagdijk<br>The Netherlands<br>2020 | Bare soil        | 313                            | 313          | 100       | 26         | 0 – 20          | 0.0979           | <0.15                             | 0.2479                                                       | <0.005                |
|                                                                |                  |                                |              |           |            | 20 - 30         | <0.005           | <0.15                             | <0.155                                                       | <0.005                |



The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                               | Portion<br>analysed | Application rate per<br>treatment |                 |              | DAT<br>(days) | Soil layer<br>(cm) | Residues (mg/kg) |                                         |                                                                       |                             |
|------------------------------------------------------------|---------------------|-----------------------------------|-----------------|--------------|---------------|--------------------|------------------|-----------------------------------------|-----------------------------------------------------------------------|-----------------------------|
|                                                            |                     | g<br>a.s./ha                      | Water<br>(L/ha) | g<br>a.s./hL |               |                    | Flupyradifurone  | DFA,<br>expressed as<br>flupyradifurone | Sum of<br>flupyradifurone and<br>DFA, expressed as<br>flupyradifurone | DFA,<br>expressed as<br>DFA |
| E20RC006-02<br>6221 Saint-Amand<br>Belgium<br>2020         | Bare soil           | 313                               | 313             | 100          | 27            | 0 – 20             | 0.0713           | <0.15                                   | 0.2213                                                                | <0.005                      |
|                                                            |                     |                                   |                 |              |               | 20 - 30            | <0.005           | <0.15                                   | <0.155                                                                | <0.005                      |
| E20RC006-03<br>31330 St Caprais<br>Southern France<br>2020 | Bare soil           | 302                               | 302             | 100          | 26            | 0 – 20             | 0.0817           | <0.15                                   | 0.2317                                                                | <0.005                      |
|                                                            |                     |                                   |                 |              |               | 20 - 30            | <0.005           | <0.15                                   | <0.155                                                                | <0.005                      |
| E20RC006-04<br>40128 Bologna<br>Italy<br>2020              | Bare soil           | 302                               | 384             | 78.6         | 29            | 0 – 20             | 0.0398           | <0.15                                   | 0.1898                                                                | <0.005                      |
|                                                            |                     |                                   |                 |              |               | 20 - 30            | <0.005           | <0.15                                   | <0.155                                                                | <0.005                      |

#### **C.3.3.2.4 Oilseed rape**

##### **C.3.3.2.4.1 Study 1**

Reference: Determination of the residues of BYI 02960 in/on the field rotational crop rape and soil after spray application of BYI 02960 SL 200 to bare soil in the Field in Belgium and the Netherlands, [REDACTED] 2018, Study ID: 16-2511, Activity ID: RARV0049

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

OECD Guidelines for the Testing of Chemicals. Residues in Rotational Crops (Limited Field Studies). 504. 2007-01-08

OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)

US EPA OCSPG Guideline No. 860.1900, Field Accumulation in Rotational Crops

US EPA OCSPG Guideline No. 860.1500 on Crop Field Trial

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### **Materials and methods**

During the 2016, 2017 and 2018 growing seasons, two trials were conducted in Belgium and the Netherlands to determine the residue level of flupyradifurone and DFA in oilseed rape, grown in soil previously treated with flupyradifurone.

BYI 02960 SL 200, an SL formulation containing 200 g/L flupyradifurone, was applied to bare soil at a rate of  $1 \times 0.175 - 0.214$  kg a.s./ha in 300-400 L/ha water. Oilseed rape was planted after a period of 137 to 147 and 330 to 335 days after application. The plant back intervals (PBIs) used simulated the scenario of replanting both in the first and second season after the original crop is harvested, reflecting agronomical practice for non-perennial crops. A plant back interval of 30 days was not tested as it was considered a

unlikely interval for a crop with such a long vegetation period. All trials included an untreated control plot.

After application, BYI 02960 SL 200 was incorporated into the soil. Before planting of the oilseed rape, the magnitude of flupyradifurone and DFA residues in the soil was determined (the top 0-20 cm).

Weather data were reported for the trials and no exceptional events were noted. Samples of oilseed rape green material planted at 137 to 147 day and 330 to 335 day PBIs were harvested at BBCH 59 (187 – 354 days after application and 385 to 549 days after application, respectively). Samples of oilseed rape seed planted at 137 to 147 day and 330 to 335 day PBIs were harvested at BBCH 89 (263 to 459 days after application and 461 to 629 days after application, respectively). Oilseed rape seed samples weighing 0.565 to 1.21 kg were collected from treated and untreated plots. Samples of oilseed rape green material weighing 1.22 to 3.49 kg were collected from treated and untreated plots. As sufficient samples were available for analysis this is considered acceptable. Samples of soil from the top 0-20 cm were collected at 137 to 147 and 330 to 335 days after application. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 218 days for oilseed rape samples and 274 days for soil at -18°C. The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage in oilseed rape. Data on the storage stability of flupyradifurone and DFA are not available, therefore the residues in soil reported in Table C.3.3.2.4.1-2 are not relied upon.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in oilseed rape. In soil, residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01074/M001 with an LOQ of 0.005 mg/kg for flupyradifurone and DFA, expressed as DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and DFA (method 01304) in oilseed rape was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to oilseed rape seed (high oil) and green material (high water). Acceptable procedural recoveries were reported in the trial report for flupyradifurone and DFA (mean recoveries ranging from 99-101% and 83-97%, respectively for oilseed rape seed and 96-105% and 99-103%, respectively for oilseed rape green material).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

A summary of the residue trials is given in Table C.3.3.2.4.1-1.

**Table C.3.3.2.4.1-1 Rotational crop study (oilseed rape)**

|                             |                                                                                                                                                                                                                                                          |                                  |                                                                     |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on the field rotational crop rape and soil after spray application of BYI 02960 SL 200 to bare soil in the Field in Belgium and the Netherlands, ██████████ 2018, Study ID: 16-2511, Activity ID: RARV0049 |                                  |                                                                     |
| GLP:                        | Yes                                                                                                                                                                                                                                                      | Sample storage conditions:       | 218 days at -18°C                                                   |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                          | Analytical method:               | Method 01304                                                        |
| Succeeding crop:            | Oilseed rape / Oilseeds                                                                                                                                                                                                                                  | Limit of Quantification (mg/kg): | Flupyradifurone: 0.01 mg/kg<br>DFA: 0.02 mg/kg (parent equivalents) |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                         | Residues calculated as:          | Flupyradifurone                                                     |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                                  |                                  |                                                                     |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                     | Commodity<br>Variety           | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest               | Application rate per<br>treatment |                 |                  | Dates or<br>number of<br>treatment<br>s and last<br>date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analysed | Residues (mg/kg)        |                                                |                                                                         |                             | PBI<br>(days) | DAT<br>(days)  |
|------------------------------------------------------------------|--------------------------------|------------------------------------------------------------------------------|-----------------------------------|-----------------|------------------|----------------------------------------------------------|-----------------------------------|-----------------------------|-------------------------|------------------------------------------------|-------------------------------------------------------------------------|-----------------------------|---------------|----------------|
|                                                                  |                                |                                                                              | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                          |                                   |                             | Flupyra<br>difuron<br>e | DFA,<br>expressed<br>as<br>flupyradifuro<br>ne | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifuone | DFA,<br>expressed<br>as DFA |               |                |
| 16-2511-01<br>1681 ND<br>Zwaagdijk<br>The<br>Netherlands<br>2017 | Oilseed<br>rape<br>Campino     | 1. 11-04-<br>2017<br>2. 01-06 to<br>01-07-2017<br>3. 12-08 to<br>22-08-2017  | 175                               | 400             | 43.8             | 25-11-<br>2016                                           | BBCH 59<br><br>BBCH 89            | Green<br>material<br>Seed   | <0.01<br><br><0.01      | 0.045<br><br>0.027                             | 0.055<br><br>0.037                                                      | 0.015<br><br>0.009          | 137           | 187<br><br>263 |
|                                                                  | Oilseed<br>rape<br>Campino     | 1. 11-04-<br>2017<br>2. 01-06 to<br>01-07-2017<br>3. 12-08 to<br>22-08-2017  | 175                               | 300             | 58.3             | 11-05-<br>2016                                           | BBCH 59<br><br>BBCH 89            | Green<br>material<br>Seed   | <0.01<br><br><0.01      | 0.023<br><br>0.020                             | 0.033<br><br>0.030                                                      | 0.008<br><br>0.007          | 335           | 385<br><br>461 |
| 16-2511-02<br>6221 Saint-<br>Amand<br>Belgium<br>2016            | Oilseed<br>rape<br>DK Explicit | 1. 08-09-<br>2016<br>2. 07-04 to<br>15-05-2017<br>3. 17-07- to<br>25-07-2017 | 175                               | 300             | 58.3             | 14-04-<br>2016                                           | BBCH 59<br><br>BBCH 89            | Green<br>material<br>Seed   | <0.01<br><br><0.01      | 0.029<br><br>0.043                             | 0.039<br><br>0.053                                                      | 0.010<br><br>0.014          | 147           | 354<br><br>459 |
|                                                                  | Oilseed<br>rape<br>Diffusion   | 1. 06-09-<br>2017<br>2. 17-04 to<br>07-05-2018<br>3. 02-07 to<br>07-07-2018  | 214                               | 367             | 58.3             | 11-10-<br>2016                                           | BBCH 59<br><br>BBCH 89            | Green<br>material<br>Seed   | <0.01<br><br><0.01      | 0.020<br><br>0.023                             | 0.030<br><br>0.033                                                      | 0.007<br><br>0.008          | 330           | 549<br><br>629 |

**Table C.3.3.2.4.1-2 Rotational crop study (soil samples)**

|                             |                                                                                                                                                                                                                                                          |                                  |                                                         |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on the field rotational crop rape and soil after spray application of BYI 02960 SL 200 to bare soil in the Field in Belgium and the Netherlands, ██████████ 2018, Study ID: 16-2511, Activity ID: RARV0049 |                                  |                                                         |
| GLP:                        | Yes                                                                                                                                                                                                                                                      | Sample storage conditions:       | 274 days at -18°C                                       |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                          | Analytical method:               | Method 01074/M001                                       |
| Succeeding crop:            | Oilseed rape / Oilseeds                                                                                                                                                                                                                                  | Limit of Quantification (mg/kg): | Flupyradifurone and DFA (expressed as DFA): 0.005 mg/kg |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                         | Residues calculated as:          | Flupyradifurone                                         |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                                  |                                  |                                                         |

| Trial No<br>Location<br>Year                                  | Portion analysed | Application rate per treatment |              |           | DAT (days) | Soil layer (cm) | Residues (mg/kg) |                                   |                                                              |                       |
|---------------------------------------------------------------|------------------|--------------------------------|--------------|-----------|------------|-----------------|------------------|-----------------------------------|--------------------------------------------------------------|-----------------------|
|                                                               |                  | g a.s./ha                      | Water (L/ha) | g a.s./hL |            |                 | Flupyradifurone  | DFA, expressed as flupyradifurone | Sum of flupyradifurone and DFA, expressed as flupyradifurone | DFA, expressed as DFA |
| 16-2511-01<br>1681 ND<br>Zwaagdijk<br>The Netherlands<br>2017 | Bare soil        | 175                            | 400          | 43.8      | 137        | 0 – 20          | 0.046            | <0.15                             | 0.196                                                        | <0.005                |
|                                                               |                  | 175                            | 300          | 58.3      | 335        | 0 – 20          | 0.019            | <0.15                             | 0.169                                                        | <0.005                |

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| Trial No<br>Location<br>Year                          | Portion<br>analysed | Application rate per<br>treatment |                 |              | DAT<br>(days) | Soil layer<br>(cm) | Residues (mg/kg) |                                         |                                                                       |                             |
|-------------------------------------------------------|---------------------|-----------------------------------|-----------------|--------------|---------------|--------------------|------------------|-----------------------------------------|-----------------------------------------------------------------------|-----------------------------|
|                                                       |                     | g<br>a.s./ha                      | Water<br>(L/ha) | g<br>a.s./hL |               |                    | Flupyradifurone  | DFA,<br>expressed as<br>flupyradifurone | Sum of<br>flupyradifurone and<br>DFA, expressed as<br>flupyradifurone | DFA,<br>expressed as<br>DFA |
| 16-2511-02<br>6221 Saint-<br>Amand<br>Belgium<br>2016 | Bare soil           | 175                               | 300             | 58.3         | 147           | 0 – 20             | 0.016            | <0.15                                   | 0.166                                                                 | <0.005                      |
|                                                       |                     | 214                               | 367             | 58.3         | 330           | 0 – 20             | 0.015            | <0.15                                   | 0.165                                                                 | <0.005                      |



#### C.3.3.2.4.2 Study 2

Reference: Determination of the residues of BYI 02960 in/on the field rotational crop Rape and Soil after spray application of BYI 02960 SL 200 to bare soil in the field in Italy and Portugal, [REDACTED] 2018, Study ID: 16-2521, Activity ID: RARV0029

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

OECD Guidelines for the Testing of Chemicals. Residues in Rotational Crops (Limited Field Studies). 504. 2007-01-08

OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)

US EPA OCSP Guideline No. 860.1900, Field Accumulation in Rotational Crops

US EPA OCSP Guideline No. 860.1500 on Crop Field Trial

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### Materials and methods

During the 2016 and 2017 growing seasons, two trials were conducted in Italy and Portugal to determine the residue level of flupyradifurone and DFA in oilseed rape, grown in soil previously treated with flupyradifurone.

BYI 02960 SL 200, an SL formulation containing 200 g/L flupyradifurone, was applied to bare soil at a rate of 1 x 0.175 kg a.s./ha in 300 L/ha water. Oilseed rape was planted after a period of 158 to 167 and 273 days after application. The plant back intervals (PBIs) used simulated the scenario of replanting both in the first and second season after the original crop is harvested, reflecting agronomical practice for non-perennial crops. A plant back interval of 30 days was not tested as it was considered a unlikely interval for a crop with such a long vegetation period. All trials included an untreated control plot.

After application, BYI 02960 SL 200 was incorporated into the soil. Before planting of the oilseed rape, the magnitude of flupyradifurone and DFA residues in the soil was determined (the top 0-20 cm). In trial 16-2521-02 (Portugal), 30-40% of the soil samples were only 0-15 cm due to soil hardness.

Weather data were reported for the trials and no exceptional events were noted. Samples of oilseed rape green material planted at 158 to 167 day and 273 day PBIs were harvested in both trials at BBCH 59 (207 to 337 days after application and 322 to 443 days after application, respectively). Samples of oilseed rape seed planted at 158 day and 273 day PBIs were harvested in trial 16-2521-01 (Italy) at BBCH 89 (267 days after application and 382 days after application, respectively). Oilseed rape seed samples weighing 0.641 to 0.880 kg were collected from treated and untreated plots. Samples of oilseed rape green material weighing 1.30 to 2.09 kg were collected from treated and untreated plots. As sufficient samples were available for analysis this is considered acceptable. Samples of soil from the top 0-20 cm (0-15 cm for trial 16-2521-02) were collected at 158 to 166 and 272 to 273 days after application. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 390 days for oilseed rape samples and 443 days for soil at -18°C. The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage in oilseed rape. Data on the storage stability of flupyradifurone and DFA are not available, therefore the residues in soil reported in Table C.3.3.2.4.2-2 are not relied upon.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in oilseed rape. In soil, residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01074/M001 with an LOQ of 0.005 mg/kg for flupyradifurone and DFA, expressed as DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and DFA (method 01304) in oilseed rape was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to oilseed rape seed (high oil) and green material (high water). Acceptable procedural recoveries were reported in the trial report for flupyradifurone and DFA (mean recoveries ranging from 99-101% and 83-97%, respectively for oilseed rape seed and 96-103% and 99-104%, respectively for oilseed rape green material).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

A summary of the residue trials is given in Table C.3.3.2.4.2-1.

**Table C.3.3.2.4.2-1 Rotational crop study (oilseed rape)**

|                             |                                                                                                                                                                                                                                                               |                                  |                                                                     |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on the field rotational crop Rape and Soil after spray application of BYI 02960 SL 200 to bare soil in the field in Italy and Portugal, ██████████<br>██████████ 2018, Study ID: 16-2521, Activity ID: RARV0029 |                                  |                                                                     |
| GLP:                        | Yes                                                                                                                                                                                                                                                           | Sample storage conditions:       | 390 days at -18°C                                                   |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                               | Analytical method:               | Method 01304                                                        |
| Succeeding crop:            | Oilseed rape / Oilseeds                                                                                                                                                                                                                                       | Limit of Quantification (mg/kg): | Flupyradifurone: 0.01 mg/kg<br>DFA: 0.02 mg/kg (parent equivalents) |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                              | Residues calculated as:          | Flupyradifurone                                                     |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                                       |                                  |                                                                     |

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest | Application rate per<br>treatment |                 |              | Dates or<br>number of<br>treatments<br>and last<br>date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analysed | Residues (mg/kg) |                                         |                                                                          |                             | PBI<br>(days) | DAT<br>(days) |
|------------------------------|----------------------|----------------------------------------------------------------|-----------------------------------|-----------------|--------------|---------------------------------------------------------|-----------------------------------|-----------------------------|------------------|-----------------------------------------|--------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                              |                      |                                                                | g<br>a.s./ha                      | Water<br>(L/ha) | g<br>a.s./hL |                                                         |                                   |                             | Flupyradifurone  | DFA,<br>expressed as<br>flupyradifurone | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |               |               |
|                              |                      |                                                                |                                   |                 |              |                                                         |                                   |                             |                  |                                         |                                                                          |                             |               |               |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

|                                                              |                                             |                                                                   |     |     |      |            |                        |                        |                    |                   |                   |                    |             |                |
|--------------------------------------------------------------|---------------------------------------------|-------------------------------------------------------------------|-----|-----|------|------------|------------------------|------------------------|--------------------|-------------------|-------------------|--------------------|-------------|----------------|
| 16-2521-01<br>12050<br>Castagnito<br>d'Alba<br>Italy<br>2017 | Oilseed rape<br>Delight<br>spring<br>hybrid | 1. 27-03-2017<br>2. 17-05 to 05-06-2017<br>3. July 2017           | 175 | 300 | 58.3 | 20-10-2016 | BBCH 59<br><br>BBCH 89 | Green material<br>Seed | <0.01<br><br><0.01 | 0.17<br><br>0.067 | 0.18<br><br>0.077 | 0.057<br><br>0.022 | 158<br><br> | 207<br><br>267 |
|                                                              | Oilseed rape<br>Delight<br>spring<br>hybrid | 1. 27-03-2017<br>2. 17-05 to 05-06-2017<br>3. July 2017           | 175 | 300 | 58.3 | 27-06-2016 | BBCH 59<br><br>BBCH 89 | Green material<br>Seed | <0.01<br><br><0.01 | 0.13<br><br>0.040 | 0.14<br><br>0.050 | 0.043<br><br>0.013 | 273<br><br> | 322<br><br>382 |
| 16-2521-02<br>2070-316<br>Ereira<br>Portugal<br>2017         | Oilseed rape<br>DK<br>Expower               | 1. 21-03-2017<br>2. 25-06 to 15-07-2018<br>3. 20-08 to 30-08-2018 | 175 | 300 | 58.3 | 05-10-2016 | BBCH 59                | Green material         | <0.01              | 0.25              | 0.26              | 0.083              | 167         | 337            |
|                                                              | Oilseed rape<br>DK<br>Expower               | 1. 21-03-2017<br>2. 25-06 to 15-07-2018<br>3. 20-08 to 30-08-2018 | 175 | 300 | 58.3 | 21-06-2016 | BBCH 59                | Green material         | <0.01              | 0.14              | 0.15              | 0.047              | 273         | 443            |

**Table C.3.3.2.4.2-2 Rotational crop study (soil samples)**

|                             |                                                                                                                                                                                                                                                               |                                  |                                                         |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on the field rotational crop Rape and Soil after spray application of BYI 02960 SL 200 to bare soil in the field in Italy and Portugal, ██████████<br>██████████ 2018, Study ID: 16-2521, Activity ID: RARV0029 |                                  |                                                         |
| GLP:                        | Yes                                                                                                                                                                                                                                                           | Sample storage conditions:       | 443 days at -18°C                                       |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                               | Analytical method:               | Method 01074/M001                                       |
| Succeeding crop:            | Oilseed rape / Oilseeds                                                                                                                                                                                                                                       | Limit of Quantification (mg/kg): | Flupyradifurone and DFA (expressed as DFA): 0.005 mg/kg |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                              | Residues calculated as:          | Flupyradifurone                                         |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                                       |                                  |                                                         |

| Trial No<br>Location<br>Year                              | Portion analysed | Application rate per treatment |              |           | DAT (days) | Soil layer (cm) | Residues (mg/kg) |                                   |                                                              |                       |
|-----------------------------------------------------------|------------------|--------------------------------|--------------|-----------|------------|-----------------|------------------|-----------------------------------|--------------------------------------------------------------|-----------------------|
|                                                           |                  | g a.s./ha                      | Water (L/ha) | g a.s./hL |            |                 | Flupyradifurone  | DFA, expressed as flupyradifurone | Sum of flupyradifurone and DFA, expressed as flupyradifurone | DFA, expressed as DFA |
| 16-2521-01<br>12050<br>Castagnito d'Alba<br>Italy<br>2017 | Soil             | 175                            | 300          | 58.3      | 158        | 0-20            | 0.032            | <0.15                             | 0.182                                                        | <0.005                |
|                                                           |                  | 175                            | 300          | 58.3      | 273        | 0-20            | 0.023            | <0.15                             | 0.173                                                        | <0.005                |

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| Trial No<br>Location<br>Year                         | Portion<br>analysed | Application rate per<br>treatment |                 |              | DAT<br>(days) | Soil layer<br>(cm) | Residues (mg/kg) |                                         |                                                                       |                             |
|------------------------------------------------------|---------------------|-----------------------------------|-----------------|--------------|---------------|--------------------|------------------|-----------------------------------------|-----------------------------------------------------------------------|-----------------------------|
|                                                      |                     | g<br>a.s./ha                      | Water<br>(L/ha) | g<br>a.s./hL |               |                    | Flupyradifurone  | DFA,<br>expressed as<br>flupyradifurone | Sum of<br>flupyradifurone and<br>DFA, expressed as<br>flupyradifurone | DFA,<br>expressed as<br>DFA |
| 16-2521-02<br>2070-316<br>Ereira<br>Portugal<br>2017 | Soil                | 175                               | 300             | 58.3         | 166           | 0-15               | 0.040            | <0.15                                   | 0.190                                                                 | <0.005                      |
|                                                      |                     | 175                               | 300             | 58.3         | 272           | 0-15               | 0.034            | <0.15                                   | 0.184                                                                 | <0.005                      |

#### C.3.3.2.4.3 Study 3

Reference: Determination of the residues of BYI 02960 in/on soil and the field rotational crop rape after spray application of BYI 02960 SL 200 to bare soil in the Netherlands, Belgium, southern France and Italy, [REDACTED] 2022, Study ID: E20RC003

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

OECD Guidelines for the Testing of Chemicals. Residues in Rotational Crops (Limited Field Studies). 504. 2007-01-08

OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)

US EPA OCSPG Guideline No. 860.1900, Field Accumulation in Rotational Crops

US EPA OCSPG Guideline No. 860.1500 on Crop Field Trial

OECD Guidance Document on Residues in Rotational Crops ENV/JM/MONO(2018)9, 22-May-2018

Deviations: No

GLP: Yes

Validity of the study: Acceptable

#### Materials and methods

During the 2020 growing season, five trials were conducted in the Netherlands (1), Belgium (1), southern France (2) and Italy (1) to determine the residue level of flupyradifurone and DFA in oilseed rape, grown in soil previously treated with flupyradifurone.

BYI 02960 SL 200, an SL formulation containing 200 g/L flupyradifurone, was applied to bare soil at a rate of  $1 \times 0.167 - 0.181$  kg a.s./ha in 300-393 L/ha water. Oilseed rape was planted after a period of 137 to 179 days after application. The plant back interval (PBI) used simulated the scenario of replanting in the same season after the original crop is

harvested, reflecting agronomical practice for non-perennial crops. A plant back interval of 30 days was not tested as it was considered a unlikely interval for a crop with such a long vegetation period. All trials included an untreated control plot.

After application, BYI 02960 SL 200 was incorporated into the soil. Before planting of the oilseed rape, the magnitude of flupyradifurone and DFA residues in the soil was determined (the top 0-20 cm and 20-30 cm).

Weather data were reported for the trials and no exceptional events were noted. Samples of oilseed rape green material were harvested at BBCH 59 (321 to 392 days after application). Samples of oilseed rape seed and straw were harvested at BBCH 89 (404 to 461 days after application). Oilseed rape seed samples weighing 0.5 to 1.59 kg were collected from treated and untreated plots. Samples of oilseed rape green material weighing 1.41 to 8.89 kg were collected from treated and untreated plots. Samples of oilseed rape straw weighing 0.5 to 2.25 kg were collected from treated and untreated plots. As sufficient samples were available for analysis this is considered acceptable. Samples of soil from the top 0-30 cm were collected at 137 to 179 days after application. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 301 days for oilseed rape samples and 475 days for soil at -18°C. The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage in oilseed rape. Data on the storage stability of flupyradifurone and DFA are not available, therefore the residues in soil reported in Table C.3.3.2.4.3-2 are not relied upon.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in oilseed rape. In soil, residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01074/M001 with an LOQ of 0.005 mg/kg for flupyradifurone and DFA, expressed as DFA.

## Results and discussions

The analytical method for analysing residues of flupyradifurone and DFA (method 01304) in oilseed rape was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to oilseed rape seed (high oil), green material (high water) and straw (no group). Acceptable procedural recoveries were reported in the trial report for flupyradifurone and DFA (mean recoveries ranging from 99-105% and 76-80%, respectively for oilseed rape seed. 102% and 73-98%, respectively for oilseed rape green material and 77-104% and 71-76%, respectively for oilseed rape straw).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.



A summary of the residue trials is given in Table C.3.3.2.4.3-1.

**Table C.3.3.2.4.3-1 Rotational crop study (oilseed rape)**

|                             |                                                                                                                                                                                                                                               |                                  |                                                                     |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on soil and the field rotational crop rape after spray application of BYI 02960 SL 200 to bare soil in the Netherlands, Belgium, southern France and Italy, [REDACTED] 2022, Study ID: E20RC003 |                                  |                                                                     |
| GLP:                        | Yes                                                                                                                                                                                                                                           | Sample storage conditions:       | 301 days at -18°C                                                   |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                               | Analytical method:               | Method 01304                                                        |
| Succeeding crop:            | Oilseed rape / Oilseeds                                                                                                                                                                                                                       | Limit of Quantification (mg/kg): | Flupyradifurone: 0.01 mg/kg<br>DFA: 0.02 mg/kg (parent equivalents) |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                              | Residues calculated as:          | Flupyradifurone                                                     |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                       |                                  |                                                                     |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                      | Commodity<br>Variety          | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest    | Application rate per<br>treatment |                 |                  | Dates or<br>number of<br>treatment<br>s and last<br>date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analysed     | Residues (mg/kg)            |                                         |                                                                          |                                | PBI<br>(days) | DAT<br>(days)         |
|-------------------------------------------------------------------|-------------------------------|-------------------------------------------------------------------|-----------------------------------|-----------------|------------------|----------------------------------------------------------|-----------------------------------|---------------------------------|-----------------------------|-----------------------------------------|--------------------------------------------------------------------------|--------------------------------|---------------|-----------------------|
|                                                                   |                               |                                                                   | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                          |                                   |                                 | Flupyradi<br>furone         | DFA,<br>expressed as<br>flupyradifurone | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA    |               |                       |
| E20RC003-01<br>1681 ND<br>Zwaagdijk<br>The<br>Netherlands<br>2021 | Oilseed<br>rape<br>Hatrick    | 1. 19-10-2020<br>2. 21-05 to 21-06-2021<br>3. 24-04 to 07-08-2021 | 167                               | 333             | 50.2             | 23-04-2020                                               | BBCH 59<br><br>BBCH 89<br>BBCH 89 | Green material<br>Seed<br>Straw | <0.01<br><br><0.01<br><0.01 | <0.02<br><br><0.02<br>0.0317            | <0.03<br><br><0.03<br>0.0417                                             | <0.007<br><br><0.007<br>0.0106 | 179           | 392<br><br>459<br>459 |
| E20RC003-02<br>6221 Saint-Amand<br>Belgium<br>2021                | Oilseed<br>rape<br>DK Extime  | 1. 02-09-2020<br>2. 25-04 to 25-05-2021<br>3. 16-07 to 22-07-2021 | 175                               | 300             | 58.3             | 17-04-2020                                               | BBCH 59<br><br>BBCH 89<br>BBCH 89 | Green material<br>Seed<br>Straw | <0.01<br><br><0.01<br><0.01 | <0.02<br><br>0.02<br><0.02              | <0.03<br><br>0.03<br><0.03                                               | <0.007<br><br>0.007<br><0.007  | 138           | 360<br><br>461<br>461 |
| E20RC003-03<br>31330 St<br>Caprais<br>Southern<br>France<br>2021  | Oilseed<br>rape<br>Sirtaki CS | 1. 31-08-2020<br>2. 15-03 to 10-05-2021<br>3. 01-07 to 10-07-2021 | 181                               | 311             | 58.2             | 16-04-2020                                               | BBCH 59<br><br>BBCH 89<br>BBCH 89 | Green material<br>Seed<br>Straw | <0.01<br><br><0.01<br><0.01 | <0.02<br><br><0.02<br><0.02             | <0.03<br><br><0.03<br><0.03                                              | <0.007<br><br><0.007<br><0.007 | 137           | 330<br><br>441<br>441 |
| E20RC003-04<br>40128<br>Bologna<br>Italy<br>2021                  | Oilseed<br>rape<br>Diffusion  | 1. 29-09-2020<br>2. 20-03 to 10-04-2021<br>3. 15-06 to 30-06-2021 | 180                               | 393             | 45.8             | 13-05-2020                                               | BBCH 59<br><br>BBCH 89<br>BBCH 89 | Green material<br>Seed<br>Straw | <0.01<br><br><0.01<br><0.01 | <0.02<br><br>0.0451<br><0.02            | <0.03<br><br>0.0551<br><0.03                                             | <0.007<br><br>0.0150<br><0.007 | 139           | 321<br><br>404<br>404 |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                                    | Commodity<br>Variety          | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest              | Application rate per<br>treatment |                 |                  | Dates or<br>number of<br>treatment<br>s and last<br>date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analysed        | Residues (mg/kg)    |                                         |                                                                          |                             | PBI<br>(days) | DAT<br>(days) |
|---------------------------------------------------------------------------------|-------------------------------|-----------------------------------------------------------------------------|-----------------------------------|-----------------|------------------|----------------------------------------------------------|-----------------------------------|------------------------------------|---------------------|-----------------------------------------|--------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                                                                                 |                               |                                                                             | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                          |                                   |                                    | Flupyradi<br>furone | DFA,<br>expressed as<br>flupyradifurone | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifruone | DFA,<br>expressed<br>as DFA |               |               |
| E20RC003-<br>05<br>13103 St<br>Etienne du<br>gres<br>Southern<br>France<br>2021 | Oilseed<br>rape<br>Sirtaki CS | 1. 26-08-<br>2020<br>2. 11-03 to<br>26-03-2021<br>3. 15-06 to<br>30-06-2021 | 178                               | 387             | 46.0             | 23-03-<br>2020                                           | BBCH 59<br><br>BBCH 89<br>BBCH 89 | Green<br>material<br>Seed<br>Straw | <0.01               | 0.0502                                  | 0.0602                                                                   | 0.0167                      | 156           | 351           |
|                                                                                 |                               |                                                                             |                                   |                 |                  |                                                          |                                   |                                    | <0.01               | 0.0582                                  | 0.0682                                                                   | 0.0194                      |               |               |
|                                                                                 |                               |                                                                             |                                   |                 |                  |                                                          |                                   |                                    | <0.01               | <0.02                                   | <0.03                                                                    | <0.007                      |               |               |

**Table C.3.3.2.4.3-2 Rotational crop study (soil samples)**

|                             |                                                                                                                                                                                                                                               |                                  |                                                         |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on soil and the field rotational crop rape after spray application of BYI 02960 SL 200 to bare soil in the Netherlands, Belgium, southern France and Italy, ██████████ 2022, Study ID: E20RC003 |                                  |                                                         |
| GLP:                        | Yes                                                                                                                                                                                                                                           | Sample storage conditions:       | 475 days at -18°C                                       |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                               | Analytical method:               | Method 01074/M001                                       |
| Succeeding crop:            | Oilseed rape / Oilseeds                                                                                                                                                                                                                       | Limit of Quantification (mg/kg): | Flupyradifurone and DFA (expressed as DFA): 0.005 mg/kg |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                              | Residues calculated as:          | Flupyradifurone                                         |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                       |                                  |                                                         |

| Trial No<br>Location<br>Year                                   | Portion analysed | Application rate per treatment |              |           | DAT (days) | Soil layer (cm) | Residues (mg/kg) |                                   |                                                              |                       |
|----------------------------------------------------------------|------------------|--------------------------------|--------------|-----------|------------|-----------------|------------------|-----------------------------------|--------------------------------------------------------------|-----------------------|
|                                                                |                  | g a.s./ha                      | Water (L/ha) | g a.s./hL |            |                 | Flupyradifurone  | DFA, expressed as flupyradifurone | Sum of flupyradifurone and DFA, expressed as flupyradifurone | DFA, expressed as DFA |
| E20RC003-01<br>1681 ND<br>Zwaagdijk<br>The Netherlands<br>2021 | Soil             | 167                            | 333          | 50.2      | 179        | 0-20            | 0.0125           | <0.015                            | 0.0275                                                       | <0.005                |
|                                                                |                  |                                |              |           |            | 20-30           | <0.005           | <0.015                            | <0.020                                                       | <0.005                |

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| Trial No<br>Location<br>Year                               | Portion<br>analysed | Application rate per<br>treatment |                 |              | DAT<br>(days) | Soil layer<br>(cm) | Residues (mg/kg) |                                         |                                                                       |                             |
|------------------------------------------------------------|---------------------|-----------------------------------|-----------------|--------------|---------------|--------------------|------------------|-----------------------------------------|-----------------------------------------------------------------------|-----------------------------|
|                                                            |                     | g<br>a.s./ha                      | Water<br>(L/ha) | g<br>a.s./hL |               |                    | Flupyradifurone  | DFA,<br>expressed as<br>flupyradifurone | Sum of<br>flupyradifurone and<br>DFA, expressed as<br>flupyradifurone | DFA,<br>expressed as<br>DFA |
| E20RC003-02<br>6221 Saint-Amand<br>Belgium<br>2021         | Soil                | 175                               | 300             | 58.3         | 138           | 0-20               | 0.0212           | <0.015                                  | 0.0362                                                                | <0.005                      |
|                                                            |                     |                                   |                 |              |               | 20-30              | <0.005           | <0.015                                  | <0.020                                                                | <0.005                      |
| E20RC003-03<br>31330 St Caprais<br>Southern France<br>2021 | Soil                | 181                               | 311             | 58.2         | 137           | 0-20               | 0.0170           | <0.015                                  | 0.0320                                                                | <0.005                      |
|                                                            |                     |                                   |                 |              |               | 20-30              | <0.005           | <0.015                                  | <0.020                                                                | <0.005                      |
| E20RC003-04<br>40128 Bologna<br>Italy<br>2021              | Soil                | 180                               | 393             | 45.8         | 139           | 0-20               | 0.0314           | <0.015                                  | 0.0464                                                                | <0.005                      |
|                                                            |                     |                                   |                 |              |               | 20-30              | <0.005           | <0.015                                  | <0.020                                                                | <0.005                      |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                       | Portion<br>analysed | Application rate per<br>treatment |                 |              | DAT<br>(days) | Soil layer<br>(cm) | Residues (mg/kg)      |                                         |                                                                       |                             |
|--------------------------------------------------------------------|---------------------|-----------------------------------|-----------------|--------------|---------------|--------------------|-----------------------|-----------------------------------------|-----------------------------------------------------------------------|-----------------------------|
|                                                                    |                     | g<br>a.s./ha                      | Water<br>(L/ha) | g<br>a.s./hL |               |                    | Flupyradifurone       | DFA,<br>expressed as<br>flupyradifurone | Sum of<br>flupyradifurone and<br>DFA, expressed as<br>flupyradifurone | DFA,<br>expressed as<br>DFA |
| E20RC003-05<br>13103 St Etienne du gres<br>Southern France<br>2021 | Soil                | 178                               | 387             | 46.0         | 156           | 0-20               | 0.0165                | <0.015                                  | 0.0315                                                                | <0.005                      |
|                                                                    |                     |                                   |                 |              |               | 20-30              | 0.0174 <sup>(a)</sup> | <0.015                                  | 0.0324                                                                | <0.005                      |

<sup>(a)</sup> Mean value of 4 repeat analyses.

### **C.3.3.2.5 Strawberry**

#### **C.3.3.2.5.1 Study 1**

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on the field rotational crop strawberry and soil after spray application of BYI 02960 SL 200 to bare soil in the field in Belgium and the Netherlands, [REDACTED] 2018, Study ID: 16-2515, Activity ID: RARV0046                                                                                                                                                                                                                                                                                         |
| Guideline(s):          | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market<br><br>OECD Guidelines for the Testing of Chemicals. Residues in Rotational Crops (Limited Field Studies). 504. 2007-01-08<br><br>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)<br><br>US EPA OCSP Guideline No. 860.1900, Field Accumulation in Rotational Crops<br><br>US EPA OCSP Guideline No. 860.1500 on Crop Field Trial |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

### **Materials and methods**

During the 2016 and 2017 growing seasons, two trials were conducted in Belgium and the Netherlands to determine the residue level of flupyradifurone and DFA in strawberries, grown in soil previously treated with flupyradifurone.

BYI 02960 SL 200, an SL formulation containing 200 g/L flupyradifurone, was applied to bare soil at a rate of  $1 \times 0.3 - 0.317$  kg a.s./ha in 300-400 L/ha water. Strawberries were planted after a period of 22 days, 139 to 141 days and 301 to 337 days after application. The 22 day plant back interval (PBI) simulated the scenario of replanting after failure of the original crop. The later PBIs simulated replanting both in the first and second season after the original crop is harvested, reflecting agronomical practice for non-perennial crops. All trials included an untreated control plot.



After application, BYI 02960 SL 200 was incorporated into the soil. Before planting of the strawberries, the magnitude of flupyradifurone and DFA residues in the soil was determined (the top 0-20 cm).

Weather data were reported for the trials and no exceptional events were noted. Samples of strawberry fruits planted at 22 day, 139 to 141 day and 301 to 337 day PBIs were harvested at BBCH 85 (70/72, 196/206 and 356/404 days after application, respectively) and BBCH 87 (77/78, 203/210 and 363/408 days after application, respectively). Strawberry fruit samples weighing 1.02 to 1.63 kg were collected from treated and untreated plots. Samples of soil from the top 0-20 cm were collected at 22, 139 to 141 and 301 to 337 days after application. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 433 days for strawberry samples and 379 days for soil at -18°C. The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage in strawberry. Data on the storage stability of flupyradifurone and DFA are not available, therefore the residues in soil reported in Table C.3.3.2.5.1-2 are not relied upon.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in strawberry. In soil, residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01074/M001 with an LOQ of 0.005 mg/kg for flupyradifurone and DFA, expressed as DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and DFA (method 01304) in strawberry was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to strawberries (high acid). Acceptable procedural recoveries were reported in the trial report for flupyradifurone and DFA (mean recoveries ranging from 103% and 97-104%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

A summary of the residue trials is given in Table C.3.3.2.5.1-1.

**Table C.3.3.2.5.1-1 Rotational crop study (strawberry)**

|                             |                                                                                                                                                                                                                                                                |                                  |                                                                     |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on the field rotational crop strawberry and soil after spray application of BYI 02960 SL 200 to bare soil in the field in Belgium and the Netherlands, [REDACTED] 2018, Study ID: 16-2515, Activity ID: RARV0046 |                                  |                                                                     |
| GLP:                        | Yes                                                                                                                                                                                                                                                            | Sample storage conditions:       | 433 days at -18°C                                                   |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                                | Analytical method:               | Method 01304                                                        |
| Succeeding crop:            | Strawberry / Fruit                                                                                                                                                                                                                                             | Limit of Quantification (mg/kg): | Flupyradifurone: 0.01 mg/kg<br>DFA: 0.02 mg/kg (parent equivalents) |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                               | Residues calculated as:          | Flupyradifurone                                                     |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                                        |                                  |                                                                     |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                     | Commodity<br>Variety            | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest              | Application rate per<br>treatment |                 |                  | Dates or<br>number of<br>treatment<br>s and last<br>date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analysed | Residues (mg/kg)        |                                                |                                                                          |                             | PBI<br>(days) | DAT<br>(days) |
|------------------------------------------------------------------|---------------------------------|-----------------------------------------------------------------------------|-----------------------------------|-----------------|------------------|----------------------------------------------------------|-----------------------------------|-----------------------------|-------------------------|------------------------------------------------|--------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                                                                  |                                 |                                                                             | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                          |                                   |                             | Flupyra<br>difuron<br>e | DFA,<br>expressed<br>as<br>flupyradifuro<br>ne | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifruone | DFA,<br>expressed<br>as DFA |               |               |
| 16-2515-01<br>1681 ND<br>Zwaagdijk<br>The<br>Netherlands<br>2016 | Strawberry<br>Felicita<br>Frigo | 1. 02-06-<br>2016<br>2. 22-06 to<br>01-08-2016<br>3. 22-07 to<br>01-08-2016 | 300                               | 400             | 75               | 11-05-<br>2016                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | 0.17<br>0.21                                   | 0.18<br>0.22                                                             | 0.057<br>0.070              | 22            | 72<br>78      |
|                                                                  | Strawberry<br>Rumba<br>Frigo    | 1. 13-04-<br>2016<br>2. 15-05 to<br>15-06-2016<br>3. 19-06 to<br>29-09-2016 | 300                               | 400             | 75               | 25-11-<br>2016                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | 0.12<br>0.14                                   | 0.13<br>0.15                                                             | 0.040<br>0.047              | 139           | 206<br>210    |
|                                                                  | Strawberry<br>Rumba<br>Frigo    | 1. 13-04-<br>2016<br>2. 15-05 to<br>15-06-2016<br>3. 19-06 to<br>29-09-2016 | 300                               | 400             | 75               | 11-05-<br>2016                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | 0.073<br>0.069                                 | 0.083<br>0.079                                                           | 0.024<br>0.023              | 337           | 404<br>408    |
| 16-2515-02<br>6221 Saint-<br>Amand<br>Belgium<br>2016            | Strawberry<br>Elsanta           | 1. 26-05-<br>2016<br>2. 06-06 to<br>19-06-2016<br>3. 15-07 to<br>26-07-2016 | 300                               | 300             | 100              | 04-05-<br>2016                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | 0.25<br>0.30                                   | 0.26<br>0.31                                                             | 0.083<br>0.10               | 22            | 70<br>77      |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year | Commodity<br>Variety | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest              | Application rate per<br>treatment |                 |                  | Dates or<br>number of<br>treatment<br>s and last<br>date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analysed | Residues (mg/kg)        |                                                |                                                                         |                             | PBI<br>(days) | DAT<br>(days) |
|------------------------------|----------------------|-----------------------------------------------------------------------------|-----------------------------------|-----------------|------------------|----------------------------------------------------------|-----------------------------------|-----------------------------|-------------------------|------------------------------------------------|-------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                              |                      |                                                                             | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                          |                                   |                             | Flupyra<br>difuron<br>e | DFA,<br>expressed<br>as<br>flupyradifuro<br>ne | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifuone | DFA,<br>expressed<br>as DFA |               |               |
|                              | Strawberry<br>Sonata | 1. 04-05-<br>2017<br>2. 31-05 to<br>10-06-2017<br>3. 01-07 to<br>12-07-2017 | 300                               | 300             | 100              | 14-12-<br>2016                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | 0.37<br>0.37                                   | 0.38<br>0.38                                                            | 0.12<br>0.12                | 141           | 196<br>203    |
|                              | Strawberry<br>Sonata | 1. 04-05-<br>2017<br>2. 31-05 to<br>10-06-2017<br>3. 01-07 to<br>12-07-2017 | 317                               | 317             | 100              | 07-07-<br>2016                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | 0.078<br>0.23                                  | 0.088<br>0.24                                                           | 0.026<br>0.077              | 301           | 356<br>363    |

**Table C.3.3.2.5.1-2 Rotational crop study (soil samples)**

|                             |                                                                                                                                                                                                                                                                |                                  |                                                         |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on the field rotational crop strawberry and soil after spray application of BYI 02960 SL 200 to bare soil in the field in Belgium and the Netherlands, [REDACTED] 2018, Study ID: 16-2515, Activity ID: RARV0046 |                                  |                                                         |
| GLP:                        | Yes                                                                                                                                                                                                                                                            | Sample storage conditions:       | 379 days at -18°C                                       |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                                | Analytical method:               | Method 01074/M001                                       |
| Succeeding crop:            | Strawberry / Fruit                                                                                                                                                                                                                                             | Limit of Quantification (mg/kg): | Flupyradifurone and DFA (expressed as DFA): 0.005 mg/kg |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                               | Residues calculated as:          | Flupyradifurone                                         |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                                        |                                  |                                                         |

| Trial No<br>Location<br>Year                                  | Portion analysed | Application rate per treatment |              |           | DAT (days) | Soil layer (cm) | Residues (mg/kg) |                                   |                                                              |                       |
|---------------------------------------------------------------|------------------|--------------------------------|--------------|-----------|------------|-----------------|------------------|-----------------------------------|--------------------------------------------------------------|-----------------------|
|                                                               |                  | g a.s./ha                      | Water (L/ha) | g a.s./hL |            |                 | Flupyradifurone  | DFA, expressed as flupyradifurone | Sum of flupyradifurone and DFA, expressed as flupyradifurone | DFA, expressed as DFA |
| 16-2515-01<br>1681 ND<br>Zwaagdijk<br>The Netherlands<br>2016 | Bare soil        | 300                            | 400          | 75        | 22         | 0 – 20          | 0.034            | <0.015                            | 0.049                                                        | <0.005                |
|                                                               |                  | 300                            | 400          | 75        | 139        | 0 – 20          | 0.052            | <0.015                            | 0.067                                                        | <0.005                |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                          | Portion<br>analysed | Application rate per<br>treatment |                 |           | DAT<br>(days) | Soil<br>layer<br>(cm) | Residues (mg/kg) |                                      |                                                                          |                             |
|-------------------------------------------------------|---------------------|-----------------------------------|-----------------|-----------|---------------|-----------------------|------------------|--------------------------------------|--------------------------------------------------------------------------|-----------------------------|
|                                                       |                     | g a.s./ha                         | Water<br>(L/ha) | g a.s./hL |               |                       | Flupyradifurone  | DFA, expressed<br>as flupyradifurone | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed<br>as DFA |
|                                                       |                     | 300                               | 400             | 75        | 337           | 0 – 20                | 0.030            | <0.015                               | 0.045                                                                    | <0.005                      |
| 16-2515-02<br>6221 Saint-<br>Amand<br>Belgium<br>2016 | Bare soil           | 300                               | 300             | 100       | 22            | 0 – 20                | 0.059            | <0.015                               | 0.074                                                                    | <0.005                      |
|                                                       |                     | 300                               | 300             | 100       | 141           | 0 – 20                | 0.086            | <0.015                               | 0.101                                                                    | <0.005                      |
|                                                       |                     | 317                               | 317             | 100       | 301           | 0 – 20                | 0.055            | <0.015                               | 0.070                                                                    | <0.005                      |

#### C.3.3.2.5.2 Study 2

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of the residues of BYI 02960 in/on the field rotational crop Strawberry and Soil after spray application of BYI 02960 SL 200 to bare soil in the field in Spain and Italy, [REDACTED] 2018, Study ID: 16-2525, Activity ID: RARV0028                                                                                                                                                                                                                                                                                                     |
| Guideline(s):          | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market<br><br>OECD Guidelines for the Testing of Chemicals. Residues in Rotational Crops (Limited Field Studies). 504. 2007-01-08<br><br>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)<br><br>US EPA OCSP Guideline No. 860.1900, Field Accumulation in Rotational Crops<br><br>US EPA OCSP Guideline No. 860.1500 on Crop Field Trial |
| Deviations:            | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GLP:                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Validity of the study: | Acceptable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

#### Materials and methods

During the 2016 and 2017 growing seasons, two trials were conducted in Spain and Italy to determine the residue level of flupyradifurone and DFA in strawberries, grown in soil previously treated with flupyradifurone.

BYI 02960 SL 200, an SL formulation containing 200 g/L flupyradifurone, was applied to bare soil at a rate of 1 x 0.3 kg a.s./ha in 300 L/ha water. Strawberries were planted after a period of 27 to 29 days, 133 to 158 days and 341 to 363 days after application. The 27 to 29 day plant back interval (PBI) simulated the scenario of replanting after failure of the original crop. The later PBIs simulated replanting both in the first and second season after the original crop is harvested, reflecting agronomical practice for non-perennial crops. All trials included an untreated control plot.

After application, BYI 02960 SL 200 was incorporated into the soil. Before planting of the strawberries, the magnitude of flupyradifurone and DFA residues in the soil was determined (the top 0-20 cm).

Weather data were reported for the trials and no exceptional events were noted. Samples of strawberry fruits planted at 27 to 29 days, 133 to 158 days and 341 to 363 day PBIs were harvested at BBCH 85 (133/211, 188/342 and 481/525 days after application, respectively) and BBCH 87 (175/224, 242/355 and 538/543 days after application, respectively). Strawberry fruit samples weighing 1.01 to 1.15 kg were collected from treated and untreated plots. Samples of soil from the top 0-20 cm were collected at 27 to 29 days, 133 to 158 days and 341 to 363 days after application. Samples were frozen within 24 hours of sampling and stored deep frozen until analysis. The maximum storage interval between harvest and analysis was 266 days for strawberry samples and 340 days for soil at -18°C. The data from the approval of the active substance (EFSA, 2015) is sufficient to cover this period of storage in strawberry. Data on the storage stability of flupyradifurone and DFA are not available, therefore the residues in soil reported in Table C.3.3.2.5.1-2 are not relied upon.

Residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01304 with an LOQ of 0.01 mg/kg for flupyradifurone and 0.02 mg/kg parent equivalents for DFA in strawberry. In soil, residues of flupyradifurone and DFA were analysed by HPLC-MS/MS method 01074/M001 with an LOQ of 0.005 mg/kg for flupyradifurone and DFA, expressed as DFA.

## **Results and discussions**

The analytical method for analysing residues of flupyradifurone and DFA (method 01304) in strawberry was satisfactorily validated during active approval on high water, high protein, high acid, high oil and high starch commodities (DAR, NL, 2015). Therefore, the method is considered applicable to strawberries (high acid). Acceptable procedural recoveries were reported in the trial report for flupyradifurone and DFA (mean recoveries ranging from 94-98% and 98-101%, respectively).

No residues at or above the LOQ were detected in control samples of flupyradifurone or its metabolite DFA for all trials.

A summary of the residue trials is given in Table C.3.3.2.5.2-1.



**Table C.3.3.2.5.2-1 Rotational crop study (strawberry)**

|                             |                                                                                                                                                                                                                                                    |                                  |                                                                     |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on the field rotational crop Strawberry and Soil after spray application of BYI 02960 SL 200 to bare soil in the field in Spain and Italy, [REDACTED] 2018, Study ID: 16-2525, Activity ID: RARV0028 |                                  |                                                                     |
| GLP:                        | Yes                                                                                                                                                                                                                                                | Sample storage conditions:       | 266 days at -18°C                                                   |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                    | Analytical method:               | Method 01304                                                        |
| Succeeding crop:            | Strawberry / Fruit                                                                                                                                                                                                                                 | Limit of Quantification (mg/kg): | Flupyradifurone: 0.01 mg/kg<br>DFA: 0.02 mg/kg (parent equivalents) |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                   | Residues calculated as:          | Flupyradifurone                                                     |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                            |                                  |                                                                     |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year                                       | Commodity<br>Variety     | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest              | Application rate per<br>treatment |                 |                  | Dates or<br>number of<br>treatment<br>s and last<br>date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analysed | Residues (mg/kg)        |                                                |                                                                          |                             | PBI<br>(days) | DAT<br>(days) |
|--------------------------------------------------------------------|--------------------------|-----------------------------------------------------------------------------|-----------------------------------|-----------------|------------------|----------------------------------------------------------|-----------------------------------|-----------------------------|-------------------------|------------------------------------------------|--------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                                                                    |                          |                                                                             | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                          |                                   |                             | Flupyra<br>difuron<br>e | DFA,<br>expressed<br>as<br>flupyradifuro<br>ne | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifruone | DFA,<br>expressed<br>as DFA |               |               |
| 16-2525-01<br>11140 Conil<br>de la<br>Frontera<br>Spain<br>2016/17 | Strawberry<br>San Andrea | 1. 04-11-<br>2016<br>2. 01-01 to<br>30-03-2017<br>3. 14-02 to<br>30-03-2017 | 300                               | 300             | 100              | 06-10-<br>2016                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | 0.027<br><0.02                                 | 0.037<br><0.03                                                           | 0.009<br><0.007             | 29            | 133<br>175    |
|                                                                    | Strawberry<br>San Andrea | 1. 16-02-<br>2017<br>2. 13-03 to<br>20-06-2017<br>3. 04-04 to<br>20-06-2017 | 300                               | 300             | 100              | 06-10-<br>2016                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | <0.02<br>0.035                                 | <0.03<br>0.045                                                           | <0.007<br>0.012             | 133           | 188<br>242    |
|                                                                    | Strawberry<br>San Andrea | 1. 10-04-<br>2017<br>2. 15-12 to<br>30-05-2017<br>3. 01-02 to<br>30-05-2018 | 300                               | 300             | 100              | 06-10-<br>2016                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | <0.02<br><0.02                                 | <0.03<br><0.03                                                           | <0.007<br><0.007            | 363           | 481<br>543    |
| 16-2525-02<br>74019<br>Palagiano<br>Italy<br>2017/18               | Strawberry<br>Melissa    | 1. 17-10-<br>2017<br>2. 01-04 to<br>31-05-2018<br>3. 19-04 to<br>31-05-2018 | 300                               | 300             | 100              | 20-09-<br>2017                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | 0.23<br>0.36                                   | 0.24<br>0.37                                                             | 0.077<br>0.12               | 27            | 211<br>224    |

The evaluation of new MRLs for flupyradifurone and its metabolite DFA in or on various commodities

| Trial No<br>Location<br>Year | Commodity<br>Variety  | Date of<br>1.Sowing<br>or planting<br>2.Flowering<br>3.Harvest              | Application rate per<br>treatment |                 |                  | Dates or<br>number of<br>treatment<br>s and last<br>date | Growth<br>stage<br>at<br>sampling | Crop<br>Portion<br>analysed | Residues (mg/kg)        |                                                |                                                                         |                             | PBI<br>(days) | DAT<br>(days) |
|------------------------------|-----------------------|-----------------------------------------------------------------------------|-----------------------------------|-----------------|------------------|----------------------------------------------------------|-----------------------------------|-----------------------------|-------------------------|------------------------------------------------|-------------------------------------------------------------------------|-----------------------------|---------------|---------------|
|                              |                       |                                                                             | g<br>a.s./<br>ha                  | Water<br>(L/ha) | g<br>a.s./<br>hL |                                                          |                                   |                             | Flupyra<br>difuron<br>e | DFA,<br>expressed<br>as<br>flupyradifuro<br>ne | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifuone | DFA,<br>expressed<br>as DFA |               |               |
|                              | Strawberry<br>Melissa | 1. 17-10-<br>2017<br>2. 01-04 to<br>31-05-2018<br>3. 19-04 to<br>31-05-2018 | 300                               | 300             | 100              | 12-05-<br>2017                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | 0.21<br>0.18                                   | 0.22<br>0.19                                                            | 0.070<br>0.060              | 158           | 342<br>355    |
|                              | Strawberry<br>Melissa | 1. 17-10-<br>2017<br>2. 01-04 to<br>31-05-2018<br>3. 19-04 to<br>31-05-2018 | 300                               | 300             | 100              | 10-11-<br>2016                                           | BBCH 85<br>BBCH 87                | Fruit<br>Fruit              | <0.01<br><0.01          | 0.051<br><0.02                                 | 0.061<br><0.03                                                          | 0.017<br><0.007             | 341           | 525<br>538    |

**Table C.3.3.2.5.2-2 Rotational crop study (soil samples)**

|                             |                                                                                                                                                                                                                                                    |                                  |                                                         |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------|
| Reference:                  | Determination of the residues of BYI 02960 in/on the field rotational crop Strawberry and Soil after spray application of BYI 02960 SL 200 to bare soil in the field in Spain and Italy, ██████████ 2018, Study ID: 16-2525, Activity ID: RARV0028 |                                  |                                                         |
| GLP:                        | Yes                                                                                                                                                                                                                                                | Sample storage conditions:       | 340 days at -18°C                                       |
| Primary crop:               | None, bare soil                                                                                                                                                                                                                                    | Analytical method:               | Method 01074/M001                                       |
| Succeeding crop:            | Strawberry / Fruit                                                                                                                                                                                                                                 | Limit of Quantification (mg/kg): | Flupyradifurone and DFA (expressed as DFA): 0.005 mg/kg |
| Formulation:                | BYI 02960 SL 200                                                                                                                                                                                                                                   | Residues calculated as:          | Flupyradifurone                                         |
| Content of active substance | 200 g/L                                                                                                                                                                                                                                            |                                  |                                                         |

| Trial No<br>Location<br>Year                              | Portion analysed | Application rate per treatment |              |           | DAT (days) | Soil layer (cm) | Residues (mg/kg) |                                   |                                                              |                       |
|-----------------------------------------------------------|------------------|--------------------------------|--------------|-----------|------------|-----------------|------------------|-----------------------------------|--------------------------------------------------------------|-----------------------|
|                                                           |                  | g a.s./ha                      | Water (L/ha) | g a.s./hL |            |                 | Flupyradifurone  | DFA, expressed as flupyradifurone | Sum of flupyradifurone and DFA, expressed as flupyradifurone | DFA, expressed as DFA |
| 16-2525-01<br>11140 Conil de la Frontera Spain<br>2016/17 | Bare soil        | 300                            | 300          | 100       | 29         | 0 – 20          | 0.053            | <0.015                            | 0.068                                                        | <0.005                |
|                                                           |                  | 300                            | 300          | 100       | 134        | 0 – 20          | 0.067            | <0.015                            | 0.082                                                        | <0.005                |

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| Trial No<br>Location<br>Year                         | Portion<br>analysed | Application rate per<br>treatment |                 |           | DAT<br>(days) | Soil<br>layer<br>(cm) | Residues (mg/kg) |                                      |                                                                          |                             |
|------------------------------------------------------|---------------------|-----------------------------------|-----------------|-----------|---------------|-----------------------|------------------|--------------------------------------|--------------------------------------------------------------------------|-----------------------------|
|                                                      |                     | g a.s./ha                         | Water<br>(L/ha) | g a.s./hL |               |                       | Flupyradifurone  | DFA, expressed<br>as flupyradifurone | Sum of<br>flupyradifurone<br>and DFA,<br>expressed as<br>flupyradifurone | DFA,<br>expressed as<br>DFA |
|                                                      |                     | 300                               | 300             | 100       | 364           | 0 – 20                | 0.039            | <0.015                               | 0.054                                                                    | <0.005                      |
| 16-2525-02<br>74019<br>Palagiano<br>Italy<br>2017/18 | Bare soil           | 300                               | 300             | 100       | 27            | 0 – 20                | 0.008            | <0.015                               | 0.023                                                                    | <0.005                      |
|                                                      |                     | 300                               | 300             | 100       | 158           | 0 – 20                | 0.022            | <0.015                               | 0.037                                                                    | <0.005                      |
|                                                      |                     | 300                               | 300             | 100       | 341           | 0 – 20                | 0.007            | <0.015                               | 0.022                                                                    | <0.005                      |

## **C.3.4 Nature and magnitude of residues in livestock**

### **C.3.4.1 Nature of residues**

No additional studies submitted.

### **C.3.4.2 Magnitude of residues (feeding studies)**

No additional studies submitted.

### **C.3.5 Residues in honey**

No additional studies submitted.

### **C.3.6 Storage stability**

No additional studies submitted.



## Appendix D – List of endpoints

The endpoints outlined in Table D.X have been derived as a result of this assessment. All other endpoints remained unchanged. The full list of endpoints is outlined in EFSA Conclusion (EFSA, 2015).

**Table D.X Residues in rotational crops**

|                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Residues in rotational or succeeding crops expected based on field rotational crop trials? | <p>Field rotational crop studies at 175 to 300 g a.s./ha on bare soil (21-30, 129-181 and 273-363 day PBI). Flupyradifurone (F; mg/kg flupyradifurone equivalent) and DFA (D; mg/kg DFA equivalent) residue levels in rotational crops at maturity:</p> <p><b>21-30 day PBI</b></p> <p>Cauliflower/broccoli:<br/>F: 4 x &lt;0.01<br/>D: 0.025, 0.043, 0.057, 0.067</p> <p>Cabbage:<br/>F: 4 x &lt;0.01<br/>D: 0.0229, 0.0317, 0.0433, 0.0467</p> <p>Strawberry:<br/>F: 4 x &lt;0.01<br/>D: 0.009, 0.070, 0.10, 0.12</p> <p><b>129-181 day PBI</b></p> <p>Potato:<br/>F: 4 x &lt;0.01<br/>D: 0.012, 0.023, 0.043, 0.087</p> <p>Cauliflower/broccoli:<br/>F: 4 x &lt;0.01<br/>D: 0.015, 0.037, 0.050, 0.060</p> |
|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Oilseed rape seed:<br/>F: 8 x &lt;0.01<br/>D: 2 x &lt;0.007, 0.007, 0.009, 0.014, 0.015, 0.0194, 0.022</p> <p>Strawberry:<br/>F: 4 x &lt;0.01<br/>D: 0.012, 0.047, 0.070, 0.12</p> <p><b>273-363 day PBI</b></p> <p>Potato:<br/>F: 4 x &lt;0.01<br/>D: &lt;0.007, 0.012, 0.018, 0.019</p> <p>Cauliflower/broccoli:<br/>F: 4 x &lt;0.01<br/>D: 0.008, 0.019, 0.023, 0.040</p> <p>Oilseed rape seed:<br/>F: 3 x &lt;0.01<br/>D: 0.007, 0.008, 0.013</p> <p>Strawberry:<br/>F: 4 x &lt;0.01<br/>D: &lt;0.007, 0.017, 0.024, 0.077</p> |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Table D.X Processing factors**

| Crop/<br>Processed<br>fraction           | Number of trials | Individual<br>processing<br>factors | Median<br>processing<br>factor <sup>(a)</sup> | Conversion<br>factor |
|------------------------------------------|------------------|-------------------------------------|-----------------------------------------------|----------------------|
| <b>RD-Enf 1) Flupyradifurone</b>         |                  |                                     |                                               |                      |
| Soyabean/<br>Aspirated grain<br>fraction | 2                | 15.88, 11.69                        | 13.79                                         | n/a                  |
| Soyabean/<br>Meal                        | 2                | 0.85, 1.25                          | 1.05                                          | n/a                  |
| Soyabean/<br>Hulls                       | 2                | 0.78, 1.17                          | 0.98                                          | n/a                  |

|                                            |   |              |                      |     |
|--------------------------------------------|---|--------------|----------------------|-----|
| Soyabean/<br>Refined oil                   | 2 | <0.01, <0.02 | <0.02                | n/a |
| Soyabean/ Milk                             | 2 | 0.04, 0.09   | 0.07 <sup>(b)</sup>  | n/a |
| Soyabean/<br>Defatted flour                | 2 | 1.05, 1.19   | 1.12                 | n/a |
| Olive/ Crude oil                           | 2 | 0.12, 0.13   | 0.13                 | n/a |
| Olive/ Refined<br>oil                      | 2 | <0.03, <0.06 | <0.05 <sup>(b)</sup> | n/a |
| Olive/ Refined<br>solvent<br>extracted oil | 2 | <0.03, <0.06 | <0.05 <sup>(b)</sup> | n/a |
| <b>RD-Enf 2) DFA, expressed as DFA</b>     |   |              |                      |     |
| Soyabean/<br>Aspirated grain<br>fraction   | 2 | 8.18, 4.81   | 6.50                 | n/a |
| Soyabean/<br>Meal                          | 2 | 1.19, 1.44   | 1.32                 | n/a |
| Soyabean/<br>Hulls                         | 2 | 1.04, 0.78   | 0.91                 | n/a |
| Soyabean/<br>Refined oil                   | 2 | <0.96, <0.16 | <0.56 <sup>(b)</sup> | n/a |
| Soyabean/ Milk                             | 2 | <0.96, <0.16 | <0.56 <sup>(b)</sup> | n/a |
| Soyabean/<br>Defatted flour                | 2 | 1.44, 1.27   | 1.36                 | n/a |
| Olive/ Crude oil                           | 2 | 0.57         | 0.57 <sup>(b)</sup>  | n/a |

|                                                                          |   |              |                      |     |
|--------------------------------------------------------------------------|---|--------------|----------------------|-----|
| Olive/ Refined oil                                                       | 2 | 0.57         | 0.57 <sup>(b)</sup>  | n/a |
| Olive/ Refined solvent extracted oil                                     | 2 | 0.57         | 0.57 <sup>(b)</sup>  | n/a |
| <b>RD-RA: Sum of flupyra-flupyradifurone difurone and DFA, expressed</b> |   |              |                      |     |
| Soyabean/ Aspirated grain fraction                                       | 2 | 15.34, 8.77  | 12.06                | n/a |
| Soyabean/ Meal                                                           | 2 | 0.88, 1.34   | 1.11                 | n/a |
| Soyabean/ Hulls                                                          | 2 | 0.80, 1.01   | 0.91                 | n/a |
| Soyabean/ Refined oil                                                    | 2 | <0.08, <0.08 | <0.08                | n/a |
| Soyabean/ Milk                                                           | 2 | 0.11, 0.12   | 0.12                 | n/a |
| Soyabean/ Defatted flour                                                 | 2 | 1.07, 1.23   | 1.15                 | n/a |
| Olive/ Crude oil                                                         | 2 | 0.15, 0.22   | 0.19                 | n/a |
| Olive/ Refined oil                                                       | 2 | <0.07, <0.15 | <0.11 <sup>(b)</sup> | n/a |
| Olive/ Refined solvent extracted oil                                     | 2 | <0.07, <0.15 | <0.11 <sup>(b)</sup> | n/a |

(a) The mean has been used to derive the Pfs as only two trials are available

(b) Tentative Pfs as derived from two trials with ≥50% difference between individual Pfs.

## Appendix E – Import Tolerances

Sufficient information was provided to confirm that the GAPs outlined in Appendix A are the basis of the MRLs adopted in the EU, USA and Canada.

A copy of the current national legislation in the exporting countries related to the MRLs under consideration was provided.

The MRLs in force in the exporting countries are tabulated in Tables E.1 and E.2.

**Table E.1 MRLs in force in the exporting country for flupyradifurone**

Enforcement residue definition for products of plant origin: Flupyradifurone

| Commodity                                    | MRL in force in the exporting country (mg/kg) | Exporting jurisdiction |
|----------------------------------------------|-----------------------------------------------|------------------------|
| Strawberries                                 | 0.4                                           | EU                     |
| Table olives                                 | 5                                             | EU                     |
| Potatoes                                     | 0.05                                          | USA & Canada           |
| Tropical root and tuber vegetables           | 0.05                                          | USA & Canada           |
| Flowering brassicas                          | 0.6                                           | EU                     |
| Brussels sprouts                             | 0.09                                          | EU                     |
| Head cabbages                                | 0.3                                           | EU                     |
| Chinese cabbages/pe-tsai                     | 4                                             | EU                     |
| Kales                                        | 4                                             | EU                     |
| Kohlrabies                                   | 0.09                                          | EU                     |
| Lamb's lettuces/corn salads                  | 6                                             | EU                     |
| Lettuces                                     | 6                                             | EU                     |
| Cresses and other sprouts and shoots         | 6                                             | EU                     |
| Land cresses                                 | 6                                             | EU                     |
| Roman rocket/rucola                          | 6                                             | EU                     |
| Red mustards                                 | 6                                             | EU                     |
| Baby leaf crops (including brassica species) | 6                                             | EU                     |

|                                                                    |     |              |
|--------------------------------------------------------------------|-----|--------------|
| Others - Lettuce and other salad plants including brassica species | 6   | EU           |
| Spinach and similar leaves                                         | 6   | EU           |
| Herbs and edible flowers                                           | 40  | EU           |
| Soyabeans                                                          | 1.5 | USA & Canada |
| Olives for oil production                                          | 5   | EU           |

**Table E.2 MRLs in force in the exporting country for DFA (from the use of flupyradifurone)**

Enforcement residue definition for products of plant origin: DFA, expressed as DFA

| <b>Commodity</b>                             | <b>MRL in force in the exporting country (mg/kg)</b> | <b>Exporting jurisdiction</b> |
|----------------------------------------------|------------------------------------------------------|-------------------------------|
| Strawberries                                 | 0.3 <sup>†</sup>                                     | EU                            |
| Table olives                                 | 0.15                                                 | EU                            |
| Potatoes                                     | n/a                                                  | USA & Canada                  |
| Tropical root and tuber vegetables           | n/a                                                  | USA & Canada                  |
| Flowering brassicas                          | 0.7 <sup>†</sup>                                     | EU                            |
| Brussels sprouts                             | 0.4 <sup>†</sup>                                     | EU                            |
| Head cabbages                                | 0.4 <sup>†</sup>                                     | EU                            |
| Chinese cabbages/pe-tsai                     | 0.7 <sup>†</sup>                                     | EU                            |
| Kales                                        | 0.7 <sup>†</sup>                                     | EU                            |
| Kohlrabies                                   | 0.4 <sup>†</sup>                                     | EU                            |
| Lamb's lettuce/corn salads                   | 0.3 <sup>†</sup>                                     | EU                            |
| Lettuces                                     | 0.2 <sup>†</sup>                                     | EU                            |
| Cresses and other sprouts and shoots         | 0.3 <sup>†</sup>                                     | EU                            |
| Land cresses                                 | 0.3 <sup>†</sup>                                     | EU                            |
| Roman rocket/rucola                          | 0.3 <sup>†</sup>                                     | EU                            |
| Red mustards                                 | 0.3 <sup>†</sup>                                     | EU                            |
| Baby leaf crops (including brassica species) | 0.3 <sup>†</sup>                                     | EU                            |

|                                                                    |                  |              |
|--------------------------------------------------------------------|------------------|--------------|
| Others - Lettuce and other salad plants including brassica species | 0.3 <sup>†</sup> | EU           |
| Spinach and similar leaves                                         | 0.3 <sup>†</sup> | EU           |
| Herbs and edible flowers                                           | 0.3 <sup>†</sup> | EU           |
| Soyabeans                                                          | n/a              | USA & Canada |
| Olives for oil production                                          | 0.15             | EU           |

n/a MRLs for DFA not set in the exporting country (USA/Canada)

<sup>†</sup> It should be noted that the MRL in the exporting country has been calculated by considering the impact of accumulation from year-on-year use. GB MRLs at this time have not applied this consideration as it is not required by the data requirements that are applicable to flupyradifurone. Consideration of accumulation from year-on-year use will be addressed separately as part of the MRL supplementary information assessment.

## Appendix F – Compound codes

No new metabolism studies were evaluated during this assessment and hence this section has not been completed.



## Appendix G – Abbreviations

|                   |                                                                                            |
|-------------------|--------------------------------------------------------------------------------------------|
| ADI               | Acceptable daily intake                                                                    |
| ADME              | Absorption, distribution, metabolism and excretion                                         |
| Animal model 2017 | EFSA model used to calculate the dietary burden of livestock using the OECD feeding tables |
| ARfD              | Acute reference dose                                                                       |
| a.s.              | Active substance                                                                           |
| BBCH              | Growth stages of mono- and dicotyledonous plants                                           |
| bw                | Body weight                                                                                |
| CF                | Conversion factor                                                                          |
| cGAP              | Critical GAP                                                                               |
| CXL               | Codex maximum residue limit                                                                |
| DAR               | Draft assessment report                                                                    |
| DAT               | Days after treatment                                                                       |
| DT <sub>90</sub>  | Period required for 90% dissipation (define method of estimation)                          |
| DT <sub>50</sub>  | Period required for 50% dissipation (define method of estimation)                          |
| EFSA              | European Food Safety Authority                                                             |
| EU                | European Union                                                                             |
| FAO               | Food and Agriculture Organization of the United Nations                                    |
| GAP               | Good Agricultural Practice                                                                 |
| GB                | Great Britain                                                                              |
| GC-MS             | Gas chromatography with mass spectrometry                                                  |

|                          |                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| GLP                      | Good laboratory practice                                                                                                                                                                                                                                                                                                                                                                 |
| HPLC-MS/MS<br>(LC-MS/MS) | High-performance liquid chromatography with tandem mass spectrometry                                                                                                                                                                                                                                                                                                                     |
| HR                       | Highest residue                                                                                                                                                                                                                                                                                                                                                                          |
| HSE                      | Health and Safety Executive                                                                                                                                                                                                                                                                                                                                                              |
| IEDI                     | International estimate of daily intake                                                                                                                                                                                                                                                                                                                                                   |
| IESTI                    | International estimate of short-term intake                                                                                                                                                                                                                                                                                                                                              |
| ILV                      | Independent laboratory validation                                                                                                                                                                                                                                                                                                                                                        |
| ISO                      | International Organisation for Standardization                                                                                                                                                                                                                                                                                                                                           |
| JMPR                     | Joint FAO/WHO Meeting on Pesticide Residues                                                                                                                                                                                                                                                                                                                                              |
| LC <sub>50</sub>         | Lethal concentration, median                                                                                                                                                                                                                                                                                                                                                             |
| LD <sub>50</sub>         | Lethal dose, median                                                                                                                                                                                                                                                                                                                                                                      |
| LOAEL                    | Lowest observed adverse effect level                                                                                                                                                                                                                                                                                                                                                     |
| LOD                      | Limit of detection or limit of determination (should be defined)                                                                                                                                                                                                                                                                                                                         |
| LoEP                     | List of endpoints                                                                                                                                                                                                                                                                                                                                                                        |
| LOQ                      | Limit of quantification<br><br><b>NB</b> the limit of quantification and limit of determination are the same.<br><br>Assimilated Regulation 396/2005 refers to the limit of determination<br><br>Assimilated Regulation 1107/2009 refers to the limit of quantification<br><br>MRLs marked with an asterisk (e.g. 0.01* mg/kg) are MRLs set at the limit of determination/quantification |
| MRL                      | Maximum residue level                                                                                                                                                                                                                                                                                                                                                                    |
| NEDI                     | National estimate of dietary intake                                                                                                                                                                                                                                                                                                                                                      |
| NESTI                    | National estimate of short-term intake                                                                                                                                                                                                                                                                                                                                                   |

|          |                                                                                                       |
|----------|-------------------------------------------------------------------------------------------------------|
| NOAEL    | No observed adverse effect level                                                                      |
| NRL      | National reference laboratory                                                                         |
| OECD     | Organisation for Economic Co-operation and Development                                                |
| PBI      | Plant-back interval                                                                                   |
| PES      | Post-extraction solids                                                                                |
| Pf       | Processing factor                                                                                     |
| PHI      | Preharvest interval                                                                                   |
| PRIMo    | (EFSA) Pesticide Residue Intake Model                                                                 |
| QuEChERS | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)                                   |
| RA       | Risk assessment                                                                                       |
| RD       | Residue definition                                                                                    |
| RD-Enf   | Residue definition for enforcement (also referred to as RD-Mo i.e. residue definition for monitoring) |
| RD-RA    | Residue definition for risk assessment                                                                |
| RTI      | Re-treatment interval                                                                                 |
| STMR     | Supervised trials median residue                                                                      |
| TRR      | Total radioactive residue                                                                             |
| TTC      | Threshold of toxicological concern                                                                    |
| WG       | Water dispersible granule                                                                             |
| WHO      | World Health Organization                                                                             |

## Additional studies relied upon

| Author(s) | Year | Title/Testing Facility/Report No/GLP or GEP Status/Published or not                                                                                                                                                              | Submitter |
|-----------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
|           | 2013 | Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in northern France, Germany, Italy and Spain<br>Study ID: 11-2093<br>Activity ID: RARVL098             | Bayer     |
|           | 2013 | Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in the Netherlands, Belgium, southern France and Germany<br>Study ID: 12-2121<br>Activity ID: RAAAN121 | Bayer     |
|           | 2022 | Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in Germany, Belgium, Northern France, the Netherlands and Italy<br>Study ID: E21RP105                  | Bayer     |
|           | 2023 | Determination of the residues of BYI 02960 in/on strawberry after spray application of BYI 02960 SL 200 in the greenhouse in Spain<br>Study ID: E22RP109                                                                         | Bayer     |
|           | 2012 | BYI 02960 200 SL – Magnitude of the Residue in Potato – Tuberous and Corm Vegetables (Crop Subgroup 1C)<br>Activity ID: RARVY015                                                                                                 | Bayer     |
|           | 2012 | Determination of the residues of BYI 02960 in/on Broccoli and Cauliflower after Spraying of BYI 02960 SL 200 in the Field in Germany, the Netherlands and United Kingdom<br>Study ID: 10-2221<br>Activity ID: RARVL026           | Bayer     |

| Author(s) | Year | Title/Testing Facility/Report No/GLP or GEP Status/Published or not                                                                                                                                                                  | Submitter |
|-----------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
|           | 2015 | Determination of the residues of BYI 02960 in/on cauliflower and broccoli after spray application of BYI 02960 SL 200 in Germany, Belgium and the Netherlands<br>Study ID: 13-2142<br>Activity ID: RARVN034                          | Bayer     |
|           | 2014 | Determination of the residues of BYI 02960 in/on broccoli and cauliflower after spray application of BYI 02960 SL 200 in the field in France (South) and Italy<br>Study ID: 11-2063<br>Activity ID: RARVL069                         | Bayer     |
|           | 2015 | Determination of the residues of BYI 02960 in/on cauliflower and broccoli after spray application of BYI 02960 SL 200 in Spain and Italy<br>Study ID: 13-2140<br>Activity ID: RARVN035                                               | Bayer     |
|           | 2018 | Determination of the residues of BYI 02960 in/on broccoli and cauliflower after spray application of BYI 02960 SL 200 in Portugal, southern France and Italy<br>Study ID: 16-2147<br>Activity ID: RARV0054                           | Bayer     |
|           | 2013 | Determination of the residues of BYI 02960 in/on savoy, red and white cabbage after spray application of BYI 02960 SL 200 in the field in Germany, northern France and the Netherlands<br>Study ID: 10-2183<br>Activity ID: RARVL009 | Bayer     |
|           | 2015 | Determination of the residues of BYI 02960 in/on cabbage after spray application of BYI 02960 SL 200 in Germany, Belgium and the Netherlands<br>Study ID: 13-2144<br>Activity ID: RARVN032                                           | Bayer     |

| Author(s) | Year | Title/Testing Facility/Report No/GLP or GEP Status/Published or not                                                                                                                                                     | Submitter |
|-----------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
|           | 2014 | Determination of the residues of BYI 02960 in/on cabbage after spray application of BYI 02960 SL 200 in the field in France (South) and Spain<br>Study ID: 11-2062<br>Activity ID: RARVL068                             | Bayer     |
|           | 2015 | Determination of the residues of BYI 02960 in/on cabbage after spray application of BYI 02960 SL 200 in Spain and Italy<br>Study ID: 13-2143<br>Activity ID: RARVN033                                                   | Bayer     |
|           | 2012 | Determination of the residues of BYI 02960 in/on Brussels sprouts after spray application of BYI 02960 SL 200 in the field in Germany, France (North) and the Netherlands<br>Study ID: 10-2222<br>Activity ID: RARVL027 | Bayer     |
|           | 2015 | Determination of the residues of BYI 02960 in/on Brussels sprouts after spray application of BYI 02960 SL 200 in Germany, Belgium and the Netherlands<br>Study ID: 13-2145<br>Activity ID: RARVN031                     | Bayer     |
|           | 2012 | Determination of the residues of BYI 02960 in/on Kale, curly after Spraying of BYI 02960 SL 200 in the Field in Germany and United Kingdom<br>Study ID: 10-2182<br>Activity ID: RARVL008                                | Bayer     |
|           | 2015 | Determination of the residues of BYI 02960 in/on curly kale after spray application of BYI 02960 SL 200 in the Netherlands and Belgium<br>Study ID: 13-2147<br>Activity ID: RARVN029                                    | Bayer     |
|           | 2019 | Determination of the residues of BYI 02960 in/on curly kale after spray application of BYI 02960 SL 200 in Germany<br>Study ID: 18-2102<br>Activity ID: RARV0266                                                        | Bayer     |

| Author(s) | Year | Title/Testing Facility/Report No/GLP or GEP Status/Published or not                                                                                                                                                                  | Submitter |
|-----------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
|           | 2013 | Determination of the residues of BYI 02960 in/on kohlrabi after spraying of BYI 02960 SL 200 in the field in Germany and the Netherlands<br>Study ID: 10-2220<br>Activity ID: RARVL025                                               | Bayer     |
|           | 2015 | Determination of the residues of BYI 02960 in/on kohlrabi after spray application of BYI 02960 SL 200 in the Netherlands and Belgium<br>Study ID: 13-2148<br>Activity ID: RARVN028                                                   | Bayer     |
|           | 2013 | Determination of the residues of BYI 02960 in/on lettuce after spraying of BYI 02960 SL 200 in the field in the Netherlands, Belgium, France (North) and Germany<br>Study ID: 10-2223<br>Activity ID: RARVL028                       | Bayer     |
|           | 2012 | Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the field in Germany, northern France and Belgium<br>Study ID: 11-2082<br>Activity ID: RARVL087                              | Bayer     |
|           | 2018 | Determination of the residues of BYI 02960 in/on lettuce (oak leaf variety) after spray application of BYI 02960 SL 200 in northern France, southern France, Italy and the Netherlands<br>Study ID: 16-2006<br>Activity ID: RARV0044 | Bayer     |
|           | 2012 | Determination of the residues of BYI 02960 in/on lettuce, head after spray application of BYI 02960 SL 200 in the field in France (south), Spain and Italy<br>Study ID: 10-2213<br>Activity ID: RARVL018                             | Bayer     |

| Author(s) | Year | Title/Testing Facility/Report No/GLP or GEP Status/Published or not                                                                                                                                                                                          | Submitter |
|-----------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
|           | 2012 | Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the field in Spain, Italy, southern France and Portugal<br>Study ID: 11-2071<br>Activity ID: RARVL076                                                | Bayer     |
|           | 2012 | BYI 02960 200 SL and BYI 02960 480 FS – Magnitude of the Residue in/on Soybeans<br>Report No.: RARVY011                                                                                                                                                      | Bayer     |
|           | 2016 | Determination of the residues of BYI 02960 in/on olive after spray application of BYI 02960 SL 200 in Italy and Spain<br>Study ID: 14-2125,<br>Activity ID: RARVN090                                                                                         | Bayer     |
|           | 2018 | Determination of the residues of BYI 02960 in/on olive after spray application of BYI 02960 SL 200 in Italy and Spain<br>Study ID: 15-2103<br>Activity ID: RARVN117                                                                                          | Bayer     |
|           | 2012 | BYI 02960 200 SL – Magnitude of the Residues in/on Soybean Processed Commodities<br>Report No.: RARVY029                                                                                                                                                     | Bayer     |
|           | 2016 | Determination of the residues of BYI 02960 in/on olive and the processed fractions (oil, crude; oil, refined and oil, solv. Extracted refined ) after spray application of BYI 02960 SL 200 in Italy and Spain<br>Study ID: 14-3125<br>Activity ID: RARVN092 | Bayer     |
|           | 2018 | Determination of the residues of BYI 02960 in/on potato and soil after Spraying of BYI 02960 SL 200 in the Field in Germany, the Netherlands, Italy and Spain<br>Study ID: 16-2510<br>Activity ID: RARV0055                                                  | Bayer     |



| Author(s) | Year | Title/Testing Facility/Report No/GLP or GEP Status/Published or not                                                                                                                                                                                                  | Submitter |
|-----------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
|           | 2018 | Determination of the residues of BYI 02960 in/on the field rotational crop cauliflower, broccoli and soil after application of BYI 02960 SL 200 to bare soil in the field in Belgium, the Netherlands, Italy and Spain<br>Study ID: 16-2516<br>Activity ID: RARV0047 | Bayer     |
|           | 2022 | Determination of the residues of BYI 02960 in/on soil and the field rotational crop cabbage after spray application of BYI 02960 SL 200 to bare soil in the Netherlands, Belgium, southern France and Italy<br>Study ID: E20RC006<br>Activity ID: RARV0380           | Bayer     |
|           | 2018 | Determination of the residues of BYI 02960 in/on the field rotational crop rape and soil after spray application of BYI 02960 SL 200 to bare soil in the Field in Belgium and the Netherlands<br>Study ID: 16-2511<br>Activity ID: RARV0049                          | Bayer     |
|           | 2018 | Determination of the residues of BYI 02960 in/on the field rotational crop Rape and Soil after spray application of BYI 02960 SL 200 to bare soil in the field in Italy and Portugal<br>Study ID: 16-2521<br>Activity ID: RARV0029                                   | Bayer     |
|           | 2022 | Determination of the residues of BYI 02960 in/on soil and the field rotational crop rape after spray application of BYI 02960 SL 200 to bare soil in the Netherlands, Belgium, southern France and Italy<br>Study ID: E20RC003                                       | Bayer     |

| Author(s) | Year | Title/Testing Facility/Report No/GLP or GEP Status/Published or not                                                                                                                                                                               | Submitter |
|-----------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
|           | 2018 | Determination of the residues of BYI 02960 in/on the field rotational crop strawberry and soil after spray application of BYI 02960 SL 200 to bare soil in the field in Belgium and the Netherlands<br>Study ID: 16-2515<br>Activity ID: RARV0046 | Bayer     |
|           | 2018 | Determination of the residues of BYI 02960 in/on the field rotational crop Strawberry and Soil after spray application of BYI 02960 SL 200 to bare soil in the field in Spain and Italy<br>Study ID: 16-2525<br>Activity ID: RARV0028             | Bayer     |



