

# **The evaluation of new MRLs for bixlozone in or on barley and wheat**

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

- Prepared under Article 8 of Assimilated Regulation 396/2005 and Data Requirements of Assimilated Regulation 283/2013
- Application Reference Number: COP 2023/00820

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## Summary

In accordance with Article 6 of Assimilated Regulation 396/2005,<sup>1</sup> HSE received an application from FMC Agro Limited on 9 August 2023 to set MRLs for the active substance bixlozone in or on wheat and barley.

Uses on wheat, barley, maize and oilseed rape were the representative uses assessed for the approval of the new active substance (June 2024). However, there is currently only a PPP authorisation proposed for 'Fundatis' on wheat, durum wheat and barley. Within this assessment only the MRLs for uses on wheat and barley have been considered.

The full details of the approval assessment and the agreed list of endpoints is available at [New active substances - HSE](#).

The applicant submitted a dossier in accordance with the data requirements outlined in Assimilated Regulation 283/2013.

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 setting the MRLs. HSE relied upon the data assessed in the assessment report for the approval of the active substance (HSE, 2024a) and additional new data submitted by the applicant relevant to the proposed uses.

Sufficiently validated analytical methods for the determination of bixlozone in products of plant origin, in line with the residue definition for enforcement, are available to support the uses under consideration in the MRL application.

Toxicological reference values were established for the approval of the active substance: an ADI of 0.3 mg/kg bw/day and an ARfD of 0.75 mg/kg bw.

The metabolism of bixlozone in primary crops was investigated in root crops, cereals/grass crops and pulses/oilseeds crop groups following foliar applications for the approval of the active substance (HSE, 2024a). The root crop metabolism study was only considered as supporting information in the GB Assessment Report of bixlozone. The proposal of residue definitions included a TTC assessment (for 2,2-dimethyl-3-hydroxy propionic acid (M118/1)

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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](#)

<sup>2</sup> [Assimilated Regulation No 1107/2009 concerning the placing of plant protection products on the market](#)

and dimethyl malonic acid (M132/1)) and only the intended uses were considered. Therefore, it was not possible to propose a universal residue definition (across all crops). However, the crops included in this MRL application belong to the cereal crop group and are, therefore, covered by the metabolism studies available.

The residue definition for risk assessment (RD-RA) in plants has been agreed (based on the uses assessed in the approval assessment) as:

- **For the intended (early application) use on oilseed rape, wheat, barley and maize:**  
Sum of the residues of bixlozone and 2 x 2,4-dichlorobenzoic acid expressed as bixlozone\*

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

- Bixlozone

\*Molecular weight conversion to express 2,4-dichlorobenzoic acid as bixlozone equivalents is x 1.435. The 2 x factor is to account for the relative toxicological potency of 2,4-dichlorobenzoic acid compared to bixlozone.

Although the RD-RA and RD-Enf are different no conversion factors have been set as almost all of the trials contained residues of bixlozone and 2,4-dichlorobenzoic acid at a level of <0.01 mg/kg (<LOQ).

Five new outdoor primary crop trials on wheat conducted using the proposed product 'Fundatis' in Northern France, Germany, Poland and the UK were submitted to support MRLs for wheat and barley. The trials are supported by validated analytical methods and storage stability data. Additional trials, evaluated in the GB approval assessment (HSE, 2024a), on wheat and barley have been relied upon to support the MRLs.

A new residues stability study demonstrating stability of residues in frozen samples was submitted and evaluated to address a data gap, on stability of residues in cereal grain, to support the uses on wheat and barley.

Hydrolysis of bixlozone under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that bixlozone is stable under standard hydrolysis conditions. A new processing hydrolysis study was submitted to address a data gap for the nature of metabolite 2,4-dichlorobenzoic acid to be addressed during processing. The new hydrolysis data demonstrated that 2,4-dichlorobenzoic acid is stable under standard hydrolysis conditions. The data gap has been addressed, therefore specific residue definitions for processed commodities are not required.

Residues in rotational crops were considered for the approval of the active substance. Bixlozone and the main metabolites found in the rotational crop metabolism study were

tested in follow on MOR (magnitude of residues) rotational crop field trials. These trials, assessed in the approval assessment, concluded that residues of parent bixlozone above the LOQ of 0.01 mg/kg are expected in rotational crops. Data evaluated for the approval and a newly submitted study was considered. This new study led to the need for a more extensive rotational crop metabolite assessment considering the potential for metabolites and parent bixlozone to be formed. The applicant proposed to refine the 10 month plant back restriction (intended to keep levels of parent bixlozone in rotational crops to <0.01 mg/kg) outlined in the approval assessment to 9 months. It was concluded that a refined 9 month plant back restriction was acceptable; the wording of the label amendment outlined in the approval assessment is now also changed to reflect that the restriction now applies to all following crops (except cereals (including maize), oilseeds and pulses (dry seed) which do not need to be included in this restriction). The following restriction, related to bixlozone, must appear on the label:

*All rotational crops, except cereals (including maize), oilseeds and pulses (dry seed), must not be planted until at least 9 months after application of bixlozone.*

As the maximum dietary burden was less than the trigger value for further assessment (0.004 mg/kg bw/day) for all livestock, further consideration of the residues in animal commodities was not required. Although not required, metabolism of bixlozone 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.

Wheat and barley are non-melliferous crops. Based on the decision tree set out in SANTE/11956/2016 rev. 9 residues in honey are not expected where the substance is applied on a crop from which it is not possible to produce honey. Significant residues of bixlozone are also not expected in rotational crops based on the requested GAP and proposed 9 month plant back restriction. The restriction ensures residues of bixlozone and the metabolites in rotational crops will be <0.01 mg/kg.

The highest UK NEDI was <1% of the ADI (infant). The highest PRIMo IEDI was 0.5% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with bixlozone.

The highest UK NESTI was 0.1% of the ARfD (4-6 year old child/wheat). The highest PRIMo IESTI was 0.1% of the ARfD (children/wheat). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with bixlozone.

HSE concludes that sufficient data have been provided to support the setting of new MRLs for the representative uses of bixlozone on wheat and barley. These will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected.

Bixlozone is currently not included in the GB MRL Statutory Register therefore the default LOQ MRL of 0.01\* mg/kg currently applies to all residues of bixlozone for all commodities. HSE concludes that the MRLs outlined in Table 0.1 for products of plant origin are fully supported.

HSE also recommends that the MRLs for all other commodities are set at the default LOQ MRL which is 0.01\* mg/kg for most commodities. The full list of MRLs recommended by HSE is outlined in section 9, Table 9.1.

**Table 0.1 MRLs recommended by HSE**

| Product code                                                                              | Product | Existing GB MRL <sup>†</sup> (mg/kg) | New or amended GB MRL (mg/kg) | Comments                                                                          |
|-------------------------------------------------------------------------------------------|---------|--------------------------------------|-------------------------------|-----------------------------------------------------------------------------------|
| <b>Enforcement residue definition for products of plant origin: Bixlozone<sup>§</sup></b> |         |                                      |                               |                                                                                   |
| 0500010                                                                                   | Barley  | 0.01*                                | 0.01*                         | The MRL is sufficiently supported by data.<br><br>No health effects are expected. |
| 0500090                                                                                   | Wheat   | 0.01*                                | 0.01*                         | The MRL is sufficiently supported by data.<br><br>No health effects are expected. |

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

† Specific MRLs for bixlozone are not currently established in the GB MRL Statutory Register. In accordance with Article 18 of Assimilated Regulation 396/2005 the default LOQ MRL of 0.01\* mg/kg applies to residues of bixlozone

§ The residue definition for enforcement applies to the new/amended MRLs only



## Background

Assimilated Regulation 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 Assimilated Regulation 1107/2009 must be provided.

On 9 August 2023, HSE accepted an application from FMC Agro limited to set new MRLs for bixlozone in or on wheat and barley.

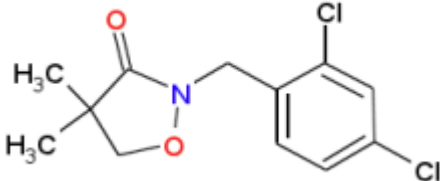
HSE evaluated the information submitted to uniform principles, as defined by Article 8 of Assimilated Regulation 396/2005 and prepared an Evaluation Report.

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

## The active substance and its use pattern

Information on the active substance bixlozone is outlined in Table 0.2.

**Table 0.2 Information on the active substance**

|                       |                                                                                     |
|-----------------------|-------------------------------------------------------------------------------------|
| Common name (ISO)     | Bixlozone                                                                           |
| Chemical name (IUPAC) | 2-[(2,4-dichlorophenyl)methyl]-4,4-dimethyl-1,2-oxazolidin-3-one                    |
| CAS number            | 81777-95-9                                                                          |
| Structural formula    |  |
| Molecular formula     | C <sub>12</sub> H <sub>13</sub> Cl <sub>2</sub> NO <sub>2</sub>                     |
| Molecular mass        | 274.14 g/mol                                                                        |

Bixlozone is an approved active substance in GB. A Competent Authority Conclusion is available (HSE, 2024b). MRLs are not currently established in the GB MRL Statutory Register.

Bixlozone is a herbicide. It inhibits carotenoid biosynthesis causing bleaching of weeds.

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

There are no CXLs available for bixlozone.

# Assessment

The assessment relevant to the setting of MRLs for bixlozone is outlined in the assessment report (HSE, 2024a) and Competent Authority Conclusion for the approval of the active substance (HSE, 2024b). The relevant areas of the assessment are summarised below but reference is made to the assessment report for the full assessment.

HSE also relied upon additional new data submitted by the applicant relevant to the proposed uses. These data are also summarised below and the detailed evaluation of the additional studies relied on is presented in Appendix C.

## 1 Methods of analysis

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

Analytical methods for the determination of bixlozone in products of plant origin, in line with the residue definition for enforcement, were assessed for the approval of the active substance (HSE, 2024a).

HPLC-MS/MS method CAM-0180 is validated for the high acid and high oil matrix groups and cereal straw (no group) with an LOQ of 0.01 mg/kg. Acceptable ILV data were provided. The method CAM-0180 is also validated for high water and high starch (dry commodities) with an LOQ of 0.01 mg/kg however, no acceptable ILV was available. This was highlighted in the Competent Authority Conclusion on the assessment of bixlozone (HSE, 2024b) as an area that required particular attention when evaluating applications for product authorisations:

- 1) *It is considered that the following areas require particular attention when evaluating applications for product authorisations:*
  - a) *Independent laboratory validation data for the method for the monitoring of residues in plants for the high water and high starch (dry) crop groups.*
  - b) *Validation and ILV of the method for the monitoring of residues in plants for the high protein crop group.*

A new HPLC-MS/MS method and ILV has been submitted and the full evaluation is presented in Appendix C.1.1.1. The new method CAM-0180/003 (version 3 of the method

considered for monitoring at active approval), and ILV, is validated and acceptable for the monitoring of bixlozone in high water, high starch (dry commodities) and high protein (dry commodities).

To conclude, the HPLC-MS/MS method CAM-0180 is validated for the high acid, high water, high starch (dry), high protein (dry) and high oil matrix groups and cereal straw (no group) with an LOQ of 0.01 mg/kg. Acceptable ILV data were provided.

Extraction efficiency was addressed in the AR (HSE, 2024a). The extraction procedures for the newly submitted version 3 of CAM-0180 are identical to those in version 002, which was considered for the active approval. Therefore, extraction efficiency is sufficiently addressed.

All components included in the enforcement residue definition are covered by the proposed method.

The commodities under consideration in the MRL application: Wheat and barley (high starch/ dry matrix groups) are covered by the analytical methods available.

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

Methods for enforcement and monitoring of residues in food of animal origin are not required. Based on the proposed uses residues in animal products will not be significant (will be < 0.01 mg/kg).

Based on the current consideration, residues for products of animal origin should be set at 0.01\* mg/kg on a default residue definition of bixlozone. The residue definitions for products of animal origin will need to be considered to establish substantive MRLs in products of animal origin.

## 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 bixlozone**

| TRVs | Source | Year | Value          | Study relied upon                               | Safety factor |
|------|--------|------|----------------|-------------------------------------------------|---------------|
| ADI  | GB     | 2024 | 0.3 mg/kg bw/d | Rat (oral), 90-day                              | 100           |
| ARfD | GB     | 2024 | 0.75 mg/kg bw  | Rat (oral gavage), developmental toxicity 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 wheat and rice (cereals), canola/oilseed rape (pulses and oilseeds) and sugar beet (root crops) for the approval of the active substance (HSE, 2024a).

A summary of the available primary crop metabolism data is presented below.

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

| Crop groups         | Crop(s)               | Applications                                                                                                                                                                      | DAT <sup>(a)</sup> (days)                           |
|---------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Root crops          | Sugar beet            | C: Foliar, 1 x 293 g a.s./ha, BBCH 09-11<br>P: Foliar, 1 x 298 g a.s./ha, BBCH 09-11                                                                                              | 28 (immature tops)<br>173 (mature tops and roots)   |
| Cereals/grass crops | Wheat                 | C: Foliar, 1 x 288 g a.s./ha, BBCH 09-11<br>P: Foliar, 1 x 307 g a.s./ha, BBCH 09-11                                                                                              | 28 (forage)<br>48 (hay)<br>ca. 60 (grain and straw) |
|                     | Rice                  | <u>Dry land rice</u><br>C & P: Foliar, 1 x 348 g a.s./ha, BBCH 13-14<br><u>Paddy rice</u><br>C: Foliar, 1 x 350 g a.s./ha, BBCH 13-14<br>P: Foliar, 1 x 344 g a.s./ha, BBCH 13-14 | 151-153 (grain and straw)                           |
| Pulses and oilseeds | Canola (oilseed rape) | C: Foliar, 1 x 276 g a.s./ha, BBCH 09-11<br>P: Foliar, 1 x 287 g a.s./ha, BBCH 09-11                                                                                              | 36 (forage)<br>70-71 (seed and straw)               |

(a) DAT where identification/characterisation of the residues has been investigated

C: carbonyl labelled

P: phenyl labelled

The sugar beet metabolism study was only considered as supporting information in the AR of bixlozone (HSE, 2024a). The proposal of residue definitions included a TTC assessment (for 2,2-dimethyl-3-hydroxy propionic acid (M118/1) and dimethyl malonic acid

(M132/1) metabolites found at significant levels in cereal crops) and only the intended uses were considered. Therefore, it was not possible to propose a universal residue definition (across all crops). However, the crops included in this MRL application belong to the cereal crop groups and are, therefore, covered by the metabolism studies and the TTC assessment available in the AR. The metabolism studies are suitable to support the proposed uses and have been carried out with an appropriate application rate and number of applications to support the GAP.

Based on the available data evaluated for the approval of the active substance the following residue definitions were proposed:

Residue definitions (HSE, 2024a)

Plant residue definition for enforcement (RD-Enf):

- Bixlozone

Plant residue definition for risk assessment (RD-RA):

- **For the intended (early application) use on oilseed rape, wheat, barley and maize:** Sum of residues of bixlozone and 2 x 2,4-dichlorobenzoic acid expressed as bixlozone

For the currently intended uses, the exposures to residues of two metabolites determined in significant amounts in cereal crop commodities, namely 2,2-dimethyl-3-hydroxy propionic acid (M118/1) and dimethyl malonic acid (M132/1), are below the TTC (for CCI, Cramer Class I). Therefore, these components are not included in the residue definition. For future assessed extension of uses, a reconsideration of the residue definition will be required. This will include a need of a recalculation of the exposure assessment versus the TTC for co-exposure of M118/1 and M132/1 if these metabolites are to remain excluded from the residue definitions. Alternatively, sufficient toxicological data must be provided to establish chemical specific reference values.

The new primary crop and rotational crop trials data do not result in a higher STMR value in grain for the TTC assessment when compared with the STMR considered at active approval. Therefore, an updated TTC is not required in this specific case.

The residue definitions for enforcement and risk assessment are applicable to the crops under consideration in the MRL application.

## 3.2 Magnitude of residues in primary crops

The uses notified in the MRL application are outlined in Appendix A.

### Residue trials

Thirteen wheat and barley trials evaluated in the AR were considered for the approval of the active substance. All thirteen trials were conducted using an SC formulation. Given the similarity of results across all trials for wheat and barley and for the trials for pre-emergence (BBCH 00-09) and post-emergence (BBCH 11-13), it was considered appropriate to combine the data (13 trials) for the uses on wheat and barley. Since application is before the edible part of the crop is present, extrapolation between wheat and barley is acceptable in accordance with SANCO 7525/VI/95 rev. 10.3.

All trials were conducted in geographical locations relevant to GB agricultural practices and climatic conditions and were conducted in accordance with the proposed GAP.

In the AR, the assessment was for intended uses on an SC, however the currently proposed authorised product 'Fundatis' is a ZC formulation.

Extrapolation between SC and ZC is not routinely undertaken (SANCO 7525/VI/95 rev. 10.3) without further assessment. ZC formulations are mixtures of SC and CS therefore, the SC part is directly covered by the trials data (same formulation type was used in the trials). However, CS is a controlled release formulation type and according to OECD 509:

*"Controlled release formulations (e.g., certain microencapsulated products) normally require a complete data set tailored to that particular use. Since these formulations are designed to control the release rate of the active ingredient, increased residues are possible compared to other formulation types."*

No trials on wheat or barley have been conducted using a CS or ZC formulation. However, CS trials on maize (a further cereal crop) as well as SC trials on maize were considered in the AR. A comparison of these data in the AR show there is not a significant difference between the results generated using either the 'SC' or 'CS' formulations. Additionally, there is a long harvest interval between application and commercial harvest. Taken together it would be unlikely that application with the proposed ZC formulation would lead to higher residues than for the SC formulation studied in trials on wheat and barley. Therefore, the 13 trials available on wheat and barley are relied on for the proposed use of 'Fundatis' on wheat and barley.

### 0500010 Barley

The proposed critical outdoor GAP in GB is 1 x 0.2 kg a.s./ha up to BBCH 09.

As outlined above, thirteen trials were considered for the approval of the active substance using an SC formulation.



All thirteen trials are suitable to support the proposed MRLs.

#### **0500090      Wheat**

The proposed critical outdoor GAP in GB is 1 x 0.2 kg a.s./ha up to BBCH 13.

As outlined above, thirteen trials were considered for the approval of the active substance using an SC formulation.

All thirteen trials are suitable to support the proposed MRLs.

Five additional field trials on wheat were undertaken using 'Fundatis' (ZC formulation) in the NEU (Northern France, Poland, Germany and the UK) in one season (Oct 2020 – Sept 2021). The nominal application rate in the trials was 1 x 0.2 kg a.s./ha, applied by foliar spray, at BBCH 11-13. Therefore, all trials were within 25% of the GAP. See Appendix C.3.1.2 for full evaluation of the trials.

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

Residues of bixlozone, 2,4-dichlorobenzoic acid (M190/1) and 5'-hydroxy-bixlozone (M289/3) in grain and straw were <0.01 mg/kg.

Residues of 2,2-dimethyl-3-hydroxy propionic acid (M118/1) in grain and straw ranged from <0.01 – 0.017 mg/kg and <0.05 – 0.076 mg/kg respectively

Residues of dimethyl-malonic acid (M132/1) in grain and straw were <0.02 – 0.05 mg/kg and 0.04 – 0.09 mg/kg respectively.

These new primary crop trials data do not result in a higher STMR value in grain for the TTC combined exposure assessment for M118/1 and M132/1 when compared with the STMR considered at active approval. Therefore, an updated TTC is not required.

Residues trial data for all relevant commodities are summarised in Table 3.2 below.

#### **Storage stability**

Stability of residues during storage of samples was considered in a number of crop matrices for the approval of the active substance (HSE, 2024a).

The available storage stability data considered for the approval of the active is not sufficient to support the proposed uses on wheat and barley, since data to support cereal grain were not available. The applicant has submitted new data to support wheat and barley (commodities containing a high water group, a high starch group and straw). A full evaluation of this data is presented in Appendix C.3.6.

A summary of the available storage stability data is presented below (HSE, 2024; and newly submitted stability study (as shown in **bold**)):

| Commodity group     | Commodity           | T (°C)      | Bixlozone stability (months) | 2,4-dichlorobenzoic acid stability (months) | 5-hydroxy-bixlozone stability (months) | 2,2-dimethyl-3-hydroxy propionic acid stability (months) |
|---------------------|---------------------|-------------|------------------------------|---------------------------------------------|----------------------------------------|----------------------------------------------------------|
| High oil            | Oilseed rape seed   | ≤-18        | 24                           | 24                                          | 18                                     | 24                                                       |
| High starch         | Potato tuber        | ≤-18        | 24                           | 24                                          | 18                                     | 24                                                       |
|                     | Radish root         | ≤-18        | -                            | -                                           | -                                      | -                                                        |
|                     | <b>Wheat grain</b>  | <b>≤-18</b> | <b>24</b>                    | <b>24</b>                                   | -                                      | <b>24</b>                                                |
| High water          | Leaf lettuce        | ≤-18        | -                            | -                                           | -                                      | -                                                        |
|                     | <b>Wheat forage</b> | <b>≤-18</b> | <b>24</b>                    | <b>24</b>                                   | -                                      | <b>24</b>                                                |
| High acid           | Grapes              | ≤-18        | 24                           | 24                                          | 18                                     | 24                                                       |
| <b>High protein</b> | <b>Dry beans</b>    | <b>≤-18</b> | <b>24</b>                    | <b>24</b>                                   | -                                      | <b>18</b>                                                |
| No group            | Wheat straw         | ≤-18        | 24                           | 24                                          | 18                                     | 24                                                       |

| Commodity group | Commodity         | T (°C) | 5'-hydroxy-bixlozone stability (months) | Bixlozone-dimethyl-malonamide stability (months) | Bixlozone-OH-isobutyramide stability (months) | 4-hydroxymethyl-bixlozone stability (months) |
|-----------------|-------------------|--------|-----------------------------------------|--------------------------------------------------|-----------------------------------------------|----------------------------------------------|
| High oil        | Oilseed rape seed | ≤-18   | 24                                      | -                                                | -                                             | -                                            |

|                     |                     |             |           |    |    |    |
|---------------------|---------------------|-------------|-----------|----|----|----|
|                     |                     |             |           |    |    |    |
| High starch         | Potato tuber        | ≤-18        | 24        | -  | -  | -  |
|                     | Radish root         | ≤-18        | -         | 24 | 24 | 24 |
|                     | Wheat grain         | ≤-18        | <b>24</b> | 24 | 24 | 24 |
| High water          | Leaf lettuce        | ≤-18        | -         | 24 | 24 | 24 |
|                     | <b>Wheat forage</b> | <b>≤-18</b> | <b>24</b> | -  | -  | -  |
| High acid           | Grapes              | ≤-18        | 24        | -  | -  | -  |
| <b>High protein</b> | <b>Dry beans</b>    | <b>≤-18</b> | <b>24</b> | -  | -  | -  |
| No group            | Wheat straw         | ≤-18        | 24        | 24 | 24 | 24 |

As the proposed uses are on wheat and barley (commodities containing a high water group, a high starch group and straw), the available storage stability data is sufficient to support residues trials for these crops where the samples are stored for up to 468 days (~15 months).

### Analytical methods

The methods used to analyse the samples, CAM-0154/001, CAM-0154/002 and CAM-0180/002, are the same methods considered in the AR (HSE, 2024a). All methods are considered satisfactorily validated in accordance with SANTE/2020/12830 rev. 1.

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

| <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: For the intended (early application) use on oilseed rape, wheat, barley and maize: Sum of residues of bixlozone and 2 x 2,4-dichlorobenzoic acid expressed as bixlozone (e)</b><br><b>RD-Enf: Bixlozone</b> |                                   |                                                                                                                                                      |                                                              |                                         |                                  |                                   |
| Wheat and barley                                                                                                                                                                                                      | GB/outdoor                        | Grain:<br>RD-Enf: 18 x <0.01<br><br>RD-RA: 17 x <0.039, 0.039 (human exposure assessment) [17 x <0.024, 0.024 (livestock dietary intake assessment)] |                                                              | 0.01*                                   | <0.039 (HR <sub>Enf</sub> <0.01) | 0.039 (STMR <sub>Enf</sub> <0.01) |
|                                                                                                                                                                                                                       |                                   | Straw:<br>RD-Enf: 18 x <0.01<br><br>RD-RA: 17 x <0.024, 0.05 (livestock dietary intake assessment)                                                   |                                                              | Not currently set for animal feed items | 0.05                             | <0.024                            |

(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:  $HR_{Enf}$ )
- (d) **STMR**: Supervised Trials Median Residue according to the residue definition risk assessment (within brackets when expressed according to the residue definition for enforcement:  $STMR_{Enf}$ )
- (e) The RD-RA is based on the early application uses assessed in the AR (HSE, 2024a) which included maize and oilseed rape, as well as wheat and barley.

### 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 therefore, a conversion factor should be proposed. However, as stated in the bixlozone LoEP (HSE, 2024c):

*“It is not possible to propose a conversion factor as mostly <LOQ residues of each analyte were observed in trials”*

Almost all of the trials contained residues of bixlozone and 2,4-dichlorobenzoic acid at a level of <0.01 mg/kg (<LOQ). OECD 2016 Guidance on Crop Field Trials states that, for the calculation of CFs, residue trials resulting in residue levels below the LOQ should not be taken into account. Therefore, it isn't possible to calculate a conversion factor.

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

#### 3.4.1 Nature of the residues in processed commodities

Data on the nature of parent bixlozone over high temperature hydrolysis conditions was assessed in the AR (HSE, 2024). The active substance was concluded to be stable under standard hydrolysis conditions simulating pasteurisation, boiling and sterilisation. A radiolabelled hydrolysis study was not available at that time for the metabolite 2,4-dichlorobenzoic acid.

Therefore, a data gap was set in the HSE Conclusion for bixlozone (HSE, 2024b) that should be considered when supporting cereal uses:

*“To support cereal uses, further data on the nature of residues of 2,4-dichlorobenzoic acid under standard hydrolysis conditions are needed. These data should be provided to support a product authorisation for cereal crops. It may be possible for an improved case for non-submission of such radiolabelled hydrolysis data for 2,4-dichlorobenzoic acid to be provided, however such a case would need to be detailed and sufficient to address the potential fate of the molecule 2,4-dichlorobenzoic acid. New data should be generated in accordance with OECD test guideline 507.”*

A hydrolysis study of 2,4-dichlorobenzoic acid under standard hydrolysis conditions has been submitted (see Appendix C.3.2.1 for full assessment). The hydrolysis data demonstrates that 2,4-dichlorobenzoic acid is stable under standard hydrolysis conditions simulating pasteurisation, boiling and sterilisation.

As both bixlozone and 2,4-dichlorobenzoic acid are stable across standard hydrolysis conditions, specific residue definitions for processed commodities are not required.

### 3.4.2 Magnitude of the residues in processed commodities

A summary of the available processing studies for bixlozone relevant to this assessment is presented below (HSE, 2024a). No new studies have been submitted within this evaluation. Only a limited number of processing factors were established, especially due to the low residues and consequent uncertainty in the derivation of processing factors. However, based on the levels of residues expected to arise following the currently proposed uses in cereals provision of further data is not required at present. Data might be needed to support more robust processing factors covering all possible analytes of the RD-RA if proposed future uses were to lead to higher levels of residues.

All Pfs that were derived were considered as indicative only therefore, it is not recommended that the Pfs are included in Part 6 of the GB MRL Statutory Register.

**Table 3.4.2 Overview of the available processing studies**

| Crop (RAC) / processed product | Number of trials | Processing factor (Pf)                   |           | CF                                                                                                      |
|--------------------------------|------------------|------------------------------------------|-----------|---------------------------------------------------------------------------------------------------------|
|                                |                  | Individual values                        | Median Pf |                                                                                                         |
| Wheat / fine bran              | 1                | 0.17 (RD-RA)                             | 0.21      | Not proposed as a number of analytes having <0.01 mg/kg residues. (all the PF are uncertain/indicative) |
| Wheat / coarse bran            | 1                | 1.58 (RD-RA)                             | 1.58      |                                                                                                         |
| Wheat / total bran             | 2                | 1.13, 0.93 (RD-RA)                       | 1.03      |                                                                                                         |
|                                | 1                | 0.82 (RD-Enf)                            | 0.82      |                                                                                                         |
| Barley / malt sprouts          | 1                | 1.49 (RD-RA)<br>RD-Enf cannot be derived | 1.49      |                                                                                                         |

## 3.5 Rotational crops

The available data (HSE LoEP, 2024c) indicate that bixlozone could be persistent in soil as the  $DT_{90} \geq 100$  days ( $DT_{90} = 819$  days, based on  $DT_{50}$  of 247 days) and therefore potential residues in rotated crops must be considered. The available data (HSE LoEP, 2024c) also suggests that accumulation of bixlozone residues in the soil following multiple

applications of active must be considered because the parent  $DT_{50} > 150$  days ( $DT_{50} = 247$  days).

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

Metabolism in rotational crops was investigated following bare soil treatment in radish (root and tuber vegetables), lettuce (leafy vegetables) and wheat (cereals) for the approval of the active substance (HSE, 2024a).

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

| Crop groups        | Crop(s) | PBI (days)    | Comments                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------|---------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Root crops         | Radish  | 30, 120 & 310 | Trials conducted with an application at 269-281 g a.s./ha (phenyl label) or 278-288 g a.s./ha (carbonyl label) on bare soil (1.35N wheat and barley GAPs).<br><br>Immature lettuce for the phenyl label was collected from a low rate (circa 100 g as/ha applied to bare soil) application as phytotoxicity was observed in the high rate (circa 300 g /ha applied to bare soil) lettuce 30 DAT plots. |
| Leafy crops        | Lettuce | 63, 153 & 310 |                                                                                                                                                                                                                                                                                                                                                                                                        |
| Cereal/grass crops | Wheat   | 30, 120 & 310 |                                                                                                                                                                                                                                                                                                                                                                                                        |

**Comments:** Bixlozone is extensively metabolised in rotational crops. Main rotational crop metabolites were tested in follow on field trials in the AR (HSE, 2024a) – further to these data it is not expected that residues of metabolites will be present in rotational crops as a result of the intended uses. However it was noted that it would be advisable, in future, to test for metabolites as well as parent in further rotational crops studies, especially in regard of increased application rates (Vol 1 of the AR (HSE, 2024a)):

*“In consideration of any future extensions of uses with increased application rates, it would be desirable for new trials to be generated. In these trials bixlozone must be included (as the main marker compound for rotational crops), however we suggest that the trials should also analyse for the main rotational crop metabolites.*

*As such, HSE propose that only parent bixlozone needs to currently be included in the proposal for residue definitions to cover rotational crops.”*



Metabolism in rotational crops was found to be via a similar pathway to primary crops.

The metabolism studies demonstrate that residues of parent bixlozone in rotational crops are expected to be >0.01 mg/kg in all crop fractions. On this basis consideration of rotational crop trials is required.

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

Residues in rotational crops were investigated following primary crop (maize) treatment in radish (root and tuber vegetables), lettuce (leafy vegetables) and wheat (cereals) for the approval of the active substance (HSE, 2024a). The metabolites sought in the samples from the treated plots were <0.01 mg/kg at all plant back intervals. Residue levels of bixlozone were <0.01 mg/kg, with the exception of two low positive residues of bixlozone detected in the 229 day PBI samples for radish tops and immature lettuce leaves (0.013 and 0.011 mg/kg respectively).

A label re-plant restriction of 10 months for leafy crops and above ground vegetables was proposed during the active approval with the aim of ensuring residues of bixlozone are below 0.01 mg/kg. However, it was stated that further trials data could be generated to further refine the plant-back interval.

Bixlozone is persistent in soil and has the potential to accumulate, as confirmed by fate and behaviour evaluation (Part B8, Volume 3 of the AR (HSE, 2024a), according to OECD 2018 Guidance Document on Rotational Crops. Therefore, the accumulation of residues in the soil following multiple applications of bixlozone must be considered.

The application rate needed in the rotational crop studies to account for likely total soil residues from long term use and crop failure ( $A_{total}$ ) would need to be 312.04 g a.s./ha. A summary of how this was calculated can be seen in the fate and behaviour evaluation of the AR (HSE, 2024a). This  $A_{total}$  is for wheat and barley, the currently proposed uses. A different  $A_{total}$  was used for the assessment in the AR (HSE, 2024), as it considered a more critical use – maize. A higher seasonal application rate was proposed for maize than is currently being considered for the use on wheat and barley.

The application rate of 312.04 g a.s./ha needed is higher than the application rate used in the rotational crop study in the AR (HSE, 2024a). The application rate used in the rotational crop studies was underdosed (0.87N). This value was calculated taking into account the presence of a maize crop (BBCH 11-13) as a primary crop at the time of treatment with bixlozone in the rotational crop study and an assumption of an interception rate of 10% for maize at this growth stage. According to the proposed uses the earliest application timing for the intended use on cereals is BBCH 00 therefore, no interception will occur and the  $A_{total}$  value would remain the same. As this is higher than the application rate used in the rotational crop study, additional consideration is needed.

The majority of results are <LOQ therefore, it is not possible to scale up the results to estimate the expected residue levels following an application intended to represent the  $A_{\text{total}}$  for each proposed use, noting that the degree of underdosing is at 0.87N. However, there were two positive results for bixlozone at 229-day PBI in lettuce (0.011 mg/kg) and radish leaves (0.013 mg/kg) that can be scaled. Given there are only two positive residue data points, and as bixlozone has an ARfD proposed and it is necessary to conduct an acute exposure assessment, it is reasonable to scale up the higher of these two data points, giving an estimated highest residue of 0.015 mg/kg for leafy crops based on the currently intended uses on wheat and barley.

As positive residues may be found in leafy crops grown in rotation, further consideration of either MRLs to accommodate these possible residues or a plant back restriction to mitigate any possible positive residues was made in the AR (HSE, 2024a). It was concluded in the AR that recommending a plant back restriction of 10 months was the most reasonable option with further consideration, based on residue trials supporting all crop groups, being required to refine or remove this restriction.

A new rotational crop field trial was submitted to refine the plant back restriction from 10 months to 9 months (see Appendix C.3.3.2 for full study details). The study was conducted at a higher application rate of 528 g a.s./ha. Residues in rotational crops were investigated following bare soil treatment in radish (root and tuber vegetables), spinach (leafy vegetables) and wheat (cereals). An overall summary on the new rotational crop field study is presented in Table 3.5.2-1 below.

**Table 3.5.2-1 Summary of the new field rotational crop study**

| Crop group  | Crop    | Application |           |                              | Residue levels (mg/kg)                              |                                       |                                       |                                              |                                              |                                              |
|-------------|---------|-------------|-----------|------------------------------|-----------------------------------------------------|---------------------------------------|---------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|
|             |         | PBI (day)   | g a.s./ha | on bare soil or primary crop | Bixlozone                                           | 2,4-dichlorobenzoic acid              | 5'-hydroxy-bixlozone                  | Bixlozone-dimethyl malonamide                | Dimethylmalonic acid                         | Bixlozone-hydroxy-isobutyramide              |
| Root crops  | Radish  | 30          | 528       | Bare soil                    | Leaves: 2 x <0.01, 0.019, 0.049<br>Roots: 4 x <0.01 | Leaves: 4 x <0.01<br>Roots: 4 x <0.01 | Leaves: 4 x <0.01<br>Roots: 4 x <0.01 | Leaves: 4 x <0.01<br>Roots: 4 x <0.01        | Leaves: 4 x <0.02<br>Roots: 4 x <0.02        | Leaves: 4 x <0.01<br>Roots: 4 x <0.01        |
|             |         | 60          |           |                              | Leaves: 3 x <0.01, 0.11<br>Roots: 3 x <0.01, 0.018  | Leaves: 4 x <0.01<br>Roots: 4 x <0.01 | Leaves: 4 x <0.01<br>Roots: 4 x <0.01 | Leaves: 3 x <0.01, 0.019<br>Roots: 4 x <0.01 | Leaves: 3 x <0.02, 0.022<br>Roots: 4 x <0.02 | Leaves: 3 x <0.01, 0.017<br>Roots: 4 x <0.01 |
|             |         | 280         |           |                              | Leaves: 3 x <0.01, 0.013<br>Roots: 4 x <0.01        | Leaves: 4 x <0.01<br>Roots: 4 x <0.01 | Leaves: 4 x <0.01<br>Roots: 4 x <0.01 | Leaves: 4 x <0.01<br>Roots: 4 x <0.01        | Leaves: 4 x <0.02<br>Roots: 4 x <0.02        | Leaves: 4 x <0.01<br>Roots: 4 x <0.01        |
| Leafy crops | Spinach | 30          | 528       | Bare soil                    | Immature: 3 x                                       | Immature: 4 x <0.01                   | Immature: 4 x <0.01                   | Immature: 3 x <0.01, 0.017                   | Immature: 3 x <0.02, 0.02                    | Immature: 4 x <0.01                          |

|                     |       |     |     |           |                                                                            |                                                                                  |                                                                                   |                                                                                  |                                                                                                                  |                                                                                  |
|---------------------|-------|-----|-----|-----------|----------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
|                     |       |     |     |           | <0.01, 0.013<br>Mature: 2 x <0.01, 0.01                                    | Mature: 3 x <0.01                                                                | Mature: 3 x <0.01                                                                 | Mature: 2 x <0.01, 0.019                                                         | Mature: 2 x <0.02, 0.021                                                                                         | Mature: 3 x <0.01                                                                |
|                     |       | 60  |     |           | Immature: 4 x <0.01<br>Mature: 3 x <0.01                                   | Immature: 4 x <0.01<br>Mature: 3 x <0.01                                         | Immature: 4 x <0.01<br>Mature: 3 x <0.01                                          | Immature: 2 x <0.01, 0.016, 0.021<br>Mature: <0.01, 0.011, 0.022                 | Immature: 4 x <0.02<br>Mature: 2 x <0.02, 0.026                                                                  | Immature: 4 x <0.01<br>Mature: 3 x <0.01                                         |
|                     |       | 280 |     |           | Immature: 4 x <0.01<br>Mature: 3 x <0.01                                   | Immature: 4 x <0.01<br>Mature: 3 x <0.01                                         | Immature: 4 x <0.01<br>Mature: 3 x <0.01                                          | Immature: 3 x <0.01, 0.013<br>Mature: 3 x <0.01                                  | Immature: 4 x <0.02<br>Mature: 3 x <0.02                                                                         | Immature: 4 x <0.01<br>Mature: 3 x <0.01                                         |
| Cereals/Grass crops | Wheat | 30  | 528 | Bare soil | Whole plant: 3 x <0.01, 0.014<br>Hay: 3 x <0.01, 0.012<br>Grain: 4 x <0.01 | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 4 x <0.01 | Whole plant: 3 x <0.01, 0.036<br>Hay: 2 x <0.01, 0.014, 0.019<br>Grain: 4 x <0.01 | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 4 x <0.01 | Whole plant: 3 x <0.02, 0.03<br>Hay: 2 x <0.02, 0.03, 0.13<br>Grain: 3 x <0.02, 0.025<br>Straw: 3 x <0.02, 0.086 | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 4 x <0.01 |

|  |  |     |  |  |                                                                                               |                                                                                         |                                                                                                                       |                                                                                  |                                                                                                                    |                                                                                  |
|--|--|-----|--|--|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
|  |  |     |  |  | Straw: 4 x <0.01                                                                              |                                                                                         | Straw: 0.014, 0.018, 0.035, 0.037                                                                                     |                                                                                  |                                                                                                                    |                                                                                  |
|  |  | 60  |  |  | Whole plant: 2 x <0.01, 0.01, 0.014<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 4 x <0.01 | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 3 x <0.01, 0.015 | Whole plant: 3 x <0.01, 0.026<br>Hay: 2 x <0.01, 0.011, 0.02<br>Grain: 4 x <0.01<br>Straw: 0.013, 0.015, 0.044, 0.057 | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 4 x <0.01 | Whole plant: 3 x <0.02, 0.044<br>Hay: 2 x <0.02, 0.027, 0.12<br>Grain: 3 x <0.02, 0.034<br>Straw: 3 x <0.02, 0.076 | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 4 x <0.01 |
|  |  | 280 |  |  | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 4 x <0.01              | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 4 x <0.01        | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 3 x                                            | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 4 x <0.01 | Whole plant: 3 x <0.02, 0.038<br>Hay: 2 x <0.02, 0.03, 0.12<br>Grain: 3 x <0.02, 0.029<br>Straw: 3 x <0.02, 0.049  | Whole plant: 4 x <0.01<br>Hay: 4 x <0.01<br>Grain: 4 x <0.01<br>Straw: 4 x <0.01 |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|  |  |  |  |  |  |  |                 |  |  |  |
|--|--|--|--|--|--|--|-----------------|--|--|--|
|  |  |  |  |  |  |  | <0.01,<br>0.012 |  |  |  |
|--|--|--|--|--|--|--|-----------------|--|--|--|

The application rate used in the new rotational crop field study is higher than the  $A_{\text{total}}$  of 312.04 g a.s./ha. Therefore, the trials are dosed at a level which is worst case with respect to the expected level of bixlozone in soil.

Whilst many findings were <0.01 mg/kg, the rotational crop residues trials demonstrated residues >0.01 mg/kg for all analytes in various commodities and replant timings. The application rate in the trials is significantly greater than (1.69N) the application rate needed following the GAP (taking account of the potential for long term soil accumulation). The results that are <LOQ are still estimated as <0.01 mg/kg following an application intended to represent the  $A_{\text{total}}$  for each proposed use. The positive results were scaled down. Following scaling, some residues are <LOQ but some positive residues remain (these are shown in Table 3.5.2-2 to Table 3.5.2-4 below). These results show higher anticipated residues of bixlozone and metabolites in rotational crops compared to the data considered previously in the approval assessment. Based on the maize GAP (HSE, 2024a), the application rates were higher, but a scaled highest residue of 0.028 mg/kg bixlozone for leafy crops was indicated (without a replant restriction). Now the application rate for wheat and barley is lower, however a (scaled) highest residue of 0.065 mg/kg of bixlozone in leafy crops is indicated. With the information from the newly evaluated trials, with no replant restriction, residues of metabolites could also be anticipated.

**Table 3.5.2-2 Positive residue levels following scaling to  $A_{\text{total}}$  in radish**

| Crop part | PBI (days) | Residue levels following scaling to $A_{\text{total}}$ (g a.s./ha) |                               |
|-----------|------------|--------------------------------------------------------------------|-------------------------------|
|           |            | Bixlozone                                                          | Bixlozone-dimethyl malonamide |
| Leaves    | 30         | 0.011, 0.029                                                       | -                             |
|           | 60         | 0.065                                                              | 0.011                         |
| Roots     | 60         | 0.011                                                              | -                             |

**Table 3.5.2-3 Positive residue levels following scaling to  $A_{\text{total}}$  in spinach**

| Crop            | PBI (days) | Residue levels following scaling to $A_{\text{total}}$ (g a.s./ha) |
|-----------------|------------|--------------------------------------------------------------------|
|                 |            | Bixlozone-dimethyl malonamide                                      |
| Immature leaves | 30         | 0.01                                                               |
|                 | 60         | 0.012                                                              |
| Mature leaves   | 30         | 0.011                                                              |
|                 | 60         | 0.013                                                              |

**Table 3.5.2-4 Positive residue levels following scaling to A<sub>total</sub> in wheat**

| Crop        | PBI (days) | Residue levels following scaling to A <sub>total</sub> (g a.s./ha) |                      |
|-------------|------------|--------------------------------------------------------------------|----------------------|
|             |            | 5'-hydroxy-bixlozone                                               | Dimethylmalonic acid |
| Whole plant | 30         | 0.021                                                              | -                    |
|             | 60         | 0.015                                                              | 0.026                |
|             | 280        | -                                                                  | 0.022                |
| Hay         | 30         | 0.011                                                              | 0.077                |
|             | 60         | 0.012                                                              | 0.071                |
|             | 280        | -                                                                  | 0.071                |
| Grain       | 30         | -                                                                  | -                    |
|             | 60         | -                                                                  | 0.020                |
| Straw       | 30         | 0.011, 0.021, 0.022                                                | 0.051                |
|             | 60         | 0.026, 0.034                                                       | 0.045                |
|             | 280        | -                                                                  | 0.029                |

The rotational crop residues trials demonstrated residues are expected to be >0.01 mg/kg for bixlozone and some of its metabolites in radish, spinach and wheat. On this basis consideration of potential residues in rotational crops is required.

As stated previously, HSE had detailed that further trials data could be generated to further refine the plant-back interval of 10 months. The new trials were submitted to better understand the rotational crop residues for bixlozone and the potential for metabolites to form, and as evidence to reduce the plant-back interval to 9 months.

In the AR (HSE, 2024a) it was stated that bixlozone was the most suitable indicator of residues for crops grown in rotation. However, it was also stated that if significant residues of bixlozone are found, it may also be necessary to consider the potential for metabolite residues to also be found. There are significant residues of bixlozone found in radish leaves (leafy crops) and radish roots (root and tuber crops).

The applicant suggested a replant restriction of 9 months before replanting of following crops to apply to leafy crops and root and tuber vegetable crops. The new rotational crop study assessed leafy crops (spinach and radish tops), radish roots and cereals only. In view of other potential crops that could be grown in rotation, and the new data showing higher anticipated residues of bixlozone and metabolites, HSE considers that the 9 month replant restriction should apply to all crops except cereals (including maize), oilseeds and



pulses (dry seed). With such a restriction, no residue levels of bixlozone above the LOQ are expected. Therefore, no further consideration of bixlozone is required. Provided there is a suitable replant restriction of 9 months to elapse after application of bixlozone before planting of following crops (except cereals and oilseeds/dry pulses - see below), then residues of bixlozone would not be expected to arise the following crops.

Additionally, there were significant residues of some metabolites found in radish, spinach and wheat. Similarly to bixlozone, all metabolites (except for dimethylmalonic acid (M132/1) in cereal grain) will not exceed 0.01 mg/kg in commodities for human consumption when considering the proposed plant back restriction.

In grain, the metabolite dimethylmalonic acid (M132/1) was found at significant levels (0.02 mg/kg) at 280 days (~9 months). This level found in the rotational crops is well below the level assessed in the AR for the TTC assessment of this metabolite allowing for the anticipated residue of M132/1 as a primary crop residue in grain (an STMR level of 0.09 mg/kg of M132/1 was assessed in the TTC assessment in grain in the AR). Therefore, in terms of consumer exposure (human dietary intake), metabolite M132/1 does not need further consideration and the 9 month replant restriction for following crops is not needed to limit this residue in cereal grain when cereals are grown as a following crop, which is in contrast to other crops grown in rotation.

Considering cereals grown as a following crop and potential for metabolites to be found in feed items: metabolite 5'-hydroxy-bixlozone was estimated (scaled residue) as a rotational crop residue in cereal crops at levels up to 0.021 in whole plant, 0.012 mg/kg in hay, and 0.034 mg/kg in straw; dimethylmalonic acid (M132/1) was estimated (scaled residue) at levels up to 0.026 mg/kg in whole plant, 0.077 mg/kg in hay, and 0.051 mg/kg in straw.

Please see section 4 below which outlines HSE's consideration that these metabolites do not need to be considered further in the livestock dietary burden, and as such the 9 month restriction proposed for rotational crops, does not need to apply to cereals at this time.

Rotational crop data that specifically addresses rotational crops such as oilseeds and pulses are not available. However, considering both the canola (oilseed rape) primary crop (early post-emergence) metabolism data and residue trials data on oilseed rape it can be concluded that oilseeds, extrapolated to pulses (dry seed), can be removed from the restriction.

The primary crop metabolism data on canola (oilseed rape), considered at active approval (HSE, 2024a), was an early post emergence study and showed that all residues of bixlozone and metabolites are <0.01 mg/kg (<LOQ) in seeds. The metabolism data in the AR (HSE, 2024a) also indicated, in both radiolabels, that individual residues (parent or metabolites) in oilseed rape forage and straw would be present at only low levels (<0.005 mg/kg for individual metabolites, except for M118/1 which was found at a low level of 0.023 mg/kg in straw). Additionally, in the oilseed rape residue field trials (7 NEU trials

presented in the AR, HSE, 2024a), all levels of bixlozone and the metabolites sought (M289/3, M118/1 and M190/1) are  $<0.01$  mg/kg ( $<LOQ$ ) in seeds. New primary crop oilseed rape trials have been submitted in an application for authorisation of a different bixlozone containing product. Whilst these new trials using a different ZC formulation have only been briefly considered at this stage, these trials (analysing only for bixlozone, M289/3 and M190/1) also support the view that the metabolites tested will be below the LOQ in oilseed rape seeds. Therefore, it is reasonable to consider that residues of bixlozone would not exceed the LOQ of 0.01 mg/kg in the harvested oilseed (seed) when oilseed rape is planted as a following crop and residue levels in oilseed forage and straw would be very low. According to the OECD 2018 Guidance, data on oilseeds (dry seed) can be extrapolated to all oilseeds and pulses (dry seed). Therefore, oilseeds and pulses (dry seed) do not need to be included in the plant back restriction. The extrapolation cannot be extended to legumes at this time as metabolite M118/1 was found at significant levels (1.3 and 2.2 mg/kg) in immature pods in some of the oilseed rape field trials considered at active approval.

## Conclusion

The rotational crop residues trials demonstrated residues are expected to be  $>0.01$  mg/kg for bixlozone and some of its metabolites. However, the applicant has proposed a refined plant back restriction of 9 months for leafy crops and root and tuber vegetables grown in rotation to ensure that residues of bixlozone (and its metabolites) are not present in livestock feed commodities.

Whilst the levels of residues in the newly submitted rotational crop study are higher at earlier replant intervals (e.g. 60 DAT) than seen before in the AR (HSE, 2024a), and include some positive residues of metabolites, the data does support the principle that a label restriction to restrict replanting of some following crops until 9 months after application of bixlozone would be anticipated to avoid residues of parent bixlozone or metabolites being found in most rotational crops. The AR (HSE, 2024a) concluded that this restriction would be needed for leafy crops and other above ground green plants. Based on the new rotational crop residue trial data that shows the metabolites may be found in a range of crops and using data from the early post emergence primary crop residues studies on oilseed rape, HSE considers that the replant restriction should apply to all rotational crops, except for cereals (including maize), oilseeds and pulses (dry seed). The rotational crop data available are limited to leafy, root crops and cereals, and there is not sufficient data to fully address rotational crop residues in crops such as legumes, broccoli, potatoes and leeks.

The newly submitted rotational crops field trial study shows that all residue levels, except for residues in cereals, are  $<LOQ$  at the 280 day PBI (~9 months) when scaled to an application rate intended to represent the  $A_{total}$ .

The assessment in this rotational crop section on cereals concludes that the highest finding of dimethyl malonic acid (M132/1) in grain at 0.02 mg/kg was at a replanting time of 280 days (~9 months) and is within the level of the TTC assessment that was performed in the AR (HSE, 2024a). Furthermore, based on the levels of rotational crop residues of 5'-hydroxy-bixlozone (M289/3) and M132/1 found in other cereal feed items at all replant timings, it is proposed that no further consideration of these in the livestock dietary burden is needed at this time (see section 4).

The assessment in this rotational crop section on oilseed rape concludes that metabolism and trials data for early post-emergence treatment using bixlozone on oilseed rape (HSE, 2024a), show that all residues in oilseed rape seed and forage and straw will be <LOQ. These data can be extrapolated to other oilseeds and dry (seed) pulses.

A label re-plant restriction is proposed:

*“All rotational crops, except cereals (including maize), oilseeds and pulses (dry seed), must not be planted until at least 9 months after application of bixlozone”.*

Since residues of parent and metabolites have been detected in the rotational crop field trials, HSE recommends that any new field rotational crop residues trials for future extensions of uses or to further refine the replant restriction must cover parent and metabolites, and also consider a wider range of commodities, as per the Tier 3 'super crop group' approach (as recommended in OECD Guidance on Residues in Rotational Crops, 2018). In addition, as the new data demonstrates that positive residues of various metabolites may be found in rotational crops, additional data and information are likely to be required to establish suitable residue definitions and MRLs for rotational crops.

## 4 Residues in livestock

### 4.1 Dietary burden

The dietary burden calculation has 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.

The proposed uses in this evaluation are within the uses considered in the AR (HSE, 2024a). In the new primary crop trials, residues of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone in grain and straw were <0.01 mg/kg. Residues of 2,2-dimethyl-3-hydroxy propionic acid (M118/1) and dimethyl-malonic acid (M132/1) in grain and straw in these trials were within the levels assessed in the AR. Therefore, reference is initially made to the dietary burdens estimates for the approval of the active substance.

In the dietary burden assessment undertaken in the AR, several inputs (all above ground vegetables and possible 'leafy' crops) were included to give a worst case indicative estimate, given the possibility of positive residues in leafy crops grown in rotation. In the current assessment, it is also indicated that a plant back restriction should also apply to all rotational crops except cereals (including maize), oilseeds and pulses (dry seed), in order to keep rotational residues of bixlozone below the LOQ. With the proposed plant back restriction in place, residues of bixlozone above the LOQ would not be expected in crops grown in rotation. Therefore, the dietary burden has been reassessed in this evaluation to remove the inclusion of rotational crop inputs. Input values are taken from the GB AR (HSE, 2024a) and are summarised in Table 4.1-1 below. The estimated animal intakes are summarised in Table 4.1-2.

Considering cereals grown as a following crop and potential for metabolites to be found in feed items as rotational crop residues, HSE has not included the following metabolites in the livestock dietary burden for these potential rotational crop residues in feed items for the following reasons:

Metabolite 5'-hydroxy-bixlozone (M289/3) was estimated (scaled residue) as a rotational crop residue in cereal crops at levels up to 0.021 in whole plant, 0.012 mg/kg in hay, and 0.034 mg/kg in straw. Considering straw the findings in rotational crops ranged from <0.01 mg/kg (7 samples), 0.011, 0.021, 0.022, 0.026 up to 0.034 mg/kg metabolite, these levels are similar to the levels considered for metabolite 5'-hydroxy-bixlozone in the primary crops assessment in the AR (12 x <0.01 mg/kg and 1 x 0.015 mg/kg), when the livestock dietary burden was considered. In the AR it was concluded that *“based on its low prevalence in trials, this metabolite is considered unlikely to contribute significantly to the overall dietary burden and it is not proposed to include it in the residue definition for risk assessment or in the livestock dietary assessment”*. It is considered that this conclusion is still valid based on the low level findings. Metabolite 5'-hydroxy-bixlozone was found <0.01 mg/kg in cereal grain in rotational crops.

Dimethylmalonic acid (M132/1) was estimated (scaled residue) as a rotational crop residue in cereal crops at levels up to 0.026 mg/kg in whole plant, 0.077 mg/kg in hay, and 0.051 mg/kg in straw. These levels are within the level (0.26 mg/kg M132/1 in straw) that was considered in the AR for M132/1, since the findings of M132/1 were considered to occur at similar levels to the findings of M118/1 in cereals. The highest primary crop residue in trials for M118/1 in straw was 0.26 mg/kg in the AR. In consideration of livestock dietary burden it was concluded in the AR that *“M118/1 and M132/1 in products of animal origin are not expected to be of concern”*. In grain, the residue of M132/1 found (as a rotational crop residue) of 0.02 mg/kg is well within the level assessed in the AR using the TTC approach as stated in section 3.5.2.

**Table 4.1-1 Input values for the dietary burden calculation**

| Feed commodity                                                                                                                  | Median dietary burden |                   | Maximum dietary burden |                 |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------|-------------------|------------------------|-----------------|
|                                                                                                                                 | Input (mg/kg)         | Comment           | Input (mg/kg)          | Comment         |
| <b>Risk assessment residue definition:</b> Sum of bixlozone and 2,4-dichlorobenzoic acid, expressed as bixlozone. <sup>\$</sup> |                       |                   |                        |                 |
| Barley straw                                                                                                                    | 0.024                 | STMR (HSE, 2024a) | 0.05                   | HR (HSE, 2024a) |
| Corn, field, stover                                                                                                             | 0.024                 | STMR (HSE, 2024a) | 0.024                  | HR (HSE, 2024a) |

| Feed commodity                                                          | Median dietary burden |                                                   | Maximum dietary burden |                 |
|-------------------------------------------------------------------------|-----------------------|---------------------------------------------------|------------------------|-----------------|
|                                                                         | Input (mg/kg)         | Comment                                           | Input (mg/kg)          | Comment         |
| Corn, pop, stover                                                       | 0.024                 | STMR (HSE, 2024a)                                 | 0.024                  | HR (HSE, 2024a) |
| Wheat straw                                                             | 0.024                 | STMR (HSE, 2024a)                                 | 0.05                   | HR (HSE, 2024a) |
| Triticale straw                                                         | 0.024                 | STMR (HSE, 2024a)                                 | 0.05                   | HR (HSE, 2024a) |
| Barley grain                                                            | 0.024                 | STMR (HSE, 2024a)                                 | -                      | -               |
| Corn, field (maize), grain                                              | 0.024                 | STMR (HSE, 2024a)                                 | -                      | -               |
| Corn, pop, grain                                                        | 0.024                 | STMR (HSE, 2024a)                                 | -                      | -               |
| Wheat grain                                                             | 0.024                 | STMR (HSE, 2024a)                                 | -                      | -               |
| Triticale grain                                                         | 0.024                 | STMR (HSE, 2024a)                                 | -                      | -               |
| Brewer's grain (dried)                                                  | 0.024                 | STMR (barley grain) x PF <sup>†</sup>             | -                      | -               |
| Canola (rape seed) meal                                                 | 0.024                 | STMR (rape meal) x PF <sup>†</sup> (HSE, 2024a)   | -                      | -               |
| Corn, field (milled by-products, hominy meal, gluten feed, gluten meal) | 0.024                 | STMR (maize grain) x PF <sup>†</sup> (HSE, 2024a) | -                      | -               |
| Distiller's grain (dried)                                               | 0.024                 | STMR (wheat grain) x PF <sup>†</sup> (HSE, 2024a) | -                      | -               |
| Rape meal                                                               | 0.024                 | STMR (rape seed) x PF <sup>†</sup> (HSE, 2024a)   | -                      | -               |
| Wheat gluten (meal)                                                     | 0.024                 | STMR (wheat grain) x PF <sup>†</sup> (HSE, 2024a) | -                      | -               |
| Wheat (milled by-products)                                              | 0.024                 | STMR (wheat grain) x PF <sup>†</sup> (HSE, 2024a) | -                      | -               |

† PF = 1; the use of default processing factors (PF) is not required as residues in the RAC are <LOQ.

§ the 2 x factor is to account for the relative toxicological potency compared to parent bixlozone. To express 2,4-dichlorobenzoic acid as bixlozone equivalence a molecular weight conversion of 1.435 also has to be applied. This then gives an overall factor of 2.87 to be applied to the level of 2,4-dichlorobenzoic acid. It should be noted that this 2 x factor is only required in assessments comparing to the toxicological endpoints for bixlozone, i.e., this additional 2 x factor has not been used in the animal dietary burden estimate of exposure as this is an estimate of livestock dietary intakes, rather than comparison with a toxicological endpoint.

**Table 4.1-2 Estimated animal intakes**

| <b>Animal</b>        | <b>Median burden (mg/kg bw)</b> | <b>Maximum burden (mg/kg bw)</b> | <b>&gt;0.004 mg /kg bw/d (Y/N)</b> | <b>Maximum burden (mg/kg DM)</b> | <b>Highest contributing commodity<sup>(a)</sup></b> |
|----------------------|---------------------------------|----------------------------------|------------------------------------|----------------------------------|-----------------------------------------------------|
| Cattle (all diets)   | 0.001                           | 0.002                            | N                                  | 0.05                             | Corn, field (gluten feed)                           |
| Cattle (dairy only)  | 0.001                           | 0.002                            | N                                  | 0.05                             | Corn, field (gluten feed)                           |
| Sheep (all diets)    | 0.002                           | 0.002                            | N                                  | 0.05                             | Corn, field (gluten feed)                           |
| Sheep (ewe only)     | 0.001                           | 0.002                            | N                                  | 0.05                             | Corn, field (gluten feed)                           |
| Swine (all diets)    | 0.001                           | 0.001                            | N                                  | 0.03                             | Corn, field (milled by products)                    |
| Poultry (all diets)  | 0.002                           | 0.002                            | N                                  | 0.03                             | Wheat straw                                         |
| Poultry (layer only) | 0.002                           | 0.002                            | N                                  | 0.03                             | Wheat straw                                         |

(a) Considering the maximum dietary animal burden



Based on the dietary burden calculations, consideration of the likely residues in products of animal origin for ruminants and poultry is not required as the trigger of 0.004 mg/kg bw/d is not exceeded.

## 4.2 Nature of residues (Animal metabolism studies)

As the maximum dietary burden was less than the trigger value for further assessment (0.004 mg/kg bw/day) for all livestock, further consideration of the residues in animal commodities was not required. Nonetheless, metabolism of bixlozone in livestock was considered for the approval of the active substance (see Table 4.2-1 for summary of studies). The approval assessment concluded that metabolic pathways in rodents and ruminants are comparable; the findings in ruminants can therefore be extrapolated to pigs. Based on the results of the livestock metabolism studies and the calculated dietary burdens, residues of bixlozone above the LOQ of 0.01 mg/kg are not expected in ruminant, swine and poultry matrices.

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

| Animal  | Dosing rate                                                        | Duration | Comment                             |
|---------|--------------------------------------------------------------------|----------|-------------------------------------|
| Poultry | 1.15 mg/kg bw/d (phenyl label)<br>1.08 mg/kg bw/d (carbonyl label) | 13 days  | ca. 216-288N                        |
| Goat    | 0.41 mg/kg bw/d (phenyl label)<br>0.49 mg/kg bw/d (carbonyl label) | 7 days   | ca. 51-163N (dairy cattle)          |
| Pig     | Not required                                                       | -        | Rat and ruminant metabolism similar |

The approval assessment concluded that a residue definition for risk assessment (RD-RA) in animals was not required for the early application proposed uses on oilseed rape, wheat, barley and maize. However, a further consideration would be needed, if residues become more prominent in animal feed items for any additional/new crop uses or further extensions of uses on oilseed rape, wheat, barley and maize.

Based on the current assessment, the residue definition for enforcement (RD-Enf) should be established as a default bixlozone only: The RD-Enf is therefore agreed as: Bixlozone

HSE stated during the approval of the active substance that the RD-Enf will need to be reconsidered if there are extensions of use beyond those considered currently in this assessment.

To conclude, if the animal metabolism studies are to be relied upon in the future (if animal dietary burden becomes significant), the points made by HSE during the approval of the active substance should be addressed and suitable residue definitions for both risk assessment and enforcement should be proposed. The impact of residues in rotational crops, including the metabolites, will also need to be part of this consideration.

### **4.3 Magnitude of residues**

No consideration of livestock feeding studies are required, as the dietary burden is calculated to be <0.004 mg/kg for all groups.

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

At this time no conversion factors are required. A further consideration may be required if significant residues arise in products of animal and suitable residue definitions are established.

## 5 Literature data

Bixlozone is an approved active substance in GB, therefore no further consideration of the literature data is required in this assessment.

## 6 Residues in honey

Wheat and barley are non-melliferous crops. Based on the decision tree set out in SANTE/11956/2016 rev. 9 residues in honey are not expected where the substance is applied on a crop from which it is not possible to produce honey. Significant residues of bixlozone are also not expected in rotational crops based on the requested GAP and proposed 9 month plant back restriction. The restriction ensures residues of bixlozone in rotational crops will be <0.01 mg/kg.

## **7 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.

No MRL extrapolations are recommended on the basis of this assessment.

## 8 Consumer risk assessment

### 8.1 Dietary exposure

Dietary exposures have been estimated using the UK chronic and acute models and the EFSA PRIMo.

Chronic dietary exposures have been estimated based on the uses of bixlozone considered in this application and the proposed uses considered in previous assessments (HSE, 2024a)

Acute dietary exposures have only been estimated for the uses of bixlozone considered in this application.

#### UK NEDIs and NESTIs

The UK NEDIs and NESTIs for the active substance and commodities listed in Table 8.1-1 have been estimated 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 Table 8.1-1.
- There is no loss of residue during transport, storage or processing of foods prior to consumption.

The input values for the UK consumer risk assessment are given in Table 8.1-1.

**Table 8.1-1 Input values for the UK consumer risk assessment**

| Commodity                                                                                                                                                                                                                                                                         | Chronic risk assessment |         | Acute risk assessment |         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------|-----------------------|---------|
|                                                                                                                                                                                                                                                                                   | Input (mg/kg)           | Comment | Input (mg/kg)         | Comment |
| <b>Risk assessment residue definition:</b> For the intended (early application) use on oilseed rape, wheat, barley and maize (RD-RA, based on the uses assessed in the approval assessment): Sum of residues of bixlozone and 2 x 2,4-dichlorobenzoic acid expressed as bixlozone |                         |         |                       |         |

| Commodity             | Chronic risk assessment                               |                                                                    | Acute risk assessment |                                                                                                  |
|-----------------------|-------------------------------------------------------|--------------------------------------------------------------------|-----------------------|--------------------------------------------------------------------------------------------------|
|                       | Input (mg/kg)                                         | Comment                                                            | Input (mg/kg)         | Comment                                                                                          |
| Barley grain          | 0.039                                                 | STMR (current assessment)                                          | 0.039                 | STMR (current assessment)                                                                        |
| Wheat grain           | 0.039                                                 | STMR (current assessment)                                          | 0.039                 | STMR (current assessment)                                                                        |
| All other commodities | 0.01 or alternative LOQ MRL as outlined in table 9.1. | Default LOQ MRL that will be set in the GB MRL Statutory Register. | N/A                   | Acute risk assessment undertaken only for the commodities relevant to the uses under assessment. |

**In bold** uses proposed 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 active substance and commodities listed in Table 8.1-2 have been estimated 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 as given in Table 8.1-2.
- There is no loss of residue during transport, storage or processing of foods prior to consumption.

The input values for the PRIMo risk assessment are given in Table 8.1-2.



**Table 8.1-2 Input values for the PRIMo consumer risk assessment**

| Commodity                                                                                                                                                                                                                                                                         | Chronic risk assessment                                      |                                                                           | Acute risk assessment |                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|---------------------------------------------------------------------------|-----------------------|--------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                   | Input (mg/kg)                                                | Comment                                                                   | Input (mg/kg)         | Comment                                                                                          |
| <b>Risk assessment residue definition:</b> For the intended (early application) use on oilseed rape, wheat, barley and maize (RD-RA, based on the uses assessed in the approval assessment): Sum of residues of bixlozone and 2 x 2,4-dichlorobenzoic acid expressed as bixlozone |                                                              |                                                                           |                       |                                                                                                  |
| <b>Barley grain</b>                                                                                                                                                                                                                                                               | <b>0.039</b>                                                 | <b>STMR (current assessment)</b>                                          | <b>0.039</b>          | <b>STMR (current assessment)</b>                                                                 |
| <b>Wheat grain</b>                                                                                                                                                                                                                                                                | <b>0.039</b>                                                 | <b>STMR (current assessment)</b>                                          | <b>0.039</b>          | <b>STMR (current assessment)</b>                                                                 |
| <b>All other commodities</b>                                                                                                                                                                                                                                                      | <b>0.01 or alternative LOQ MRL as outlined in table 9.1.</b> | <b>Default LOQ MRL that will be set in the GB MRL Statutory Register.</b> | <b>N/A</b>            | Acute risk assessment undertaken only for the commodities relevant to the uses under assessment. |

**In bold** uses proposed as part of the current assessment.

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

## Conclusions

The highest UK NEDI was <1% of the ADI (infant). The highest PRIMo IEDI was 0.5% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with bixlozone.

The highest UK NESTI was 0.1% of the ARfD (4-6 year old child/wheat). The highest PRIMo IESTI was 0.1% of the ARfD (children/wheat). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with bixlozone.

## 8.2 Other routes of exposure

At active approval, the metabolite 2,4-dichlorobenzoic acid was predicted to occur in groundwater at concentrations above 0.1 µg/L (HSE, 2024a). A groundwater assessment

was performed according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 and concluded that:

*“2,4-dichlorobenzoic acid is not of toxicological relevance at the maximum predicted concentration of 4.148 µg/L in groundwater. In terms of the risk assessment, this residue of 4.148 µg/L (2,4-dichlorobenzoic acid) has been assessed on the basis of ‘parent bixlozone equivalents’ as 11.90 µg/L. This takes account of the proposed two fold toxicological potency of residues of 2,4-dichlorobenzoic acid compared to parent bixlozone, and also includes an adjustment due to molecular weight (x 1.435).*

*The refined risk assessment above (at step 5 of the assessment) concludes that overall chronic dietary intakes from food and drinking water sources are low: metabolite 2,4-dichlorobenzoic acid from both drinking water (<1% of the ADI of 0.3 mg/kg bw/day for bixlozone); food sources (‘total residues’ dietary intakes assessed taking account of the higher toxicity of 2,4-dichlorobenzoic acid, all <1% of the ADI of 0.3 mg/kg bw/day for bixlozone). Taken together these exposures are low.*

*As such, following the stepwise assessment, it is concluded that 2,4-dichlorobenzoic acid is not a relevant metabolite in groundwater.”*

The proposed uses on wheat and barley are within the uses considered at active approval. Therefore, a groundwater assessment has not been reassessed and it is considered that there are no other routes of exposure from the use of bixlozone on wheat and barley.

## 9 The conclusion of the competent authority

Sufficiently validated analytical methods for the determination of bixlozone in products of plant origin, in line with the residue definition for enforcement, are available to support the uses under consideration in the MRL application.

Toxicological reference values were established for the approval of the active substance: an ADI of 0.3 mg/kg bw/day and an ARfD of 0.75 mg/kg bw.

The metabolism of bixlozone in primary crops was investigated in root crops, cereals/grass crops and pulses/oilseeds crop groups following foliar applications for the approval of the active substance (HSE, 2024a). The root crop metabolism study was only considered as supporting information in the GB Assessment Report of bixlozone. The proposal of residue definitions included a TTC assessment (for 2,2-dimethyl-3-hydroxy propionic acid (M118/1) and dimethyl malonic acid (M132/1)) and only the intended uses were considered. Therefore, it was not possible to propose a universal residue definition (across all crops). However, the crops included in this MRL application belong to the cereal crop group and are, therefore, covered by the metabolism studies available.

The residue definition for risk assessment (RD-RA) in plants has been agreed as (based on the uses assessed in the approval assessment):

- **For the intended (early application) use on oilseed rape, wheat, barley and maize:**  
Sum of the residues of bixlozone and 2 x 2,4-dichlorobenzoic acid expressed as bixlozone\*

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

- Bixlozone

\*Molecular weight conversion to express 2,4-dichlorobenzoic acid as bixlozone equivalents is x 1.435. The 2 x factor is to account for the relative toxicological potency of 2,4-dichlorobenzoic acid compared to bixlozone.

Although the RD-RA and RD-Enf are different no conversion factors have been set as almost all of the trials contained residues of bixlozone and 2,4-dichlorobenzoic acid at a level of <0.01 mg/kg (<LOQ).

Five new outdoor primary crop trials on wheat conducted using the proposed product 'Fundatis' in Northern France, Germany, Poland and the UK were submitted to support

MRLs for wheat and barley. The trials are supported by validated analytical methods and storage stability data. Additional trials, evaluated in the GB approval assessment (HSE, 2024a), on wheat and barley have been relied upon to support the MRLs.

A new residues stability study demonstrating stability of residues in frozen samples was submitted and evaluated to address a data gap, on stability of residues in cereal grain, to support the uses on wheat and barley.

Hydrolysis of bixlozone under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that bixlozone is stable under standard hydrolysis conditions. A new processing hydrolysis study was submitted to address a data gap for the nature of metabolite 2,4-dichlorobenzoic acid to be addressed during processing. The new hydrolysis data demonstrated that 2,4-dichlorobenzoic acid is stable under standard hydrolysis conditions. The data gap has been addressed, therefore specific residue definitions for processed commodities are not required.

Residues in rotational crops were considered for the approval of the active substance. Bixlozone and the main metabolites found in the rotational crop metabolism study were tested in follow on MOR (magnitude of residues) rotational crop field trials. These trials, assessed in the approval assessment, concluded that residues of parent bixlozone above the LOQ of 0.01 mg/kg are expected in rotational crops. Data evaluated for the approval and a newly submitted study was considered. This new study led to the need for a more extensive rotational crop metabolite assessment considering the potential for metabolites and parent to be formed. The applicant proposed to refine the 10 month plant back restriction (intended to keep levels of parent bixlozone in rotational crops to <0.01 mg/kg) outlined in the approval assessment to 9 months. It was concluded that a refined 9 month plant back restriction was acceptable; the wording of the label amendment outlined in the approval assessment is now also changed to reflect that the restriction now applies to all following crops (except cereals, oilseeds and pulses (dry seed) which do not need to be included in this restriction). The following restriction, related to bixlozone, must appear on the label:

*All rotational crops, except cereals (including maize), oilseeds and pulses (dry seed), must not be planted until at least 9 months after application of bixlozone.*

As the maximum dietary burden was less than the trigger value for further assessment (0.004 mg/kg bw/day) for all livestock, further consideration of the residues in animal commodities was not required. Although not required, metabolism of bixlozone 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.

Wheat and barley are non-melliferous crops. Based on the decision tree set out in SANTE/11956/2016 rev. 9 residues in honey are not expected where the substance is applied on a crop from which it is not possible to produce honey. Significant residues of bixlozone are also not expected in rotational crops based on the requested GAP and proposed 9 month plant back restriction. The restriction ensures residues of bixlozone and metabolites in rotational crops will be <0.01 mg/kg.

The highest UK NEDI was <1% of the ADI (infant). The highest PRIMo IEDI was 0.5% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with bixlozone.

The highest UK NESTI was 0.1% of the ARfD (4-6 year old child/wheat). The highest PRIMo IESTI was 0.1% of the ARfD (children/wheat). Therefore, no health effects due to acute exposure are expected from the consumption of commodities treated with bixlozone.

HSE concludes that sufficient data have been provided to support the setting of new MRLs for the representative uses of bixlozone on wheat and barley. These will not result in consumer exposures exceeding the toxicological reference values and therefore harmful effects on human health are not expected.

Bixlozone is currently not included in the GB MRL Statutory Register therefore the default LOQ MRL of 0.01\* mg/kg currently applies to all residues of bixlozone and all commodities. HSE concludes that the MRLs outlined in Table 9.1 for barley and wheat are fully supported. HSE also recommends that the MRLs for all other commodities are set at the default LOQ MRL which is 0.01\* mg/kg for most commodities. The notes under Table 9.1 indicate the commodities for which the default LOQ MRL is higher than 0.01\* mg/kg.

**Table 9.1 MRLs recommended by HSE**

| GB Code No                                                                                     | Commodity to which the MRL applies    | Current MRL in force (mg/kg) <sup>†</sup> | New/ amended MRL (mg/kg) | Footnotes |
|------------------------------------------------------------------------------------------------|---------------------------------------|-------------------------------------------|--------------------------|-----------|
| Enforcement residue definition for products of plant and animal origin: Bixlozone <sup>§</sup> |                                       |                                           |                          |           |
| 0100000                                                                                        | FRUITS, FRESH or FROZEN;<br>TREE NUTS |                                           |                          |           |
| 0110000                                                                                        | Citrus fruits                         |                                           |                          |           |
| 0110010                                                                                        | Grapefruits                           | 0.01*                                     | 0.01*                    |           |
| 0110020                                                                                        | Oranges                               | 0.01*                                     | 0.01*                    |           |
| 0110030                                                                                        | Lemons                                | 0.01*                                     | 0.01*                    |           |
| 0110040                                                                                        | Limes                                 | 0.01*                                     | 0.01*                    |           |
| 0110050                                                                                        | Mandarins                             | 0.01*                                     | 0.01*                    |           |
| 0110990                                                                                        | Others - Citrus Fruit                 | 0.01*                                     | 0.01*                    |           |
| 0120000                                                                                        | Tree Nuts                             |                                           |                          |           |
| 0120010                                                                                        | Almonds                               | 0.01*                                     | 0.01*                    |           |
| 0120020                                                                                        | Brazil nuts                           | 0.01*                                     | 0.01*                    |           |
| 0120030                                                                                        | Cashew nuts                           | 0.01*                                     | 0.01*                    |           |
| 0120040                                                                                        | Chestnuts                             | 0.01*                                     | 0.01*                    |           |
| 0120050                                                                                        | Coconuts                              | 0.01*                                     | 0.01*                    |           |
| 0120060                                                                                        | Hazelnuts/cobnuts                     | 0.01*                                     | 0.01*                    |           |
| 0120070                                                                                        | Macadamias                            | 0.01*                                     | 0.01*                    |           |

| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b> | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0120080</b>    | Pecans                                    | 0.01*                                           | 0.01*                           |                  |
| <b>0120090</b>    | Pine nut kernels                          | 0.01*                                           | 0.01*                           |                  |
| <b>0120100</b>    | Pistachios                                | 0.01*                                           | 0.01*                           |                  |
| <b>0120110</b>    | Walnuts                                   | 0.01*                                           | 0.01*                           |                  |
| <b>0120990</b>    | Others - Tree nuts                        | 0.01*                                           | 0.01*                           |                  |
| <b>0130000</b>    | Pome fruits                               |                                                 |                                 |                  |
| <b>0130010</b>    | Apples                                    | 0.01*                                           | 0.01*                           |                  |
| <b>0130020</b>    | Pears                                     | 0.01*                                           | 0.01*                           |                  |
| <b>0130030</b>    | Quinces                                   | 0.01*                                           | 0.01*                           |                  |
| <b>0130040</b>    | Medlars                                   | 0.01*                                           | 0.01*                           |                  |
| <b>0130050</b>    | Loquats/Japanese medlars                  | 0.01*                                           | 0.01*                           |                  |
| <b>0130990</b>    | Others - Pome fruit                       | 0.01*                                           | 0.01*                           |                  |
| <b>0140000</b>    | Stone fruits                              |                                                 |                                 |                  |
| <b>0140010</b>    | Apricots                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0140020</b>    | Cherries (sweet)                          | 0.01*                                           | 0.01*                           |                  |
| <b>0140030</b>    | Peaches                                   | 0.01*                                           | 0.01*                           |                  |
| <b>0140040</b>    | Plums                                     | 0.01*                                           | 0.01*                           |                  |
| <b>0140990</b>    | Others - Stone fruit                      | 0.01*                                           | 0.01*                           |                  |

| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b> | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0150000</b>    | Berries and small fruits                  |                                                 |                                 |                  |
| <b>0151000</b>    | Grapes                                    |                                                 |                                 |                  |
| <b>0151010</b>    | Table grapes                              | 0.01*                                           | 0.01*                           |                  |
| <b>0151020</b>    | Wine grapes                               | 0.01*                                           | 0.01*                           |                  |
| <b>0152000</b>    | Strawberries                              |                                                 |                                 |                  |
| <b>0152000</b>    | Strawberries                              | 0.01*                                           | 0.01*                           |                  |
| <b>0153000</b>    | Cane fruits                               |                                                 |                                 |                  |
| <b>0153010</b>    | Blackberries                              | 0.01*                                           | 0.01*                           |                  |
| <b>0153020</b>    | Dewberries                                | 0.01*                                           | 0.01*                           |                  |
| <b>0153030</b>    | Raspberries (red and yellow)              | 0.01*                                           | 0.01*                           |                  |
| <b>0153990</b>    | Others - Cane fruit                       | 0.01*                                           | 0.01*                           |                  |
| <b>0154000</b>    | Other small fruits and berries            |                                                 |                                 |                  |
| <b>0154010</b>    | Blueberries                               | 0.01*                                           | 0.01*                           |                  |
| <b>0154020</b>    | Cranberries                               | 0.01*                                           | 0.01*                           |                  |
| <b>0154030</b>    | Currants (black, red and white)           | 0.01*                                           | 0.01*                           |                  |
| <b>0154040</b>    | Gooseberries (green, red and yellow)      | 0.01*                                           | 0.01*                           |                  |
| <b>0154050</b>    | Rose hips                                 | 0.01*                                           | 0.01*                           |                  |



| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b> | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0154060</b>    | Mulberries (black and white)              | 0.01*                                           | 0.01*                           |                  |
| <b>0154070</b>    | Azaroles/Mediterranean medlars            | 0.01*                                           | 0.01*                           |                  |
| <b>0154080</b>    | Elderberries                              | 0.01*                                           | 0.01*                           |                  |
| <b>0154990</b>    | Others - Other small fruit and berries    | 0.01*                                           | 0.01*                           |                  |
| <b>0160000</b>    | Miscellaneous fruits with                 |                                                 |                                 |                  |
| <b>0161000</b>    | Edible peel                               |                                                 |                                 |                  |
| <b>0161010</b>    | Dates                                     | 0.01*                                           | 0.01*                           |                  |
| <b>0161020</b>    | Figs                                      | 0.01*                                           | 0.01*                           |                  |
| <b>0161030</b>    | Table olives                              | 0.01*                                           | 0.01*                           |                  |
| <b>0161040</b>    | Kumquats                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0161050</b>    | Carambolas                                | 0.01*                                           | 0.01*                           |                  |
| <b>0161060</b>    | Kaki/Japanese persimmons                  | 0.01*                                           | 0.01*                           |                  |
| <b>0161070</b>    | Jambuls/jambolans                         | 0.01*                                           | 0.01*                           |                  |
| <b>0161990</b>    | Others - Edible peel                      | 0.01*                                           | 0.01*                           |                  |
| <b>0162000</b>    | Inedible peel, small                      |                                                 |                                 |                  |
| <b>0162010</b>    | Kiwi fruits (green, red, yellow)          | 0.01*                                           | 0.01*                           |                  |
| <b>0162020</b>    | Litchis/lychees                           | 0.01*                                           | 0.01*                           |                  |

| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b> | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0162030</b>    | Passionfruits/maracujas                   | 0.01*                                           | 0.01*                           |                  |
| <b>0162040</b>    | Prickly pears/cactus fruits               | 0.01*                                           | 0.01*                           |                  |
| <b>0162050</b>    | Star apples/cainitos                      | 0.01*                                           | 0.01*                           |                  |
| <b>0162060</b>    | American persimmons/Virginia kaki         | 0.01*                                           | 0.01*                           |                  |
| <b>0162990</b>    | Others - Inedible peel, small             | 0.01*                                           | 0.01*                           |                  |
| <b>0163000</b>    | Inedible peel, large                      |                                                 |                                 |                  |
| <b>0163010</b>    | Avocados                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0163020</b>    | Bananas                                   | 0.01*                                           | 0.01*                           |                  |
| <b>0163030</b>    | Mangoes                                   | 0.01*                                           | 0.01*                           |                  |
| <b>0163040</b>    | Papayas                                   | 0.01*                                           | 0.01*                           |                  |
| <b>0163050</b>    | Granate apples/pomegranates               | 0.01*                                           | 0.01*                           |                  |
| <b>0163060</b>    | Cherimoyas                                | 0.01*                                           | 0.01*                           |                  |
| <b>0163070</b>    | Guavas                                    | 0.01*                                           | 0.01*                           |                  |
| <b>0163080</b>    | Pineapples                                | 0.01*                                           | 0.01*                           |                  |
| <b>0163090</b>    | Breadfruits                               | 0.01*                                           | 0.01*                           |                  |
| <b>0163100</b>    | Durians                                   | 0.01*                                           | 0.01*                           |                  |
| <b>0163110</b>    | Soursops/guanabanas                       | 0.01*                                           | 0.01*                           |                  |
| <b>0163990</b>    | Others - Inedible peel, large             | 0.01*                                           | 0.01*                           |                  |

| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b>          | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|----------------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0200000</b>    | <b>VEGETABLES, FRESH or FROZEN</b>                 |                                                 |                                 |                  |
| <b>0210000</b>    | Root and tuber vegetables                          |                                                 |                                 |                  |
| <b>0211000</b>    | Potatoes                                           | 0.01*                                           | 0.01*                           |                  |
| <b>0211000</b>    | Potatoes                                           | 0.01*                                           | 0.01*                           |                  |
| <b>0212000</b>    | Tropical root and tuber vegetables                 |                                                 |                                 |                  |
| <b>0212010</b>    | Cassava roots/manioc                               | 0.01*                                           | 0.01*                           |                  |
| <b>0212020</b>    | Sweet potatoes                                     | 0.01*                                           | 0.01*                           |                  |
| <b>0212030</b>    | Yams                                               | 0.01*                                           | 0.01*                           |                  |
| <b>0212040</b>    | Arrowroots                                         | 0.01*                                           | 0.01*                           |                  |
| <b>0212990</b>    | Others - Tropical root and tuber vegetables        | 0.01*                                           | 0.01*                           |                  |
| <b>0213000</b>    | Other root and tuber vegetables except sugar beets |                                                 |                                 |                  |
| <b>0213010</b>    | Beetroots                                          | 0.01*                                           | 0.01*                           |                  |
| <b>0213020</b>    | Carrots                                            | 0.01*                                           | 0.01*                           |                  |
| <b>0213030</b>    | Celeriacs/turnip rooted celeries                   | 0.01*                                           | 0.01*                           |                  |
| <b>0213040</b>    | Horseradishes                                      | 0.01*                                           | 0.01*                           |                  |
| <b>0213050</b>    | Jerusalem artichokes                               | 0.01*                                           | 0.01*                           |                  |

| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b>                     | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|---------------------------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0213060</b>    | Parsnips                                                      | 0.01*                                           | 0.01*                           |                  |
| <b>0213070</b>    | Parsley roots/Hamburg roots<br>parsley                        | 0.01*                                           | 0.01*                           |                  |
| <b>0213080</b>    | Radishes                                                      | 0.01*                                           | 0.01*                           |                  |
| <b>0213090</b>    | Salsifies                                                     | 0.01*                                           | 0.01*                           |                  |
| <b>0213100</b>    | Swedes/rutabagas                                              | 0.01*                                           | 0.01*                           |                  |
| <b>0213110</b>    | Turnips                                                       | 0.01*                                           | 0.01*                           |                  |
| <b>0213990</b>    | Others - Other root and tuber<br>vegetables except sugar beet | 0.01*                                           | 0.01*                           |                  |
| <b>0220000</b>    | Bulb vegetables                                               |                                                 |                                 |                  |
| <b>0220010</b>    | Garlic                                                        | 0.01*                                           | 0.01*                           |                  |
| <b>0220020</b>    | Onions                                                        | 0.01*                                           | 0.01*                           |                  |
| <b>0220030</b>    | Shallots                                                      | 0.01*                                           | 0.01*                           |                  |
| <b>0220040</b>    | Spring onions/green onions and<br>Welsh onions                | 0.01*                                           | 0.01*                           |                  |
| <b>0220990</b>    | Others - bulb vegetables                                      | 0.01*                                           | 0.01*                           |                  |
| <b>0230000</b>    | Fruiting vegetables                                           |                                                 |                                 |                  |
| <b>0231000</b>    | Solanaceae and Malvaceae                                      | 0.01*                                           | 0.01*                           |                  |
| <b>0231010</b>    | Tomatoes                                                      | 0.01*                                           | 0.01*                           |                  |

| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b> | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0231020</b>    | Sweet peppers/bell peppers                | 0.01*                                           | 0.01*                           |                  |
| <b>0231030</b>    | Aubergines/eggplants                      | 0.01*                                           | 0.01*                           |                  |
| <b>0231040</b>    | Okra/lady's fingers                       | 0.01*                                           | 0.01*                           |                  |
| <b>0231990</b>    | Others - Solanacea                        | 0.01*                                           | 0.01*                           |                  |
| <b>0232000</b>    | Cucurbits with edible peel                |                                                 |                                 |                  |
| <b>0232010</b>    | Cucumbers                                 | 0.01*                                           | 0.01*                           |                  |
| <b>0232020</b>    | Gherkins                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0232030</b>    | Courgettes                                | 0.01*                                           | 0.01*                           |                  |
| <b>0232990</b>    | Others - Cucurbits-edible peel            | 0.01*                                           | 0.01*                           |                  |
| <b>0233000</b>    | Cucurbits with inedible peel              |                                                 |                                 |                  |
| <b>0233010</b>    | Melons                                    | 0.01*                                           | 0.01*                           |                  |
| <b>0233020</b>    | Pumpkins                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0233030</b>    | Watermelons                               | 0.01*                                           | 0.01*                           |                  |
| <b>0233990</b>    | Others - Cucurbits - inedible peel        | 0.01*                                           | 0.01*                           |                  |
| <b>0234000</b>    | Sweet corn                                |                                                 |                                 |                  |
| <b>0234000</b>    | Sweet corn                                | 0.01*                                           | 0.01*                           |                  |
| <b>0239000</b>    | Other fruiting vegetables                 |                                                 |                                 |                  |
| <b>0239000</b>    | Other fruiting vegetables                 | 0.01*                                           | 0.01*                           |                  |

| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b>                                   | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|-----------------------------------------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0240000</b>    | Brassica vegetables (excluding brassica roots and brassica baby leaf crops) |                                                 |                                 |                  |
| <b>0241000</b>    | Flowering brassica                                                          |                                                 |                                 |                  |
| <b>0241010</b>    | Broccoli                                                                    | 0.01*                                           | 0.01*                           |                  |
| <b>0241020</b>    | Cauliflowers                                                                | 0.01*                                           | 0.01*                           |                  |
| <b>0241990</b>    | Others - Flowering Brassicas                                                | 0.01*                                           | 0.01*                           |                  |
| <b>0242000</b>    | Head brassica                                                               |                                                 |                                 |                  |
| <b>0242010</b>    | Brussels sprouts                                                            | 0.01*                                           | 0.01*                           |                  |
| <b>0242020</b>    | Head cabbages                                                               | 0.01*                                           | 0.01*                           |                  |
| <b>0242990</b>    | Others - Head Brassicas                                                     | 0.01*                                           | 0.01*                           |                  |
| <b>0243000</b>    | Leafy brassica                                                              |                                                 |                                 |                  |
| <b>0243010</b>    | Chinese cabbages/pe-tsai                                                    | 0.01*                                           | 0.01*                           |                  |
| <b>0243020</b>    | Kales                                                                       | 0.01*                                           | 0.01*                           | 1                |
| <b>0243990</b>    | Others - Leafy Brassicas                                                    | 0.01*                                           | 0.01*                           |                  |
| <b>0244000</b>    | Kohlrabies                                                                  |                                                 |                                 |                  |
| <b>0244000</b>    | Kohlrabies                                                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0250000</b>    | Leaf vegetables, herbs and edible flowers                                   |                                                 |                                 |                  |

| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b>                  | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|------------------------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0251000</b>    | Lettuces and salad plants                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0251010</b>    | Lamb's lettuces/corn salads                                | 0.01*                                           | 0.01*                           |                  |
| <b>0251020</b>    | Lettuces                                                   | 0.01*                                           | 0.01*                           |                  |
| <b>0251030</b>    | Escaroles/broad-leaved endives                             | 0.01*                                           | 0.01*                           |                  |
| <b>0251040</b>    | Cresses and other sprouts and shoots                       | 0.01*                                           | 0.01*                           |                  |
| <b>0251050</b>    | Land cresses                                               | 0.01*                                           | 0.01*                           |                  |
| <b>0251060</b>    | Roman rocket/rucola                                        | 0.01*                                           | 0.01*                           |                  |
| <b>0251070</b>    | Red mustards                                               | 0.01*                                           | 0.01*                           |                  |
| <b>0251080</b>    | Baby leaf crops (including brassica species)               | 0.01*                                           | 0.01*                           |                  |
| <b>0251990</b>    | Others - Lettuce and other salad plants including brassica | 0.01*                                           | 0.01*                           |                  |
| <b>0252000</b>    | Spinaches and similar leaves                               |                                                 |                                 |                  |
| <b>0252010</b>    | Spinaches                                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0252020</b>    | Purslanes                                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0252030</b>    | Chards/beet leaves                                         | 0.01*                                           | 0.01*                           |                  |
| <b>0252990</b>    | Others - Spinach and similar (leaves)                      | 0.01*                                           | 0.01*                           |                  |

| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b> | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0253000</b>    | Grape leaves and similar species          |                                                 |                                 |                  |
| <b>0253000</b>    | Grape leaves and similar species          | 0.01*                                           | 0.01*                           |                  |
| <b>0254000</b>    | Watercresses                              |                                                 |                                 |                  |
| <b>0254000</b>    | Watercresses                              | 0.01*                                           | 0.01*                           |                  |
| <b>0255000</b>    | Witloofs/Belgian endives                  |                                                 |                                 |                  |
| <b>0255000</b>    | Witloofs/Belgian endives                  | 0.01*                                           | 0.01*                           |                  |
| <b>0256000</b>    | Herbs and edible flowers                  |                                                 |                                 |                  |
| <b>0256010</b>    | Chervil                                   | 0.01*                                           | 0.02*                           |                  |
| <b>0256020</b>    | Chives                                    | 0.01*                                           | 0.02*                           |                  |
| <b>0256030</b>    | Celery leaves                             | 0.01*                                           | 0.02*                           |                  |
| <b>0256040</b>    | Parsley                                   | 0.01*                                           | 0.02*                           |                  |
| <b>0256050</b>    | Sage                                      | 0.01*                                           | 0.02*                           |                  |
| <b>0256060</b>    | Rosemary                                  | 0.01*                                           | 0.02*                           |                  |
| <b>0256070</b>    | Thyme                                     | 0.01*                                           | 0.02*                           |                  |
| <b>0256080</b>    | Basil and edible flowers                  | 0.01*                                           | 0.02*                           |                  |
| <b>0256090</b>    | Laurel/bay leaves                         | 0.01*                                           | 0.02*                           |                  |
| <b>0256100</b>    | Tarragon                                  | 0.01*                                           | 0.02*                           |                  |
| <b>0256990</b>    | Others - Herbs                            | 0.01*                                           | 0.02*                           |                  |



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|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0260000</b>    | Legume vegetables                         |                                                 |                                 |                  |
| <b>0260010</b>    | Beans (with pods)                         | 0.01*                                           | 0.01*                           |                  |
| <b>0260020</b>    | Beans (without pods)                      | 0.01*                                           | 0.01*                           |                  |
| <b>0260030</b>    | Peas (with pods)                          | 0.01*                                           | 0.01*                           |                  |
| <b>0260040</b>    | Peas (without pods)                       | 0.01*                                           | 0.01*                           |                  |
| <b>0260050</b>    | Lentils                                   | 0.01*                                           | 0.01*                           |                  |
| <b>0260990</b>    | Others - Legume vegetables (fresh)        | 0.01*                                           | 0.01*                           |                  |
| <b>0270000</b>    | Stem vegetables                           |                                                 |                                 |                  |
| <b>0270010</b>    | Asparagus                                 | 0.01*                                           | 0.01*                           |                  |
| <b>0270020</b>    | Cardoons                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0270030</b>    | Celeries                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0270040</b>    | Florence fennels                          | 0.01*                                           | 0.01*                           |                  |
| <b>0270050</b>    | Globe artichokes                          | 0.01*                                           | 0.01*                           |                  |
| <b>0270060</b>    | Leeks                                     | 0.01*                                           | 0.01*                           |                  |
| <b>0270070</b>    | Rhubarbs                                  | 0.01*                                           | 0.01*                           |                  |
| <b>0270080</b>    | Bamboo shoots                             | 0.01*                                           | 0.01*                           |                  |
| <b>0270090</b>    | Palm hearts                               | 0.01*                                           | 0.01*                           |                  |

| GB Code No | Commodity to which the MRL applies | Current MRL in force (mg/kg) <sup>†</sup> | New/ amended MRL (mg/kg) | Footnotes |
|------------|------------------------------------|-------------------------------------------|--------------------------|-----------|
| 0270990    | Others - Stem vegetables (fresh)   | 0.01*                                     | 0.01*                    |           |
| 0280000    | Fungi, mosses and lichens          |                                           |                          |           |
| 0280010    | Cultivated fungi                   | 0.01*                                     | 0.01*                    |           |
| 0280020    | Wild fungi                         | 0.01*                                     | 0.01*                    |           |
| 0280990    | Mosses and lichens                 | 0.01*                                     | 0.01*                    |           |
| 0290000    | Algae and prokaryotes organisms    | 0.01*                                     | 0.01*                    |           |
| 0290000    | Algae and prokaryotes organisms    | 0.01*                                     | 0.01*                    |           |
| 0300000    | <b>PULSES, DRY</b>                 |                                           |                          |           |
| 0300010    | Beans                              | 0.01*                                     | 0.01*                    |           |
| 0300020    | Lentils                            | 0.01*                                     | 0.01*                    |           |
| 0300030    | Peas                               | 0.01*                                     | 0.01*                    |           |
| 0300040    | Lupins/lupini beans                | 0.01*                                     | 0.01*                    |           |
| 0300990    | Others - pulses                    | 0.01*                                     | 0.01*                    |           |
| 0400000    | <b>OILSEEDS AND OIL FRUITS</b>     |                                           |                          |           |
| 0401000    | Oilseeds                           |                                           |                          |           |
| 0401010    | Linseeds                           | 0.01*                                     | 0.01*                    |           |
| 0401020    | Peanuts/groundnuts                 | 0.01*                                     | 0.01*                    |           |
| 0401030    | Poppy seeds                        | 0.01*                                     | 0.01*                    |           |

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|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0401040</b>    | Sesame seeds                              | 0.01*                                           | 0.01*                           |                  |
| <b>0401050</b>    | Sunflower seeds                           | 0.01*                                           | 0.01*                           |                  |
| <b>0401060</b>    | Rapeseeds/canola seeds                    | 0.01*                                           | 0.01*                           |                  |
| <b>0401070</b>    | Soyabeans                                 | 0.01*                                           | 0.01*                           |                  |
| <b>0401080</b>    | Mustard seeds                             | 0.01*                                           | 0.01*                           |                  |
| <b>0401090</b>    | Cotton seeds                              | 0.01*                                           | 0.01*                           |                  |
| <b>0401100</b>    | Pumpkin seeds                             | 0.01*                                           | 0.01*                           |                  |
| <b>0401110</b>    | Safflower seeds                           | 0.01*                                           | 0.01*                           |                  |
| <b>0401120</b>    | Borage seeds                              | 0.01*                                           | 0.01*                           |                  |
| <b>0401130</b>    | Gold of pleasure seeds                    | 0.01*                                           | 0.01*                           |                  |
| <b>0401140</b>    | Hemp seeds                                | 0.01*                                           | 0.01*                           |                  |
| <b>0401150</b>    | Castor beans                              | 0.01*                                           | 0.01*                           |                  |
| <b>0401990</b>    | Others - Oilseeds                         | 0.01*                                           | 0.01*                           |                  |
| <b>0402000</b>    | Oil fruits                                |                                                 |                                 |                  |
| <b>0402010</b>    | Olives for oil production                 | 0.01*                                           | 0.01*                           |                  |
| <b>0402020</b>    | Oil palms kernels                         | 0.01*                                           | 0.01*                           |                  |
| <b>0402030</b>    | Oil palms fruits                          | 0.01*                                           | 0.01*                           |                  |
| <b>0402040</b>    | Kapok                                     | 0.01*                                           | 0.01*                           |                  |

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|------------|---------------------------------------------------------|-------------------------------------------|--------------------------|-----------|
| 0402990    | Others - Oilfruits                                      | 0.01*                                     | 0.01*                    |           |
| 0500000    | <b>CEREALS</b>                                          |                                           |                          |           |
| 0500010    | Barley                                                  | 0.01*                                     | 0.01*                    |           |
| 0500020    | Buckwheat and other pseudocereals                       | 0.01*                                     | 0.01*                    |           |
| 0500030    | Maize/corn                                              | 0.01*                                     | 0.01*                    |           |
| 0500040    | Common millet/proso millet                              | 0.01*                                     | 0.01*                    |           |
| 0500050    | Oat                                                     | 0.01*                                     | 0.01*                    |           |
| 0500060    | Rice                                                    | 0.01*                                     | 0.01*                    |           |
| 0500070    | Rye                                                     | 0.01*                                     | 0.01*                    |           |
| 0500080    | Sorghum                                                 | 0.01*                                     | 0.01*                    |           |
| 0500090    | Wheat                                                   | 0.01*                                     | 0.01*                    |           |
| 0500990    | Others - cereals                                        | 0.01*                                     | 0.01*                    |           |
| 0600000    | <b>TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS</b> |                                           |                          |           |
| 0610000    | Teas                                                    |                                           |                          |           |
| 0610000    | Teas                                                    | 0.01*                                     | 0.05*                    |           |
| 0620000    | Coffee beans                                            |                                           |                          |           |

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|-------------------|----------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0620000</b>    | Coffee beans                                 | 0.01*                                           | 0.05*                           |                  |
| <b>0630000</b>    | Herbal infusions from Dried product          |                                                 |                                 |                  |
| <b>0631000</b>    | Flowers                                      |                                                 |                                 |                  |
| <b>0631010</b>    | Chamomile                                    | 0.01*                                           | 0.05*                           |                  |
| <b>0631020</b>    | Hibiscus/roselle                             | 0.01*                                           | 0.05*                           |                  |
| <b>0631030</b>    | Rose                                         | 0.01*                                           | 0.05*                           |                  |
| <b>0631040</b>    | Jasmine                                      | 0.01*                                           | 0.05*                           |                  |
| <b>0631050</b>    | Lime/linden                                  | 0.01*                                           | 0.05*                           |                  |
| <b>0631990</b>    | Others - Flowers                             | 0.01*                                           | 0.05*                           |                  |
| <b>0632000</b>    | Leaves and herbs                             |                                                 |                                 |                  |
| <b>0632010</b>    | Strawberry                                   | 0.01*                                           | 0.05*                           |                  |
| <b>0632020</b>    | Rooibos                                      | 0.01*                                           | 0.05*                           |                  |
| <b>0632030</b>    | Mate                                         | 0.01*                                           | 0.05*                           |                  |
| <b>0632990</b>    | Others - Herbal infusions (leaves and herbs) | 0.01*                                           | 0.05*                           |                  |
| <b>0633000</b>    | Roots                                        |                                                 |                                 |                  |
| <b>0633010</b>    | Valerian                                     | 0.01*                                           | 0.05*                           |                  |
| <b>0633020</b>    | Ginseng                                      | 0.01*                                           | 0.05*                           |                  |

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|-------------------|---------------------------------------------------------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0633990</b>    | Others - Roots                                                                              | 0.01*                                           | 0.05*                           |                  |
| <b>0639000</b>    | Other herbal Infusions - Parts of the plant other than flowers, leaves and herbs, and roots | 0.01*                                           | 0.05*                           |                  |
| <b>0639000</b>    | Any other parts of the plant                                                                | 0.01*                                           | 0.05*                           |                  |
| <b>0640000</b>    | Cocoa beans                                                                                 | 0.01*                                           | 0.05*                           |                  |
| <b>0640000</b>    | Cocoa beans                                                                                 | 0.01*                                           | 0.05*                           |                  |
| <b>0650000</b>    | Carobs/Saint John's breads                                                                  | 0.01*                                           | 0.05*                           |                  |
| <b>0650000</b>    | Carobs/Saint John's breads                                                                  | 0.01*                                           | 0.05*                           |                  |
| <b>0700000</b>    | <b>HOPS</b>                                                                                 |                                                 |                                 |                  |
| <b>0700000</b>    | Hops                                                                                        | 0.01*                                           | 0.05*                           |                  |
| <b>0800000</b>    | <b>SPICES</b>                                                                               |                                                 |                                 |                  |
| <b>0810000</b>    | Seed spices                                                                                 |                                                 |                                 |                  |
| <b>0810010</b>    | Anise/aniseed                                                                               | 0.01*                                           | 0.05*                           |                  |
| <b>0810020</b>    | Black caraway/black cumin                                                                   | 0.01*                                           | 0.05*                           |                  |
| <b>0810030</b>    | Celery seed                                                                                 | 0.01*                                           | 0.05*                           |                  |
| <b>0810040</b>    | Coriander seed                                                                              | 0.01*                                           | 0.05*                           |                  |
| <b>0810050</b>    | Cumin seed                                                                                  | 0.01*                                           | 0.05*                           |                  |
| <b>0810060</b>    | Dill seed                                                                                   | 0.01*                                           | 0.05*                           |                  |

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|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0810070</b>    | Fennel seed                               | 0.01*                                           | 0.05*                           |                  |
| <b>0810080</b>    | Fenugreek                                 | 0.01*                                           | 0.05*                           |                  |
| <b>0810090</b>    | Nutmeg                                    | 0.01*                                           | 0.05*                           |                  |
| <b>0810990</b>    | Others - Seeds                            | 0.01*                                           | 0.05*                           |                  |
| <b>0820000</b>    | Fruit spices                              |                                                 |                                 |                  |
| <b>0820010</b>    | Allspice/pimento                          | 0.01*                                           | 0.05*                           |                  |
| <b>0820020</b>    | Sichuan pepper                            | 0.01*                                           | 0.05*                           |                  |
| <b>0820030</b>    | Caraway                                   | 0.01*                                           | 0.05*                           |                  |
| <b>0820040</b>    | Cardamom                                  | 0.01*                                           | 0.05*                           |                  |
| <b>0820050</b>    | Juniper berry                             | 0.01*                                           | 0.05*                           |                  |
| <b>0820060</b>    | Peppercorn (black, green and white)       | 0.01*                                           | 0.05*                           |                  |
| <b>0820070</b>    | Vanilla                                   | 0.01*                                           | 0.05*                           |                  |
| <b>0820080</b>    | Tamarind                                  | 0.01*                                           | 0.05*                           |                  |
| <b>0820990</b>    | Others - Fruit spices                     | 0.01*                                           | 0.05*                           |                  |
| <b>0830000</b>    | Bark spices                               |                                                 |                                 |                  |
| <b>0830010</b>    | Cinnamon                                  | 0.01*                                           | 0.05*                           |                  |
| <b>0830990</b>    | Others - Bark                             | 0.01*                                           | 0.05*                           |                  |

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|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>0840000</b>    | Root and rhizome spices                   |                                                 |                                 |                  |
| <b>0840010</b>    | Liquorice                                 | 0.01*                                           | 0.05*                           |                  |
| <b>0840020</b>    | Ginger                                    | 0.01*                                           | 0.05*                           | 2                |
| <b>0840030</b>    | Turmeric/curcuma                          | 0.01*                                           | 0.05*                           |                  |
| <b>0840040</b>    | Horseradish                               | 0.01*                                           | 0.05*                           | 3                |
| <b>0840990</b>    | Others - Roots or rhizome                 | 0.01*                                           | 0.05*                           |                  |
| <b>0850000</b>    | Bud spices                                |                                                 |                                 |                  |
| <b>0850010</b>    | Cloves                                    | 0.01*                                           | 0.05*                           |                  |
| <b>0850020</b>    | Capers                                    | 0.01*                                           | 0.05*                           |                  |
| <b>0850990</b>    | Others - Buds                             | 0.01*                                           | 0.05*                           |                  |
| <b>0860000</b>    | Flower pistil spices                      | 0.01*                                           | 0.05*                           |                  |
| <b>0860010</b>    | Saffron                                   | 0.01*                                           | 0.05*                           |                  |
| <b>0860990</b>    | Others - Flower pistil spices             | 0.01*                                           | 0.05*                           |                  |
| <b>0870000</b>    | Aril spices                               |                                                 |                                 |                  |
| <b>0870010</b>    | Mace                                      | 0.01*                                           | 0.05*                           |                  |
| <b>0870990</b>    | Others - Aril spices                      | 0.01*                                           | 0.05*                           |                  |
| <b>0900000</b>    | <b>SUGAR PLANTS</b>                       |                                                 |                                 |                  |
| <b>0900010</b>    | Sugar beet roots                          | 0.01*                                           | 0.01*                           |                  |



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|------------|--------------------------------------------------------|-------------------------------------------|--------------------------|-----------|
| 0900020    | Sugar canes                                            | 0.01*                                     | 0.01*                    |           |
| 0900030    | Chicory roots                                          | 0.01*                                     | 0.01*                    |           |
| 0900990    | Others - Sugar plants                                  | 0.01*                                     | 0.01*                    |           |
| 1000000    | <b>PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS</b> |                                           |                          |           |
| 1010000    | Commodities from                                       |                                           |                          |           |
| 1011000    | Swine                                                  |                                           |                          |           |
| 1011010    | Muscle - swine                                         | 0.01*                                     | 0.01*                    |           |
| 1011020    | Fat - swine                                            | 0.01*                                     | 0.01*                    |           |
| 1011030    | Liver - swine                                          | 0.01*                                     | 0.01*                    |           |
| 1011040    | Kidney - swine                                         | 0.01*                                     | 0.01*                    |           |
| 1011050    | Edible offals (other than liver and kidney) - swine    | 0.01*                                     | 0.01*                    |           |
| 1011990    | Others - swine                                         | 0.01*                                     | 0.01*                    |           |
| 1012000    | Bovine                                                 |                                           |                          |           |
| 1012010    | Muscle - bovine                                        | 0.01*                                     | 0.01*                    |           |
| 1012020    | Fat - bovine                                           | 0.01*                                     | 0.01*                    |           |
| 1012030    | Liver - bovine                                         | 0.01*                                     | 0.01*                    |           |

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|-------------------|------------------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>1012040</b>    | Kidney - bovine                                      | 0.01*                                           | 0.01*                           |                  |
| <b>1012050</b>    | Edible offals (other than liver and kidney) - bovine | 0.01*                                           | 0.01*                           |                  |
| <b>1012990</b>    | Others - bovine                                      | 0.01*                                           | 0.01*                           |                  |
| <b>1013000</b>    | Sheep                                                |                                                 |                                 |                  |
| <b>1013010</b>    | Muscle - sheep                                       | 0.01*                                           | 0.01*                           |                  |
| <b>1013020</b>    | Fat - sheep                                          | 0.01*                                           | 0.01*                           |                  |
| <b>1013030</b>    | Liver - sheep                                        | 0.01*                                           | 0.01*                           |                  |
| <b>1013040</b>    | Kidney - sheep                                       | 0.01*                                           | 0.01*                           |                  |
| <b>1013050</b>    | Edible offals (other than liver and kidney) - sheep  | 0.01*                                           | 0.01*                           |                  |
| <b>1013990</b>    | Others - sheep                                       | 0.01*                                           | 0.01*                           |                  |
| <b>1014000</b>    | Goat                                                 |                                                 |                                 |                  |
| <b>1014010</b>    | Muscle - goat                                        | 0.01*                                           | 0.01*                           |                  |
| <b>1014020</b>    | Fat - goat                                           | 0.01*                                           | 0.01*                           |                  |
| <b>1014030</b>    | Liver - goat                                         | 0.01*                                           | 0.01*                           |                  |
| <b>1014040</b>    | Kidney - goat                                        | 0.01*                                           | 0.01*                           |                  |

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|-------------------|-------------------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>1014050</b>    | Edible offals (other than liver and kidney) - goat    | 0.01*                                           | 0.01*                           |                  |
| <b>1014990</b>    | Others - goat                                         | 0.01*                                           | 0.01*                           |                  |
| <b>1015000</b>    | Equine                                                |                                                 |                                 |                  |
| <b>1015010</b>    | Muscle - equine                                       | 0.01*                                           | 0.01*                           |                  |
| <b>1015020</b>    | Fat - equine                                          | 0.01*                                           | 0.01*                           |                  |
| <b>1015030</b>    | Liver - equine                                        | 0.01*                                           | 0.01*                           |                  |
| <b>1015040</b>    | Kidney - equine                                       | 0.01*                                           | 0.01*                           |                  |
| <b>1015050</b>    | Edible offals (other than liver and kidney) - equine  | 0.01*                                           | 0.01*                           |                  |
| <b>1015990</b>    | Others - equine                                       | 0.01*                                           | 0.01*                           |                  |
| <b>1016000</b>    | Poultry                                               |                                                 |                                 |                  |
| <b>1016010</b>    | Muscle - poultry                                      | 0.01*                                           | 0.01*                           |                  |
| <b>1016020</b>    | Fat - poultry                                         | 0.01*                                           | 0.01*                           |                  |
| <b>1016030</b>    | Liver - poultry                                       | 0.01*                                           | 0.01*                           |                  |
| <b>1016040</b>    | Kidney - poultry                                      | 0.01*                                           | 0.01*                           |                  |
| <b>1016050</b>    | Edible offals (other than liver and kidney) - poultry | 0.01*                                           | 0.01*                           |                  |

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|-------------------|--------------------------------------------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>1016990</b>    | Others - poultry                                                               | 0.01*                                           | 0.01*                           |                  |
| <b>1017000</b>    | Other farmed terrestrial animals                                               |                                                 |                                 |                  |
| <b>1017010</b>    | Muscle - other farmed terrestrial animals                                      | 0.01*                                           | 0.01*                           |                  |
| <b>1017020</b>    | Fat - other farmed terrestrial animals                                         | 0.01*                                           | 0.01*                           |                  |
| <b>1017030</b>    | Liver - other farmed terrestrial animals                                       | 0.01*                                           | 0.01*                           |                  |
| <b>1017040</b>    | Kidney - other farmed terrestrial animals                                      | 0.01*                                           | 0.01*                           |                  |
| <b>1017050</b>    | Edible offals (other than liver and kidney) - other farmed terrestrial animals | 0.01*                                           | 0.01*                           |                  |
| <b>1017990</b>    | Others - Other farm animals                                                    | 0.01*                                           | 0.01*                           |                  |
| <b>1020000</b>    | Milk                                                                           |                                                 |                                 |                  |
| <b>1020010</b>    | Cattle - milk                                                                  | 0.01*                                           | 0.01*                           |                  |
| <b>1020020</b>    | Sheep - milk                                                                   | 0.01*                                           | 0.01*                           |                  |
| <b>1020030</b>    | Goat - milk                                                                    | 0.01*                                           | 0.01*                           |                  |

| <b>GB Code No</b> | <b>Commodity to which the MRL applies</b> | <b>Current MRL in force (mg/kg)<sup>†</sup></b> | <b>New/ amended MRL (mg/kg)</b> | <b>Footnotes</b> |
|-------------------|-------------------------------------------|-------------------------------------------------|---------------------------------|------------------|
| <b>1020040</b>    | Horse - milk                              | 0.01*                                           | 0.01*                           |                  |
| <b>1020990</b>    | Others - Milk and cream                   | 0.01*                                           | 0.01*                           |                  |
| <b>1030000</b>    | Birds eggs                                |                                                 |                                 |                  |
| <b>1030010</b>    | Chicken - eggs                            | 0.01*                                           | 0.01*                           |                  |
| <b>1030020</b>    | Duck - eggs                               | 0.01*                                           | 0.01*                           |                  |
| <b>1030030</b>    | Geese - eggs                              | 0.01*                                           | 0.01*                           |                  |
| <b>1030040</b>    | Quail - eggs                              | 0.01*                                           | 0.01*                           |                  |
| <b>1030990</b>    | Others - Birds' eggs                      | 0.01*                                           | 0.01*                           |                  |
| <b>1040000</b>    | Honey and other apiculture products       |                                                 |                                 |                  |
| <b>1040000</b>    | Honey and other apiculture products       | 0.01*                                           | 0.05*                           |                  |
| <b>1050000</b>    | Amphibians and reptiles                   |                                                 |                                 |                  |
| <b>1050000</b>    | Amphibians and reptiles                   | 0.01*                                           | 0.01*                           |                  |
| <b>1060000</b>    | Terrestrial invertebrate animals          |                                                 |                                 |                  |
| <b>1060000</b>    | Terrestrial invertebrate animals          | 0.01*                                           | 0.01*                           |                  |
| <b>1070000</b>    | Wild terrestrial vertebrate animals       |                                                 |                                 |                  |

| GB Code No | Commodity to which the MRL applies  | Current MRL in force (mg/kg) <sup>†</sup> | New/ amended MRL (mg/kg) | Footnotes |
|------------|-------------------------------------|-------------------------------------------|--------------------------|-----------|
| 1070000    | Wild terrestrial vertebrate animals | 0.01*                                     | 0.01*                    |           |

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

† Specific MRLs for bixlozone are not currently established in the GB MRL Statutory Register. In accordance with Article 18 of Assimilated Regulation 396/2005 the default LOQ MRL of 0.01\* mg/kg applies to residues of bixlozone.

§ The residue definition for enforcement applies to the new/amended MRLs only. For products of animal origin, a default residue definition of bixlozone only applies at this time. The adoption of substantive MRLs for products of animal origin will require a consideration of suitable residue definitions for risk assessment and enforcement.

Part 1 of the GB MRL Statutory Register should be consulted for the full list of products of plant and animal origin to which the maximum residue levels of pesticides ('MRLs') apply

## Footnotes

### 1) Kales

MRLs shall apply to radish leaves as from 1 January 2025.

### 2) Ginger

The applicable maximum residue level for ginger (*Zingiber officinale*) in the spice group (code 0840020) is the one set for ginger roots (*Zingiber officinale*) in the Part 1B of the Statutory Register (code 0213040-006, equal to the one of horseradish (*Armoracia rusticana*) code 0213040), taking into account changes in the levels by processing (drying), according to Art. 20 (1) of Assimilated Regulation 396/2005.

### 3) Horseradish

The applicable maximum residue level for horseradish (*Armoracia rusticana*) in the spice group (code 0840040) is the one set for horseradish (*Armoracia rusticana*) in the Vegetables category, root and tuber vegetables group (code 0213040), taking into account changes in the levels by processing (drying) according to Art. 20 (1) of Assimilated Regulation 396/2005.

### Notes

- Herbs and edible flowers (code 0256000) are regarded as difficult to analyse matrices and therefore the default LOQ MRL for these products should be set at  $2 \times 0.02^*$  mg/kg.
- Teas, coffee, herbal infusions, cocoa and carobs (code 0600000), hops (code 0700000) and spices (code 0800000) are regarded as difficult to analyse matrices and therefore the default LOQ MRL for these products should be set at  $5 \times 0.01^*$  mg/kg.
- The default LOQ MRL for honey is  $0.05^*$  mg/kg

## References

HSE, 2024a. Assessment Report (AR) on the active substance bixlozone, January 2024

HSE, 2024b. Conclusion of the Assessing Competent Authority on the Active Substance Bixlozone. March 2024

HSE, 2024c. List of Endpoints on the active substance bixlozone. January 2024



## 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)                  |                |                                                                                                                                                                    |
| Winter barley             | GB                                 | X8Q85<br>325 g/L<br>ZC<br>(Fundatis) | F            | Annual broadleaved weeds and selected annual grasses | ZC          | 125 g/L beflubutamid;<br>200 g/L bixlozone<br>[Product contains 34.5 g/L cloquintocet-mexyl as safener] | Broadcast soil directed spray | Pre-emergence/<br>BBCH 00-09<br>(Autumn) | 1                  | n/a                                | 0.05-0.1                       | 200-400              | Beflubutamid: 0.125<br>Bixlozone: 0.200 | n/a            | All rotational crops, except cereals (including maize), oilseeds and pulses (dry seed), must not be planted until at least 9 months after application of bixlozone |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|               |    |                                      |   |                                                      |    |                                                                                                         |                               |                                          |   |     |          |         |                                               |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------|----|--------------------------------------|---|------------------------------------------------------|----|---------------------------------------------------------------------------------------------------------|-------------------------------|------------------------------------------|---|-----|----------|---------|-----------------------------------------------|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Winter barley | GB | X8Q85<br>325 g/L<br>ZC<br>(Fundatis) | F | Annual broadleaved weeds and selected annual grasses | ZC | 125 g/L beflubutamid;<br>200 g/L bixlozone<br>[Product contains 34.5 g/L cloquintocet-mexyl as safener] | Row -, band application       | Pre-emergence/<br>BBCH 00-09<br>(Autumn) | 1 | n/a | 0.05-0.1 | 200-400 | Beflubutamid:<br>0.125<br>Bixlozone:<br>0.200 | n/a | <p>All rotational crops, except cereals (including maize), oilseeds and pulses (dry seed), must not be planted until at least 9 months after application of bixlozone</p> <p>A maximum of 50% of the field can be treated, at a rate which results in the treated bands receiving the same rate of product compared to a broadcast application (i.e. 1 litre product/ha in just the row/band area that is treated, equating to 0.5 litres product/ha on a field area overall).</p> |
| Winter wheat  | GB | X8Q85<br>325 g/L<br>ZC<br>(Fundatis) | F | Annual broadleaved weeds and selected                | ZC | 125 g/L beflubutamid;<br>200 g/L bixlozone                                                              | Broadcast soil directed spray | Pre to early post emergence/             | 1 | n/a | 0.05-0.1 | 200-400 | Beflubutamid:<br>0.125<br>Bixlozone:<br>0.200 | n/a | All rotational crops, except cereals (including                                                                                                                                                                                                                                                                                                                                                                                                                                    |

The evaluation of new MRLs for bixlozone in or on barley and wheat

| 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) |                |                                                                                                                    |
|                           |                                    |              |              | annual grasses [grass weed growth stage BBCH 00-11]] |             | [Product contains 34.5 g/L cloquintocet-mexyl as safener] |                   | BBCH 00-13 (Autumn)                 |                    |                                    |                                |                      |                        |                | maize), oilseeds and pulses (dry seed), must not be planted until at least 9 months after application of bixlozone |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                    |    |                                      |   |                                                                                            |    |                                                                                                   |                               |                                                  |   |     |          |         |                                         |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------------|----|--------------------------------------|---|--------------------------------------------------------------------------------------------|----|---------------------------------------------------------------------------------------------------|-------------------------------|--------------------------------------------------|---|-----|----------|---------|-----------------------------------------|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Winter wheat       | GB | X8Q85<br>325 g/L<br>ZC<br>(Fundatis) | F | Annual broadleaved weeds and selected annual grasses [grass weed growth stage BBCH 00-11]] | ZC | 125 g/L beflubutamid; 200 g/L bixlozone [Product contains 34.5 g/L cloquintocet-mexyl as safener] | Row -, band application       | Pre to early post emergence/ BBCH 00-13 (Autumn) | 1 | n/a | 0.05-0.1 | 200-400 | Beflubutamid: 0.125<br>Bixlozone: 0.200 | n/a | <p>All rotational crops, except cereals (including maize), oilseeds and pulses (dry seed), must not be planted until at least 9 months after application of bixlozone</p> <p>A maximum of 50% of the field can be treated, at a rate which results in the treated bands receiving the same rate of product compared to a broadcast application (i.e. 1 litre product/ha in just the row/band area that is treated, equating to 0.5 litres product/ha on a field area overall).</p> |
| Winter durum wheat | GB | X8Q85<br>325 g/L<br>ZC<br>(Fundatis) | F | Annual broadleaved weeds and selected                                                      | ZC | 125 g/L beflubutamid; 200 g/L bixlozone                                                           | Broadcast soil directed spray | Pre to early post emergence/                     | 1 | n/a | 0.05-0.1 | 200-400 | Beflubutamid: 0.125<br>Bixlozone: 0.200 | n/a | All rotational crops, except cereals (including                                                                                                                                                                                                                                                                                                                                                                                                                                    |

The evaluation of new MRLs for bixlozone in or on barley and wheat

| 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) |                |                                                                                                                    |
|                           |                                    |              |              | annual grasses [grass weed growth stage BBCH 00-11]] |             | [Product contains 34.5 g/L cloquintocet-mexyl as safener] |                   | BBCH 00-13 (Autumn)                 |                    |                                    |                                |                      |                        |                | maize), oilseeds and pulses (dry seed), must not be planted until at least 9 months after application of bixlozone |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                    |    |                                      |   |                                                                                            |    |                                                                                                         |                         |                                                        |   |     |          |         |                                               |     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------------|----|--------------------------------------|---|--------------------------------------------------------------------------------------------|----|---------------------------------------------------------------------------------------------------------|-------------------------|--------------------------------------------------------|---|-----|----------|---------|-----------------------------------------------|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Winter durum wheat | GB | X8Q85<br>325 g/L<br>ZC<br>(Fundatis) | F | Annual broadleaved weeds and selected annual grasses [grass weed growth stage BBCH 00-11]] | ZC | 125 g/L beflubutamid;<br>200 g/L bixlozone<br>[Product contains 34.5 g/L cloquintocet-mexyl as safener] | Row -, band application | Pre to early post emergence/<br>BBCH 00-13<br>(Autumn) | 1 | n/a | 0.05-0.1 | 200-400 | Beflubutamid:<br>0.125<br>Bixlozone:<br>0.200 | n/a | <p>All rotational crops, except cereals (including maize), oilseeds and pulses (dry seed), must not be planted until at least 9 months after application of bixlozone</p> <p>A maximum of 50% of the field can be treated, at a rate which results in the treated bands receiving the same rate of product compared to a broadcast application (i.e. 1 litre product/ha in just the row/band area that is treated, equating to 0.5 litres product/ha on a field area overall).</p> |
|--------------------|----|--------------------------------------|---|--------------------------------------------------------------------------------------------|----|---------------------------------------------------------------------------------------------------------|-------------------------|--------------------------------------------------------|---|-----|----------|---------|-----------------------------------------------|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

# The evaluation of new MRLs for bixlozone in or on barley and wheat

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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.</p> <p>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. benthialvalicarb-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> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## Appendix B – UK models and Pesticide Residues Intake Model (PRIMo)

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

Active substance: Bixlozone      ADI: 0.3 mg/kg bw/day      Source:

| TOTAL INTAKE based on 97.5th percentile |         |         |          |           |            |             |             |            |                    |                       |
|-----------------------------------------|---------|---------|----------|-----------|------------|-------------|-------------|------------|--------------------|-----------------------|
|                                         | ADULT   | INFANT  | TODDLER  | 4-6 YEARS | 7-10 YEARS | 11-14 YEARS | 15-18 YEARS | VEGETARIAN | ELDERLY (OWN HOME) | ELDERLY (RESIDENTIAL) |
| mg/kg bw/day                            | 0.00044 | 0.00166 | 0.001543 | 0.001093  | 0.00086    | 0.00059     | 0.00051     | 0.00045    | 0.00037            | 0.00045               |
| % of ADI                                | <1%     | <1%     | <1%      | <1%       | <1%        | <1%         | <1%         | <1%        | <1%                | <1%                   |

| Commodity   | STMR (mg/kg) | P | COMMODITY INTAKES (mg/kg bw/day) |         |         |           |            |             |             |            |                    |                       |
|-------------|--------------|---|----------------------------------|---------|---------|-----------|------------|-------------|-------------|------------|--------------------|-----------------------|
|             |              |   | ADULT                            | INFANT  | TODDLER | 4-6 YEARS | 7-10 YEARS | 11-14 YEARS | 15-18 YEARS | VEGETARIAN | ELDERLY (OWN HOME) | ELDERLY (RESIDENTIAL) |
| Grapefruit  | 0.01         |   | 0.00002                          | 0.00002 | 0.00006 | 0.00005   | 0.00012    | 0.00002     | 0.00001     | 0.00002    | 0.00002            | 0.00002               |
| Lemons      | 0.01         |   | 0.00000                          | 0.00001 | 0.00000 | 0.00000   | 0.00000    | 0.00000     | 0.00000     | 0.00000    | 0.00000            | 0.00000               |
| Limes       | 0.01         |   | 0.00000                          | L/C     | 0.00002 | 0.00000   | 0.00000    | 0.00000     | 0.00000     | 0.00000    | 0.00000            | 0.00001               |
| Mandarins   | 0.01         |   | 0.00001                          | L/C     | 0.00006 | 0.00004   | 0.00003    | 0.00002     | 0.00002     | 0.00001    | 0.00002            | 0.00001               |
| Oranges     | 0.01         |   | 0.00004                          | 0.00011 | 0.00016 | 0.00001   | 0.00008    | 0.00008     | 0.00007     | 0.00005    | 0.00004            | 0.00003               |
| Almonds     | 0.01         |   | 0.00000                          | 0.00000 | 0.00000 | 0.00000   | 0.00000    | 0.00000     | 0.00000     | 0.00000    | 0.00000            | 0.00000               |
| Brazil nuts | 0.01         |   | 0.00000                          | L/C     | 0.00000 | 0.00000   | 0.00000    | 0.00000     | 0.00000     | 0.00000    | 0.00000            | L/C                   |



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|              |      |             |             |         |             |             |             |             |         |             |         |
|--------------|------|-------------|-------------|---------|-------------|-------------|-------------|-------------|---------|-------------|---------|
| Cashew nuts  | 0.01 | 0.000<br>00 | L/C         | 0.00001 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Chestnuts    | 0.01 | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | L/C         | 0.000<br>00 | 0.00000 | 0.0000<br>0 | L/C     |
| Coconuts     | 0.01 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Hazelnuts    | 0.01 | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Pecan nuts   | 0.01 | 0.000<br>00 | L/C         | 0.00000 | L/C         | 0.000<br>00 | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>0 | L/C     |
| Pistachios   | 0.01 | 0.000<br>00 | L/C         | 0.00000 | L/C         | 0.000<br>00 | L/C         | L/C         | 0.00000 | L/C         | L/C     |
| Walnuts      | 0.01 | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Peanuts      | 0.01 | 0.000<br>00 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Apples       | 0.01 | 0.000<br>03 | 0.000<br>08 | 0.00015 | 0.0000<br>9 | 0.000<br>08 | 0.000<br>04 | 0.000<br>04 | 0.00003 | 0.0000<br>2 | 0.00001 |
| Pears        | 0.01 | 0.000<br>01 | 0.000<br>03 | 0.00007 | 0.0000<br>4 | 0.000<br>02 | 0.000<br>02 | 0.000<br>01 | 0.00002 | 0.0000<br>2 | 0.00001 |
| Apricots     | 0.01 | 0.000<br>00 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>0 | 0.00000 |
| Peaches      | 0.01 | 0.000<br>01 | 0.000<br>01 | 0.00003 | 0.0000<br>2 | 0.000<br>01 | 0.000<br>01 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.00000 |
| Plums        | 0.01 | 0.000<br>01 | 0.000<br>00 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.00000 |
| Cherries     | 0.01 | 0.000<br>00 | 0.000<br>01 | 0.00001 | 0.0000<br>2 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>0 | 0.00000 |
| Table grapes | 0.01 | 0.000<br>01 | 0.000<br>02 | 0.00005 | 0.0000<br>2 | 0.000<br>03 | 0.000<br>01 | 0.000<br>01 | 0.00002 | 0.0000<br>1 | 0.00000 |
| Wine grapes  | 0.01 | 0.000<br>10 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.000<br>00 | 0.000<br>01 | 0.000<br>04 | 0.00010 | 0.0000<br>7 | 0.00001 |
| Wine         | 0.01 | 0.000<br>06 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.000<br>00 | 0.000<br>01 | 0.000<br>02 | 0.00006 | 0.0000<br>4 | 0.00001 |
| Strawberries | 0.01 | 0.000<br>01 | 0.000<br>02 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Blackberries | 0.01 | 0.000<br>00 | L/C         | 0.00002 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Loganberries | 0.01 | 0.000<br>00 | 0.000<br>01 | 0.00001 | 0.0000<br>0 | 0.000<br>01 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Raspberries  | 0.01 | 0.000<br>00 | L/C         | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>1 | 0.00000 |
| Gooseberries | 0.01 | 0.000<br>00 | 0.000<br>01 | 0.00001 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.00000 |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                      |      |             |             |         |             |             |             |             |         |             |         |
|----------------------|------|-------------|-------------|---------|-------------|-------------|-------------|-------------|---------|-------------|---------|
| Blackcurrants        | 0.01 | 0.000<br>01 | 0.000<br>01 | 0.00002 | 0.0000<br>2 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00000 | 0.0000<br>1 | 0.00000 |
| Red currants         | 0.01 | 0.000<br>00 | L/C         | 0.00001 | L/C         | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | L/C     |
| White currants       | 0.01 | L/C         | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | L/C     | L/C         | L/C     |
| Avocados             | 0.01 | 0.000<br>01 | L/C         | 0.00001 | L/C         | L/C         | L/C         | 0.000<br>00 | 0.00001 | 0.0000<br>1 | L/C     |
| Bananas              | 0.01 | 0.000<br>02 | 0.000<br>07 | 0.00007 | 0.0000<br>4 | 0.000<br>03 | 0.000<br>02 | 0.000<br>01 | 0.00002 | 0.0000<br>2 | 0.00002 |
| Dates                | 0.01 | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>1 | 0.00000 |
| Figs                 | 0.01 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>0 | 0.00000 |
| Kiwi fruit           | 0.01 | 0.000<br>01 | L/C         | 0.00002 | 0.0000<br>2 | 0.000<br>01 | 0.000<br>01 | 0.000<br>02 | 0.00001 | 0.0000<br>1 | 0.00000 |
| Lychees              | 0.01 | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | L/C     | L/C         | L/C     |
| Mangoes              | 0.01 | 0.000<br>01 | L/C         | 0.00002 | 0.0000<br>1 | 0.000<br>02 | 0.000<br>01 | 0.000<br>04 | 0.00001 | 0.0000<br>0 | L/C     |
| Olives               | 0.01 | 0.000<br>00 | L/C         | 0.00001 | 0.0000<br>1 | L/C         | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>0 | L/C     |
| Passion fruit        | 0.01 | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | 0.00000 | L/C         | L/C     |
| Pineapples           | 0.01 | 0.000<br>01 | 0.000<br>05 | 0.00005 | 0.0000<br>7 | 0.000<br>02 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Pomegranates         | 0.01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>01 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Beetroot             | 0.01 | 0.000<br>00 | L/C         | 0.00001 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Carrots              | 0.01 | 0.000<br>01 | 0.000<br>04 | 0.00002 | 0.0000<br>2 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Celeriac             | 0.01 | 0.000<br>00 | L/C         | L/C     | 0.0000<br>0 | 0.000<br>00 | L/C         | L/C         | L/C     | L/C         | L/C     |
| Horseradish          | 0.01 | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | L/C     | 0.0000<br>0 | L/C     |
| Jerusalem artichokes | 0.01 | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | L/C     | L/C         | L/C     |
| Parsnips             | 0.01 | 0.000<br>00 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>1 | 0.00000 |
| Radishes             | 0.01 | 0.000<br>00 | L/C         | 0.00001 | L/C         | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Salsify              | 0.01 | L/C         | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | L/C     | L/C         | L/C     |
| Swedes               | 0.01 | 0.000<br>00 | 0.000<br>03 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>00 | 0.00000 | 0.0000<br>1 | 0.00000 |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                  |      |             |             |         |             |             |             |             |         |             |         |
|------------------|------|-------------|-------------|---------|-------------|-------------|-------------|-------------|---------|-------------|---------|
| Turnips          | 0.01 | 0.000<br>00 | L/C         | 0.00001 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>00 | 0.00000 | 0.0000<br>1 | 0.00000 |
| Yam              | 0.01 | 0.000<br>03 | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | L/C     | L/C         | L/C     |
| Garlic           | 0.01 | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | L/C     |
| Onions           | 0.01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00000 |
| Spring onions    | 0.01 | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>1 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Tomatoes         | 0.01 | 0.000<br>01 | 0.000<br>02 | 0.00003 | 0.0000<br>2 | 0.000<br>02 | 0.000<br>01 | 0.000<br>01 | 0.00002 | 0.0000<br>1 | 0.00001 |
| Peppers          | 0.01 | 0.000<br>00 | L/C         | 0.00001 | 0.0000<br>0 | 0.000<br>01 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.00000 |
| Aubergines       | 0.01 | 0.000<br>00 | L/C         | 0.00002 | 0.0000<br>1 | 0.000<br>00 | 0.000<br>01 | 0.000<br>00 | 0.00001 | 0.0000<br>0 | L/C     |
| Marrows          | 0.01 | 0.000<br>01 | L/C         | 0.00002 | 0.0000<br>0 | 0.000<br>01 | 0.000<br>01 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Cucumbers        | 0.01 | 0.000<br>00 | 0.000<br>00 | 0.00002 | 0.0000<br>2 | 0.000<br>01 | 0.000<br>01 | 0.000<br>00 | 0.00001 | 0.0000<br>0 | 0.00000 |
| Gourd            | 0.01 | 0.000<br>01 | L/C         | L/C     | L/C         | L/C         | 0.000<br>00 | L/C         | 0.00000 | L/C         | L/C     |
| Courgettes       | 0.01 | 0.000<br>00 | 0.000<br>01 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.00000 |
| Melons           | 0.01 | 0.000<br>02 | 0.000<br>03 | 0.00005 | 0.0000<br>4 | 0.000<br>03 | 0.000<br>02 | 0.000<br>03 | 0.00003 | 0.0000<br>3 | 0.00001 |
| Sweet corn       | 0.01 | 0.000<br>01 | 0.000<br>01 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>00 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00000 |
| Broccoli         | 0.01 | 0.000<br>01 | 0.000<br>01 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00000 |
| Cauliflower      | 0.01 | 0.000<br>01 | 0.000<br>03 | 0.00002 | 0.0000<br>2 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Brussels sprouts | 0.01 | 0.000<br>01 | 0.000<br>02 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00000 |
| Head cabbage     | 0.01 | 0.000<br>01 | 0.000<br>02 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Chinese cabbage  | 0.01 | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | 0.00001 | 0.0000<br>0 | L/C     |
| Kohl Rabi        | 0.01 | L/C         | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | L/C     | L/C         | L/C     |
| Cress            | 0.01 | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Lettuce          | 0.01 | 0.000<br>01 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.00000 |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                      |      |             |             |         |             |             |             |             |         |             |         |
|----------------------|------|-------------|-------------|---------|-------------|-------------|-------------|-------------|---------|-------------|---------|
| Spinach              | 0.01 | 0.000<br>01 | 0.000<br>01 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.00000 |
| Watercress           | 0.01 | 0.000<br>00 | L/C         | L/C     | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>0 | L/C     |
| Chicory              | 0.01 | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | 0.00000 | L/C         | L/C     |
| Parsley              | 0.01 | 0.000<br>00 | L/C         | 0.00000 | L/C         | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Beans with pods      | 0.01 | 0.000<br>01 | 0.000<br>01 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>00 | 0.000<br>01 | 0.00000 | 0.0000<br>1 | 0.00000 |
| Runner Beans         | 0.01 | 0.000<br>01 | L/C         | 0.00001 | 0.0000<br>0 | 0.000<br>01 | 0.000<br>01 | 0.000<br>00 | 0.00002 | 0.0000<br>1 | 0.00001 |
| Beans without pods   | 0.01 | 0.000<br>00 | 0.000<br>01 | 0.00002 | 0.0000<br>0 | 0.000<br>01 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Peas with pods       | 0.01 | 0.000<br>00 | L/C         | 0.00000 | 0.0000<br>1 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>1 | L/C     |
| Peas without pods    | 0.01 | 0.000<br>01 | 0.000<br>02 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Beansprouts          | 0.01 | 0.000<br>00 | L/C         | 0.00001 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>1 | 0.00000 |
| Asparagus            | 0.01 | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | L/C         | 0.000<br>00 | 0.00001 | 0.0000<br>0 | L/C     |
| Bamboo shoots        | 0.01 | 0.000<br>00 | L/C         | 0.00000 | L/C         | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | L/C     |
| Celery               | 0.01 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Fennel               | 0.01 | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | L/C     | L/C         | L/C     |
| Globe artichokes     | 0.01 | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | 0.00000 | L/C         | L/C     |
| Leeks                | 0.01 | 0.000<br>00 | L/C         | 0.00001 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>1 | 0.00000 |
| Rhubarb              | 0.01 | 0.000<br>00 | 0.000<br>01 | 0.00001 | 0.0000<br>0 | 0.000<br>01 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>1 | 0.00000 |
| Cultivated mushrooms | 0.01 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>0 | 0.00000 |
| Beans                | 0.01 | 0.000<br>02 | 0.000<br>06 | 0.00005 | 0.0000<br>3 | 0.000<br>03 | 0.000<br>02 | 0.000<br>02 | 0.00002 | 0.0000<br>1 | 0.00001 |
| Lentils              | 0.01 | 0.000<br>01 | 0.000<br>01 | 0.00002 | 0.0000<br>2 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00000 |
| dried Peas           | 0.01 | 0.000<br>01 | L/C         | 0.00002 | 0.0000<br>0 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Oils                 | 0.01 | 0.000<br>01 | 0.000<br>01 | 0.00002 | 0.0000<br>2 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                            |       |             |             |         |             |             |             |             |         |             |         |
|----------------------------|-------|-------------|-------------|---------|-------------|-------------|-------------|-------------|---------|-------------|---------|
| Oilseeds                   | 0.01  | 0.000<br>03 | 0.000<br>06 | 0.00007 | 0.0000<br>7 | 0.000<br>06 | 0.000<br>04 | 0.000<br>04 | 0.00005 | 0.0000<br>3 | 0.00004 |
| Potatoes                   | 0.01  | 0.000<br>03 | 0.000<br>11 | 0.00009 | 0.0000<br>8 | 0.000<br>07 | 0.000<br>05 | 0.000<br>05 | 0.00004 | 0.0000<br>3 | 0.00003 |
| canned/bottled Potatoes    | 0.01  | 0.000<br>01 | 0.000<br>04 | 0.00003 | 0.0000<br>1 | 0.000<br>02 | 0.000<br>01 | 0.000<br>02 | 0.00001 | 0.0000<br>1 | 0.00001 |
| jacket Potatoes            | 0.01  | 0.000<br>02 | L/C         | 0.00005 | 0.0000<br>3 | 0.000<br>03 | 0.000<br>02 | 0.000<br>01 | 0.00002 | 0.0000<br>2 | 0.00002 |
| misc. Potato products      | 0.01  | 0.000<br>01 | 0.000<br>03 | 0.00003 | 0.0000<br>3 | 0.000<br>02 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| dried (instant) Potatoes   | 0.01  | 0.000<br>00 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| boiled Potatoes            | 0.01  | 0.000<br>02 | 0.000<br>10 | 0.00006 | 0.0000<br>4 | 0.000<br>03 | 0.000<br>02 | 0.000<br>02 | 0.00002 | 0.0000<br>3 | 0.00002 |
| Crisps                     | 0.01  | 0.000<br>01 | 0.000<br>01 | 0.00002 | 0.0000<br>2 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>0 | 0.00000 |
| Potato chips               | 0.01  | 0.000<br>02 | 0.000<br>03 | 0.00006 | 0.0000<br>4 | 0.000<br>03 | 0.000<br>03 | 0.000<br>03 | 0.00002 | 0.0000<br>2 | 0.00001 |
| Tea (dried leaves)         | 0.05  | 0.000<br>01 | 0.000<br>04 | 0.00001 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Hops (dried 0.25% of beer) | 0.01  | 0.000<br>00 | L/C         | L/C     | L/C         | L/C         | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Oats                       | 0.01  | 0.000<br>00 | 0.000<br>02 | 0.00001 | 0.0000<br>1 | 0.000<br>00 | 0.000<br>00 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Barley                     | 0.039 | 0.000<br>01 | L/C         | 0.00001 | 0.0000<br>1 | 0.000<br>03 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Millet                     | 0.01  | L/C         | L/C         | 0.00000 | L/C         | L/C         | L/C         | L/C         | L/C     | L/C         | L/C     |
| Buckwheat                  | 0.01  | L/C         | L/C         | L/C     | L/C         | L/C         | L/C         | L/C         | L/C     | L/C         | L/C     |
| Cornmeal & Cornflour       | 0.01  | 0.000<br>00 | 0.000<br>03 | 0.00000 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Maize                      | 0.01  | 0.000<br>00 | 0.000<br>05 | 0.00001 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Wheat                      | 0.039 | 0.000<br>14 | 0.000<br>11 | 0.00033 | 0.0003<br>5 | 0.000<br>26 | 0.000<br>19 | 0.000<br>16 | 0.00017 | 0.0001<br>3 | 0.00013 |
| Rice                       | 0.01  | 0.000<br>02 | 0.000<br>03 | 0.00005 | 0.0000<br>4 | 0.000<br>05 | 0.000<br>04 | 0.000<br>03 | 0.00002 | 0.0000<br>1 | 0.00000 |
| Rye                        | 0.01  | 0.000<br>01 | 0.000<br>01 | 0.00000 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>0 | 0.00000 |
| Poultry                    | 0.01  | 0.000<br>02 | 0.000<br>02 | 0.00003 | 0.0000<br>3 | 0.000<br>02 | 0.000<br>02 | 0.000<br>02 | 0.00002 | 0.0000<br>2 | 0.00001 |
| Meat fat                   | 0.01  | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | 0.00000 | 0.0000<br>0 | 0.00000 |
| Meat excl. poultry & offal | 0.01  | 0.000<br>02 | 0.000<br>04 | 0.00004 | 0.0000<br>3 | 0.000<br>03 | 0.000<br>02 | 0.000<br>02 | 0.00000 | 0.0000<br>2 | 0.00002 |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                      |      |  |             |             |         |             |             |             |             |         |             |         |
|----------------------|------|--|-------------|-------------|---------|-------------|-------------|-------------|-------------|---------|-------------|---------|
| All types of kidney  | 0.01 |  | 0.000<br>00 | 0.000<br>00 | 0.00001 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>00 | 0.000<br>00 | L/C     | 0.0000<br>0 | 0.00000 |
| All types of Liver   | 0.01 |  | 0.000<br>00 | 0.000<br>02 | 0.00002 | 0.0000<br>0 | 0.000<br>00 | 0.000<br>01 | 0.000<br>00 | L/C     | 0.0000<br>1 | 0.00000 |
| Other types of offal | 0.01 |  | 0.000<br>01 | 0.000<br>02 | 0.00002 | 0.0000<br>1 | 0.000<br>01 | 0.000<br>01 | 0.000<br>00 | 0.00000 | 0.0000<br>1 | 0.00001 |
| Eggs                 | 0.01 |  | 0.000<br>01 | 0.000<br>05 | 0.00003 | 0.0000<br>2 | 0.000<br>02 | 0.000<br>01 | 0.000<br>01 | 0.00001 | 0.0000<br>1 | 0.00001 |
| Milk                 | 0.01 |  | 0.000<br>08 | 0.000<br>98 | 0.00056 | 0.0002<br>9 | 0.000<br>18 | 0.000<br>12 | 0.000<br>09 | 0.00010 | 0.0000<br>9 | 0.00012 |
| Sugar beet           | 0.01 |  | 0.000<br>14 | 0.000<br>33 | 0.00056 | 0.0003<br>4 | 0.000<br>31 | 0.000<br>20 | 0.000<br>19 | 0.00012 | 0.0001<br>1 | 0.00015 |
| Refined sugar        | 0.01 |  | 0.000<br>02 | 0.000<br>05 | 0.00008 | 0.0000<br>5 | 0.000<br>05 | 0.000<br>03 | 0.000<br>03 | 0.00002 | 0.0000<br>2 | 0.00002 |

\* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value  
≥0.000005 is rounded to 0.00001

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

**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 : -- |                                              |                                  |                                             |                                  |                                             |                                  | 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 or to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor or 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) | 0.5%                           | NL toddler        | 1.36                               | 0.2%                                         | Milk: Cattle                     | 0.1%                                        | Wheat                            | 0.0%                                        | Apples                           |                                   |                                                |
|                                                                | 0.3%                           | NL child          | 0.78                               | 0.1%                                         | Milk: Cattle                     | 0.1%                                        | Wheat                            | 0.0%                                        | Sugar beet roots                 |                                   |                                                |
|                                                                | 0.3%                           | DE child          | 0.76                               | 0.1%                                         | Milk: Cattle                     | 0.1%                                        | Wheat                            | 0.0%                                        | Apples                           |                                   |                                                |
|                                                                | 0.2%                           | UK infant         | 0.69                               | 0.1%                                         | Milk: Cattle                     | 0.0%                                        | Wheat                            | 0.0%                                        | Potatoes                         |                                   |                                                |
|                                                                | 0.2%                           | FR child 3 15 yr  | 0.69                               | 0.1%                                         | Milk: Cattle                     | 0.1%                                        | Wheat                            | 0.0%                                        | Sugar beet roots                 |                                   |                                                |
|                                                                | 0.2%                           | FR toddler 2 3 yr | 0.65                               | 0.1%                                         | Milk: Cattle                     | 0.0%                                        | Wheat                            | 0.0%                                        | Apples                           |                                   |                                                |
|                                                                | 0.2%                           | GEMS/Food G06     | 0.59                               | 0.1%                                         | Wheat                            | 0.0%                                        | Tomatoes                         | 0.0%                                        | Milk: Cattle                     |                                   |                                                |
|                                                                | 0.2%                           | UK toddler        | 0.56                               | 0.1%                                         | Milk: Cattle                     | 0.1%                                        | Wheat                            | 0.0%                                        | Potatoes                         |                                   |                                                |
|                                                                | 0.2%                           | GEMS/Food G11     | 0.54                               | 0.0%                                         | Wheat                            | 0.0%                                        | Milk: Cattle                     | 0.0%                                        | Potatoes                         |                                   |                                                |
|                                                                | 0.2%                           | DK child          | 0.54                               | 0.1%                                         | Wheat                            | 0.0%                                        | Milk: Cattle                     | 0.0%                                        | Rye                              |                                   |                                                |
|                                                                | 0.2%                           | GEMS/Food G15     | 0.54                               | 0.1%                                         | Wheat                            | 0.0%                                        | Milk: Cattle                     | 0.0%                                        | Potatoes                         |                                   |                                                |
|                                                                | 0.2%                           | RO general        | 0.52                               | 0.1%                                         | Wheat                            | 0.0%                                        | Milk: Cattle                     | 0.0%                                        | Potatoes                         |                                   |                                                |
|                                                                | 0.2%                           | GEMS/Food G07     | 0.52                               | 0.1%                                         | Wheat                            | 0.0%                                        | Milk: Cattle                     | 0.0%                                        | Potatoes                         |                                   |                                                |
|                                                                | 0.2%                           | GEMS/Food G08     | 0.52                               | 0.1%                                         | Wheat                            | 0.0%                                        | Milk: Cattle                     | 0.0%                                        | Potatoes                         |                                   |                                                |
|                                                                | 0.2%                           | ES child          | 0.50                               | 0.1%                                         | Wheat                            | 0.0%                                        | Milk: Cattle                     | 0.0%                                        | Cocoa beans                      |                                   |                                                |
|                                                                | 0.2%                           | GEMS/Food G10     | 0.50                               | 0.1%                                         | Wheat                            | 0.0%                                        | Milk: Cattle                     | 0.0%                                        | Soyabeans                        |                                   |                                                |
|                                                                | 0.2%                           | SE general        | 0.47                               | 0.0%                                         | Wheat                            | 0.0%                                        | Milk: Cattle                     | 0.0%                                        | Bovine: Muscle/meat              |                                   |                                                |

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|                                                                                                                                                                                                   |                   |      |      |              |      |               |      |                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|------|------|--------------|------|---------------|------|------------------|
| 0.1%                                                                                                                                                                                              | DE women 14-50 yr | 0.44 | 0.0% | Milk: Cattle | 0.0% | Wheat         | 0.0% | Sugar beet roots |
| 0.1%                                                                                                                                                                                              | DE general        | 0.43 | 0.0% | Milk: Cattle | 0.0% | Wheat         | 0.0% | Sugar beet roots |
| 0.1%                                                                                                                                                                                              | IE adult          | 0.40 | 0.0% | Wheat        | 0.0% | Milk: Cattle  | 0.0% | Sweet potatoes   |
| 0.1%                                                                                                                                                                                              | NL general        | 0.36 | 0.0% | Milk: Cattle | 0.0% | Wheat         | 0.0% | Sugar beet roots |
| 0.1%                                                                                                                                                                                              | FI adult          | 0.36 | 0.1% | Coffee beans | 0.0% | Wheat         | 0.0% | Potatoes         |
| 0.1%                                                                                                                                                                                              | IT toddler        | 0.36 | 0.1% | Wheat        | 0.0% | Other cereals | 0.0% | Tomatoes         |
| 0.1%                                                                                                                                                                                              | PT general        | 0.32 | 0.1% | Wheat        | 0.0% | Potatoes      | 0.0% | Wine grapes      |
| 0.1%                                                                                                                                                                                              | FR infant         | 0.32 | 0.1% | Milk: Cattle | 0.0% | Wheat         | 0.0% | Potatoes         |
| 0.1%                                                                                                                                                                                              | ES adult          | 0.29 | 0.0% | Wheat        | 0.0% | Milk: Cattle  | 0.0% | Barley           |
| 0.1%                                                                                                                                                                                              | FR adult          | 0.28 | 0.0% | Wheat        | 0.0% | Milk: Cattle  | 0.0% | Wine grapes      |
| 0.1%                                                                                                                                                                                              | IT adult          | 0.24 | 0.1% | Wheat        | 0.0% | Tomatoes      | 0.0% | Apples           |
| 0.1%                                                                                                                                                                                              | FI 3 yr           | 0.21 | 0.0% | Potatoes     | 0.0% | Wheat         | 0.0% | Bananas          |
| 0.1%                                                                                                                                                                                              | UK vegetarian     | 0.21 | 0.0% | Wheat        | 0.0% | Milk: Cattle  | 0.0% | Potatoes         |
| 0.1%                                                                                                                                                                                              | DK adult          | 0.20 | 0.0% | Milk: Cattle | 0.0% | Wheat         | 0.0% | Potatoes         |
| 0.1%                                                                                                                                                                                              | LT adult          | 0.19 | 0.0% | Wheat        | 0.0% | Milk: Cattle  | 0.0% | Potatoes         |
| 0.1%                                                                                                                                                                                              | UK adult          | 0.19 | 0.0% | Wheat        | 0.0% | Milk: Cattle  | 0.0% | Potatoes         |
| 0.1%                                                                                                                                                                                              | FI 6 yr           | 0.17 | 0.0% | Potatoes     | 0.0% | Wheat         | 0.0% | Cocoa beans      |
| 0.0%                                                                                                                                                                                              | IE child          | 0.11 | 0.0% | Wheat        | 0.0% | Milk: Cattle  | 0.0% | Potatoes         |
| 0.0%                                                                                                                                                                                              | PL general        | 0.10 | 0.0% | Potatoes     | 0.0% | Apples        | 0.0% | Tomatoes         |
| <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 Bixlozone is unlikely to present a public health concern. |                   |      |      |              |      |               |      |                  |



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

|           |      |   | 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 |
| Barley    | 0.04 |   | 0.00003 | 0.0   | 0.00000 | 0.0   | 0.00003 | 0.0   | 0.00007            | 0.0   | 0.00022             | 0.0   |
| Wheat     | 0.04 |   | 0.00024 | 0.0   | 0.00050 | 0.1   | 0.00051 | 0.1   | 0.00056            | 0.1   | 0.00043             | 0.1   |

|           |      |   | 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 |
| Barley    | 0.04 |   | 0.00002              | 0.0   | 0.00002              | 0.0   | 0.00003    | 0.0   | 0.00002            | 0.0   | 0.00001               | 0.0   |
| Wheat     | 0.04 |   | 0.00035              | 0.0   | 0.00033              | 0.0   | 0.00031    | 0.0   | 0.00018            | 0.0   | 0.00018               | 0.0   |

Pesticide            Bixlozone  
ARfD                 0.750    mg/Kg bw/day

Source

\* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

**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) |
|                         | 0.08%                                                                                                     | Wheat       | 0 / 0.04                   | 0.56                | 0.04%                                                                                       | Wheat       | 0 / 0.04                   | 0.33                |
|                         | 0.03%                                                                                                     | Barley      | 0 / 0.04                   | 0.22                | 0.03%                                                                                       | Barley      | 0 / 0.04                   | 0.19                |
| Processed commodities   | Expand/collapse list                                                                                      |             |                            |                     |                                                                                             |             |                            |                     |
|                         | <b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b> |             |                            |                     |                                                                                             |             |                            |                     |

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|                      | Highest % of | Processed commodities              | MRL / input       | Exposure |  | Highest % of | Processed commodities        | MRL / input | Exposure |
|----------------------|--------------|------------------------------------|-------------------|----------|--|--------------|------------------------------|-------------|----------|
|                      | ARfD/ADI     |                                    | for RA<br>(mg/kg) |          |  | (µg/kg bw)   |                              | ARfD/ADI    |          |
|                      | 0.06%        | Wheat / milling (flour)            | 0 / 0.04          | 0.47     |  | 0.04%        | Barley / beer                | 0 / 0.01    | 0.28     |
|                      | 0.0%         | Wheat / milling (wholemeal)-baking | 0 / 0.04          | 0.22     |  | 0.02%        | Wheat / bread/pizza          | 0 / 0.04    | 0.17     |
|                      | 0.0%         | Barley / cooked                    | 0 / 0.04          | 0.14     |  | 0.02%        | Wheat / pasta                | 0 / 0.04    | 0.15     |
|                      | 0.0%         | Barley / milling (flour)           | 0 / 0.04          | 0.07     |  | 0.02%        | Wheat / bread<br>(wholemeal) | 0 / 0.04    | 0.14     |
|                      |              |                                    |                   |          |  |              |                              |             |          |
| Expand/collapse list |              |                                    |                   |          |  |              |                              |             |          |

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

### C.1 Methods of analysis

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

##### C.1.1.1 Method validation

Reference: Bixlozone - Validation of the Analytical Method CAM-0180 for the Determination of Bixlozone (F9600) and Metabolites 2,4-dichlorobenzoic acid and 5'-hydroxy-F9600 in Lettuce, Wheat Grain and Dried Beans by LC-MS/MS, [REDACTED] 2023, FMC-81447, CEMR-10638

GLP: Yes

Acceptability of the method: Valid

Method CAM-180 (version 003) was validated for the analytes bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone in lettuce (high water), wheat grain (dry) and dried beans (high protein). The RD-Enf includes parent only. However, the results of 2,4-dichlorobenzoic acids and 5'-hydroxy-bixlozone have been presented below for completeness.

The extraction procedures for version 3 are identical to those in version 002, which as considered for the active approval. The update included a footnote to indicate that if low recoveries for bixlozone are obtained using the high-water procedure, the low water content procedure should be used.

#### Principle of the method

##### *Extraction of matrices with a high-water content:*

Samples (10 g) are weighed into round bottom flasks (500 mL) and 100 mL 1N hydrochloric acid is added. The sample is weighed and refluxed for one hour. After cooling, the weight loss is compensated using 1N HCl. After settling, 10mL aliquot of the supernatant is taken and 5mL of acetonitrile is added. QuEChERS (EN 15662) salt is

added, and the mixture shaken vigorously, followed by centrifugation to separate layers. 1mL of the acetonitrile layer is transferred to a 2mL Eppendorf tube with 150 anhydrous magnesium sulphate and 50mg of end capped C18. The mix is vortexed and shaken for 10 minutes and centrifuged. After centrifugation, 50µL of the supernatant is transferred into a glass autosampler and diluted with 950µL HPLC water containing 0.05% acetic acid. The final sample concentration is 0.01 g/mL.

*Extraction of matrices with a low water content (dry matrices):*

Samples (10 g) are weighed into round bottom flasks (500 mL) and 100 mL 1N hydrochloric acid is added. The sample is weighed and refluxed for one hour. After cooling, the weight loss is compensated using 1N HCl. 50mL acetonitrile is added, and the mixture shaken for 1 hour, followed by centrifugation. After settling, 15mL of the supernatant is taken. QuEChERS (EN 15662) salt is added, and the mixture shaken vigorously, followed by centrifugation to separate layers. 1mL of the acetonitrile layer is transferred to a 2mL Eppendorf tube with 150 anhydrous magnesium sulphate and 50mg of end capped C18. The mix is vortexed and shaken for 10 minutes. After centrifugation, 50µL of the supernatant is transferred into a glass autosampler and diluted with 950µL HPLC water containing 0.05% acetic acid. The final sample concentration is 0.01 g/mL.

*Extraction of matrices with a high protein content:*

The procedure for low water content (dry matrices) was followed.

*Analysis*

The samples are analysed by high performance liquid chromatography with tandem mass specific detection (HPLC-MS/MS) in both positive and negative ionisation modes.

A Phenomenex Kinetex C18 column (50 mm × 2.1 mm, 2.6 µm particle size) was used.

In all cases the analytes are chromatographed by gradient elution with mobile phases of 0.05% acetic acid in water and acetonitrile. Quantification is performed using matrix matched standards using the following ion transitions:

| Analyte                  | Ionisation mode | Quantification Ion Transition (m/z) | Confirmatory Ion Transition (m/z) |
|--------------------------|-----------------|-------------------------------------|-----------------------------------|
| bixlozone                | positive        | 274.2 > 159.0                       | 274.2 > 123.0                     |
| 2,4-dichlorobenzoic acid | negative        | 189.0 > 144.8                       | 190.9 > 147.0                     |
| 5'-hydroxy-bixlozone     | positive        | 290.2 > 175.0                       | 290.2 > 111.0                     |

## Results and discussion

**Table C.1.1.1-1 Recovery Results in lettuce**

Standards prepared in matrix matched methanol.

| Analyte                  | Matrix                   | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RS D (%) | Comments   |
|--------------------------|--------------------------|---------------|----------------------|-------------------------|---------------|----------|------------|
| Bixlozone                | Lettuce (quantification) | 0.01          | 5                    | 98 – 103                | 100           | 2.2      | Acceptable |
|                          |                          | 0.1           | 5                    | 90 – 93                 | 92            | 1.4      | Acceptable |
|                          | Lettuce (confirmation)   | 0.01          | 5                    | 89 – 106                | 95            | 7.7      | Acceptable |
|                          |                          | 0.1           | 5                    | 92 – 94                 | 93            | 1.1      | Acceptable |
| 2,4-dichlorobenzoic acid | Lettuce (quantification) | 0.01          | 5                    | 109 – 116               | 114           | 3.0      | Acceptable |
|                          |                          | 0.1           | 5                    | 111 – 114               | 113           | 1.2      | Acceptable |
|                          | Lettuce (confirmation)   | 0.01          | 5                    | 104 – 114               | 108           | 4.0      | Acceptable |
|                          |                          | 0.1           | 5                    | 108 – 114               | 111           | 2.1      | Acceptable |
| 5'-hydroxy-bixlozone     | Lettuce (quantification) | 0.01          | 5                    | 101 – 129               | 118           | 8.7      | Acceptable |
|                          |                          | 0.1           | 5                    | 93 – 115                | 105           | 8.0      | Acceptable |
|                          | Lettuce (confirmation)   | 0.01          | 5                    | 97 – 128                | 116           | 9.9      | Acceptable |
|                          |                          | 0.1           | 5                    | 92 – 113                | 103           | 8.1      | Acceptable |

**Table C.1.1.1-2 Characteristics of the analytical method for the quantitation of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone residues in lettuce**

|                                                                                                    | Bixlozone                                                                                                                                                                                                                                                                                                              | 2,4-dichlorobenzoic acid                                                                                                                                                                                                                                                                                              | 5'-hydroxy-bixlozone                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chromatographic method                                                                             | HPLC-MS/MS                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                      |
| Specificity demonstrated (yes/no, by...)                                                           | Yes by MS ions and retention time matching with certified reference standards.                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                      |
| Linearity demonstrated (yes/no)                                                                    | Yes                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                      |
| Calibration                                                                                        |                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                      |
| Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)                         | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 670914x + 3490</math></p> <p><math>r = 0.9989</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 87548x + 1528</math></p> <p><math>r = 0.9999</math></p> | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 632264x + 504</math></p> <p><math>r = 0.9999</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 364063x + 764</math></p> <p><math>r = 0.9998</math></p> | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 345013x - 2786</math></p> <p><math>r = 0.9992</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 6972x - 461</math></p> <p><math>r = 0.9990</math></p> |
| Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/no) | Yes (n=7)                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                      |

|                                                                                   | <b>Bixlozone</b>                                                                                                                                      | <b>2,4-dichlorobenzoic acid</b>                                                                                                                         | <b>5'-hydroxy-bixlozone</b>                                                                                                                           |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Matrix effects                                                                    | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to not be significant (<20%). However, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. |
| Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)      | Yes                                                                                                                                                   |                                                                                                                                                         |                                                                                                                                                       |
| Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ration? (yes/no) | Yes                                                                                                                                                   |                                                                                                                                                         |                                                                                                                                                       |
| <b>LOQ</b> (mg/kg)                                                                | 0.01                                                                                                                                                  | 0.01                                                                                                                                                    | 0.01                                                                                                                                                  |

**Table C.1.1.1-3 Recovery Results in wheat grain**

Standards prepared in matrix matched methanol.

| <b>Analyte</b> | <b>Matrix</b>                | <b>level (mg/kg)</b> | <b>No samples per level</b> | <b>Range of recoveries (%)</b> | <b>Mean recovery</b> | <b>RS D (%)</b> | <b>Comments</b> |
|----------------|------------------------------|----------------------|-----------------------------|--------------------------------|----------------------|-----------------|-----------------|
| Bixlozone      | Wheat grain (quantification) | 0.01                 | 5                           | 90 – 101                       | 97                   | 5.0             | Acceptable      |
|                |                              | 0.1                  | 5                           | 87 – 98                        | 91                   | 5.0             | Acceptable      |
|                |                              | 0.01                 | 5                           | 93 – 103                       | 98                   | 4.3             | Acceptable      |



| Analyte                  | Matrix                       | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RS D (%) | Comments   |
|--------------------------|------------------------------|---------------|----------------------|-------------------------|---------------|----------|------------|
|                          | Wheat grain (confirmation)   | 0.1           | 5                    | 87 – 101                | 92            | 6.3      | Acceptable |
| 2,4-dichlorobenzoic acid | Wheat grain (quantification) | 0.01          | 5                    | 95 – 110                | 104           | 5.4      | Acceptable |
|                          |                              | 0.1           | 5                    | 95 – 105                | 101           | 3.9      | Acceptable |
|                          | Wheat grain (confirmation)   | 0.01          | 5                    | 83 – 101                | 93            | 6.4      | Acceptable |
|                          |                              | 0.1           | 5                    | 99 – 114                | 108           | 5.1      | Acceptable |
| 5'-hydroxy-bixlozone     | Wheat grain (quantification) | 0.01          | 5                    | 88 – 100                | 95            | 5.1      | Acceptable |
|                          |                              | 0.1           | 5                    | 76 – 110                | 91            | 14.0     | Acceptable |
|                          | Wheat grain (confirmation)   | 0.01          | 5                    | 88 – 97                 | 92            | 4.1      | Acceptable |
|                          |                              | 0.1           | 5                    | 75 – 109                | 90            | 13.9     | Acceptable |

**Table C.1.1.1-4 Characteristics of the analytical method for the quantitation of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone residues in wheat grain**

|                                          | Bixlozone                                                                      | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone |
|------------------------------------------|--------------------------------------------------------------------------------|--------------------------|----------------------|
| Chromatographic method                   | HPLC-MS/MS                                                                     |                          |                      |
| Specificity demonstrated (yes/no, by...) | Yes by MS ions and retention time matching with certified reference standards. |                          |                      |
| Linearity demonstrated (yes/no)          | Yes                                                                            |                          |                      |

|                                                                                                    | <b>Bixlozone</b>                                                                                                                                                                                                                                                                                                                          | <b>2,4-dichlorobenzoic acid</b>                                                                                                                                                                                                                                                                                                         | <b>5'-hydroxy-bixlozone</b>                                                                                                                                                                                                                                                                                                                      |
|----------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Calibration                                                                                        |                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                  |
| Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)                         | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 4431088x + 19809</math></p> <p><math>r = 0.9993</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 522958x + 2900</math></p> <p><math>r = 0.9998</math></p> | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 779609x + 2933</math></p> <p><math>r = 0.9992</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 485916x - 6264</math></p> <p><math>r = 0.9985</math></p> | <p><i>Quantification:</i><br/>0.03 – 2<br/>ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 1325905x - 1692</math></p> <p><math>r = 0.9989</math></p> <p><i>Confirmation:</i><br/>0.03 – 2<br/>ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 235172x + 1160</math></p> <p><math>r = 0.9987</math></p> |
| Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/no) | Yes (n=7)                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                  |

|                                                                                   | <b>Bixlozone</b>                                                                                                                                      | <b>2,4-dichlorobenzoic acid</b>                                                                                                                         | <b>5'-hydroxy-bixlozone</b>                                                                                                                           |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Matrix effects                                                                    | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to not be significant (<20%). However, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. |
| Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)      | Yes                                                                                                                                                   |                                                                                                                                                         |                                                                                                                                                       |
| Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ration? (yes/no) | Yes                                                                                                                                                   |                                                                                                                                                         |                                                                                                                                                       |
| <b>LOQ</b> (mg/kg)                                                                | 0.01                                                                                                                                                  | 0.01                                                                                                                                                    | 0.01                                                                                                                                                  |

**Table C.1.1.1-5 Recovery Results in dried beans**

Standards prepared in matrix matched methanol.

| <b>Analyte</b> | <b>Matrix</b>                | <b>level (mg/kg)</b> | <b>No samples per level</b> | <b>Range of recoveries (%)</b> | <b>Mean recovery</b> | <b>RS D (%)</b> | <b>Comments</b> |
|----------------|------------------------------|----------------------|-----------------------------|--------------------------------|----------------------|-----------------|-----------------|
| Bixlozone      | Dried beans (quantification) | 0.01                 | 5                           | 89 – 92                        | 91                   | 1.3             | Acceptable      |
|                |                              | 0.1                  | 5                           | 88 – 94                        | 91                   | 2.5             | Acceptable      |
|                |                              | 0.01                 | 5                           | 87 – 95                        | 91                   | 3.5             | Acceptable      |

| Analyte                  | Matrix                       | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RSD (%) | Comments   |
|--------------------------|------------------------------|---------------|----------------------|-------------------------|---------------|---------|------------|
|                          | Dried beans (confirmation)   | 0.1           | 5                    | 91 – 94                 | 92            | 1.2     | Acceptable |
| 2,4-dichlorobenzoic acid | Dried beans (quantification) | 0.01          | 5                    | 94 – 116                | 107           | 8.6     | Acceptable |
|                          |                              | 0.1           | 5                    | 93 – 108                | 103           | 6.3     | Acceptable |
|                          | Dried beans (confirmation)   | 0.01          | 5                    | 102 – 113               | 105           | 4.4     | Acceptable |
|                          |                              | 0.1           | 5                    | 93 – 108                | 102           | 5.8     | Acceptable |
| 5'-hydroxy-bixlozone     | Dried beans (quantification) | 0.01          | 5                    | 97 – 194*               | 98            | 0.5     | Acceptable |
|                          |                              | 0.1           | 5                    | 90 – 100                | 95            | 4.7     | Acceptable |
|                          | Dried beans (confirmation)   | 0.01          | 5                    | 92 – 192*               | 96            | 2.7     | Acceptable |
|                          |                              | 0.1           | 5                    | 91 – 99                 | 94            | 3.8     | Acceptable |

\* Value is a statistical outlier and not included in the mean and RSD calculations

**Table C.1.1.1-6 Characteristics of the analytical method for the quantitation of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone residues in dried beans**

|                                          | Bixlozone                                                                      | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone |
|------------------------------------------|--------------------------------------------------------------------------------|--------------------------|----------------------|
| Chromatographic method                   | HPLC-MS/MS                                                                     |                          |                      |
| Specificity demonstrated (yes/no, by...) | Yes by MS ions and retention time matching with certified reference standards. |                          |                      |
| Linearity demonstrated (yes/no)          | Yes                                                                            |                          |                      |

|                                                                                                    | <b>Bixlozone</b>                                                                                                                                                                                                                                                                                                                          | <b>2,4-dichlorobenzoic acid</b>                                                                                                                                                                                                                                                                                                         | <b>5'-hydroxy-bixlozone</b>                                                                                                                                                                                                                                                                                                                      |
|----------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Calibration</b>                                                                                 |                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                  |
| Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)                         | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 7624843x + 20087</math></p> <p><math>r = 0.9997</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 912858x + 1042</math></p> <p><math>r = 0.9998</math></p> | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 782097x + 5638</math></p> <p><math>r = 0.9997</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 471850x + 3020</math></p> <p><math>r = 1.0000</math></p> | <p><i>Quantification:</i><br/>0.03 – 2<br/>ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 1313706x + 9516</math></p> <p><math>r = 0.9998</math></p> <p><i>Confirmation:</i><br/>0.03 – 2<br/>ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 2231664x + 635</math></p> <p><math>r = 0.9997</math></p> |
| Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/no) | Yes (n=7)                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                  |

|                                                                                   | <b>Bixlozone</b>                                                                                                                                      | <b>2,4-dichlorobenzoic acid</b>                                                                                                                         | <b>5'-hydroxy-bixlozone</b>                                                                                                                           |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Matrix effects                                                                    | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to not be significant (<20%). However, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. |
| Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)      | Yes                                                                                                                                                   |                                                                                                                                                         |                                                                                                                                                       |
| Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ration? (yes/no) | Yes                                                                                                                                                   |                                                                                                                                                         |                                                                                                                                                       |
| <b>LOQ</b> (mg/kg)                                                                | 0.01                                                                                                                                                  | 0.01                                                                                                                                                    | 0.01                                                                                                                                                  |

### Final extract stability

The stability of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone in final sample extracts was assessed following at least 7 days in refrigerated storage at 2 – 8 °C.

The recoveries in the fortified samples were within the acceptable range of 70 - 120% when measured against freshly prepared standards.

### Solution stability

Individual stock standard solutions and mixed standard solutions in methanol were shown to be stable for up to 90 and 85 days, respectively when stored between 2 and 8 °C.

Sample extracts were shown to be stable for up to 7 days when stored between 2 and 8 °C.

## Extraction efficiency

Extraction efficiency was sufficiently addressed in the AR (HSE, 2024a) for the methods CAM-0180/001 and CAM-0180/002. The extraction procedures for version 3 are identical to those in version 002 therefore, extraction efficiency has been addressed for CAM-0180/003.

## Conclusion

The method has been satisfactorily validated in accordance with SANTE/2020/12830 Rev.1 for the monitoring of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone in lettuce (high water), wheat grain (high starch/dry commodities) and dried beans (high protein). Extraction efficiency has been sufficiently addressed.

### C.1.1.2 Independent laboratory validation

Reference: Independent Laboratory Validation of an Analytical Method for the Determination of Bixlozone (F9600) and Metabolites 2,4-dichlorobenzoic acid and 5'-hydroxy-F9600 in Lettuce, Wheat Grain and Dried Bean, [REDACTED] 2023, FMC-81446, 20430475

GLP: Yes

Acceptability of the method: Valid

## Principle of the method

See Appendix C.1.1.1 for sample preparation. Initially the ILV was conducted on version 2 of the method; when poor recoveries for lettuce were obtained this was reported to the laboratory who conducted the primary validation. As a result, the method was revised to give version 3, and the primary validation of version 3 was repeated (see Appendix C.1.1.1). The ILV of Version 3 was then undertaken with no communication between the laboratory and no deviations from the method version 3 were recorded.

## Results and discussion

### Table C.1.1.1-1 Recovery Results in lettuce

Standards prepared in matrix matched methanol.

| Analyte                  | Matrix                   | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RS D (%) | Comments   |
|--------------------------|--------------------------|---------------|----------------------|-------------------------|---------------|----------|------------|
| Bixlozone                | Lettuce (quantification) | 0.01          | 5                    | 78 – 120                | 92            | 18       | Acceptable |
|                          |                          | 0.1           | 5                    | 98 – 129                | 115           | 11       | Acceptable |
|                          | Lettuce (confirmation)   | 0.01          | 5                    | 72 – 108                | 89            | 17       | Acceptable |
|                          |                          | 0.1           | 5                    | 83 – 103                | 94            | 10       | Acceptable |
| 2,4-dichlorobenzoic acid | Lettuce (quantification) | 0.01          | 5                    | 111 – 124               | 117           | 5        | Acceptable |
|                          |                          | 0.1           | 5                    | 116 – 124               | 120           | 3        | Acceptable |
|                          | Lettuce (confirmation)   | 0.01          | 5                    | 107 – 119               | 115           | 4        | Acceptable |
|                          |                          | 0.1           | 5                    | 116 – 127               | 120           | 4        | Acceptable |
| 5'-hydroxy-bixlozone     | Lettuce (quantification) | 0.01          | 5                    | 91 – 101                | 95            | 5        | Acceptable |
|                          |                          | 0.1           | 5                    | 94 – 104                | 100           | 4        | Acceptable |
|                          | Lettuce (confirmation)   | 0.01          | 5                    | 86 – 100                | 94            | 6        | Acceptable |
|                          |                          | 0.1           | 5                    | 85 – 100                | 91            | 7        | Acceptable |

**Table C.1.1.1-2 Characteristics of the analytical method for the quantitation of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone residues in lettuce**

|                        | Bixlozone  | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone |
|------------------------|------------|--------------------------|----------------------|
| Chromatographic method | HPLC-MS/MS |                          |                      |



|                                                                                                    | Bixlozone                                                                                                                                                                                                                                                                                                               | 2,4-dichlorobenzoic acid                                                                                                                                                                                                                                                                                               | 5'-hydroxy-bixlozone                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Specificity demonstrated (yes/no, by...)                                                           | Yes by MS ions and retention time matching with certified reference standards.                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                       |
| Linearity demonstrated (yes/no)                                                                    | Yes                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                       |
| Calibration                                                                                        |                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                       |
| Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)                         | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 588000x + 23800</math></p> <p><math>r = 0.9990</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 95100x + 2720</math></p> <p><math>r = 0.9990</math></p> | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 124000x + 1920</math></p> <p><math>r = 0.9993</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 69800x + 1720</math></p> <p><math>r = 0.9995</math></p> | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 77100x + 2590</math></p> <p><math>r = 0.9997</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to 0.003 – 0.2 mg/kg)</p> <p><math>y = 189000x - 116</math></p> <p><math>r = 0.9992</math></p> |
| Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/no) | Yes (n=7)                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                       |

|                                                                                   | <b>Bixlozone</b>                                                                                                                                        | <b>2,4-dichlorobenzoic acid</b>                                                                                                                       | <b>5'-hydroxy-bixlozone</b>                                                                                                                           |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Matrix effects                                                                    | Matrix effects were investigated and were found to not be significant (<20%). However, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. |
| Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)      | Yes                                                                                                                                                     |                                                                                                                                                       |                                                                                                                                                       |
| Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ration? (yes/no) | Yes                                                                                                                                                     |                                                                                                                                                       |                                                                                                                                                       |
| <b>LOQ</b> (mg/kg)                                                                | 0.01                                                                                                                                                    | 0.01                                                                                                                                                  | 0.01                                                                                                                                                  |

**Table C.1.1.1-3 Recovery Results in wheat grain**

Standards prepared in matrix matched methanol.

| <b>Analyte</b> | <b>Matrix</b>                | <b>level (mg/kg)</b> | <b>No samples per level</b> | <b>Range of recoveries (%)</b> | <b>Mean recovery</b> | <b>RS D (%)</b> | <b>Comments</b> |
|----------------|------------------------------|----------------------|-----------------------------|--------------------------------|----------------------|-----------------|-----------------|
| Bixlozone      | Wheat grain (quantification) | 0.01                 | 5                           | 75 – 91                        | 84                   | 7               | Acceptable      |
|                |                              | 0.1                  | 5                           | 74 – 104                       | 85                   | 14              | Acceptable      |
|                |                              | 0.01                 | 5                           | 72 – 84                        | 79                   | 6               | Acceptable      |

| Analyte                  | Matrix                       | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RS D (%) | Comments   |
|--------------------------|------------------------------|---------------|----------------------|-------------------------|---------------|----------|------------|
|                          | Wheat grain (confirmation)   | 0.1           | 5                    | 68 – 84                 | 74            | 8        | Acceptable |
| 2,4-dichlorobenzoic acid | Wheat grain (quantification) | 0.01          | 5                    | 98 – 107                | 102           | 4        | Acceptable |
|                          |                              | 0.1           | 5                    | 94 – 97                 | 95            | 1        | Acceptable |
|                          | Wheat grain (confirmation)   | 0.01          | 5                    | 106 – 119               | 113           | 5        | Acceptable |
|                          |                              | 0.1           | 5                    | 93 – 98                 | 96            | 2        | Acceptable |
| 5'-hydroxy-bixlozone     | Wheat grain (quantification) | 0.01          | 5                    | 95 – 101                | 98            | 2        | Acceptable |
|                          |                              | 0.1           | 5                    | 95 – 103                | 98            | 4        | Acceptable |
|                          | Wheat grain (confirmation)   | 0.01          | 5                    | 81 – 108                | 91            | 12       | Acceptable |
|                          |                              | 0.1           | 5                    | 90 – 100                | 95            | 5        | Acceptable |

**Table C.1.1.1-4 Characteristics of the analytical method for the quantitation of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone residues in wheat grain**

|                                          | Bixlozone                                                                      | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone |
|------------------------------------------|--------------------------------------------------------------------------------|--------------------------|----------------------|
| Chromatographic method                   | HPLC-MS/MS                                                                     |                          |                      |
| Specificity demonstrated (yes/no, by...) | Yes by MS ions and retention time matching with certified reference standards. |                          |                      |
| Linearity demonstrated (yes/no)          | Yes                                                                            |                          |                      |

|                                                                                                    | <b>Bixlozone</b>                                                                                                                                                                                                                                                                                                                      | <b>2,4-dichlorobenzoic acid</b>                                                                                                                                                                                                                                                                                                      | <b>5'-hydroxy-bixlozone</b>                                                                                                                                                                                                                                                                                                                   |
|----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Calibration</b>                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                               |
| Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)                         | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 536000x + 3660</math></p> <p><math>r = 0.9991</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 90600x + 374</math></p> <p><math>r = 0.9987</math></p> | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 125000x + 577</math></p> <p><math>r = 0.9986</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 73400x + 508</math></p> <p><math>r = 0.9984</math></p> | <p><i>Quantification:</i><br/>0.03 – 2<br/>ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 159000x + 1850</math></p> <p><math>r = 0.9979</math></p> <p><i>Confirmation:</i><br/>0.03 – 2<br/>ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 36600x + 537</math></p> <p><math>r = 0.9983</math></p> |
| Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/no) | Yes (n=7)                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                               |

|                                                                                   | <b>Bixlozone</b>                                                                                                                                        | <b>2,4-dichlorobenzoic acid</b>                                                                                                                       | <b>5'-hydroxy-bixlozone</b>                                                                                                                           |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Matrix effects                                                                    | Matrix effects were investigated and were found to not be significant (<20%). However, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. |
| Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)      | Yes                                                                                                                                                     |                                                                                                                                                       |                                                                                                                                                       |
| Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ration? (yes/no) | Yes                                                                                                                                                     |                                                                                                                                                       |                                                                                                                                                       |
| <b>LOQ</b> (mg/kg)                                                                | 0.01                                                                                                                                                    | 0.01                                                                                                                                                  | 0.01                                                                                                                                                  |

**Table C.1.1.1-5 Recovery Results in dried beans**

Standards prepared in matrix matched methanol.

| <b>Analyte</b> | <b>Matrix</b>                | <b>level (mg/kg)</b> | <b>No samples per level</b> | <b>Range of recoveries (%)</b> | <b>Mean recovery</b> | <b>RS D (%)</b> | <b>Comments</b> |
|----------------|------------------------------|----------------------|-----------------------------|--------------------------------|----------------------|-----------------|-----------------|
| Bixlozone      | Dried beans (quantification) | 0.01                 | 5                           | 65 – 98                        | 77                   | 18              | Acceptable      |
|                |                              | 0.1                  | 5                           | 79 – 98                        | 88                   | 10              | Acceptable      |
|                |                              | 0.01                 | 5                           | 66 – 100                       | 82                   | 15              | Acceptable      |

| Analyte                  | Matrix                       | level (mg/kg) | No samples per level | Range of recoveries (%) | Mean recovery | RSD (%) | Comments   |
|--------------------------|------------------------------|---------------|----------------------|-------------------------|---------------|---------|------------|
|                          | Dried beans (confirmation)   | 0.1           | 5                    | 74 – 86                 | 79            | 6       | Acceptable |
| 2,4-dichlorobenzoic acid | Dried beans (quantification) | 0.01          | 5                    | 109 – 119               | 114           | 4       | Acceptable |
|                          |                              | 0.1           | 5                    | 110 – 121               | 114           | 4       | Acceptable |
|                          | Dried beans (confirmation)   | 0.01          | 5                    | 102 – 126               | 112           | 8       | Acceptable |
|                          |                              | 0.1           | 5                    | 108 – 119               | 113           | 4       | Acceptable |
| 5'-hydroxy-bixlozone     | Dried beans (quantification) | 0.01          | 5                    | 78 – 87                 | 81            | 4       | Acceptable |
|                          |                              | 0.1           | 5                    | 78 – 90                 | 84            | 6       | Acceptable |
|                          | Dried beans (confirmation)   | 0.01          | 5                    | 80 – 89                 | 85            | 4       | Acceptable |
|                          |                              | 0.1           | 5                    | 84 – 90                 | 86            | 3       | Acceptable |

\* Value is a statistical outlier and not included in the mean and RSD calculations

**Table C.1.1.1-6 Characteristics of the analytical method for the quantitation of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone residues in dried beans**

|                                          | Bixlozone                                                                      | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone |
|------------------------------------------|--------------------------------------------------------------------------------|--------------------------|----------------------|
| Chromatographic method                   | HPLC-MS/MS                                                                     |                          |                      |
| Specificity demonstrated (yes/no, by...) | Yes by MS ions and retention time matching with certified reference standards. |                          |                      |
| Linearity demonstrated (yes/no)          | Yes                                                                            |                          |                      |

|                                                                                                    | <b>Bixlozone</b>                                                                                                                                                                                                                                                                                                                      | <b>2,4-dichlorobenzoic acid</b>                                                                                                                                                                                                                                                                                                        | <b>5'-hydroxy-bixlozone</b>                                                                                                                                                                                                                                                                                                                   |
|----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Calibration</b>                                                                                 |                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                               |
| Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)                         | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 427000x + 4460</math></p> <p><math>r = 0.9992</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 70900x + 214</math></p> <p><math>r = 0.9973</math></p> | <p><i>Quantification:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 115000x + 1080</math></p> <p><math>r = 0.9999</math></p> <p><i>Confirmation:</i><br/>0.03 – 2 ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 69100x + 1180</math></p> <p><math>r = 0.9999</math></p> | <p><i>Quantification:</i><br/>0.03 – 2<br/>ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 345000x + 1340</math></p> <p><math>r = 0.9994</math></p> <p><i>Confirmation:</i><br/>0.03 – 2<br/>ng/mL<br/>(equivalent to<br/>0.003 – 0.2<br/>mg/kg)</p> <p><math>y = 79400x - 782</math></p> <p><math>r = 0.9987</math></p> |
| Calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/no) | Yes (n=7)                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                               |

|                                                                                   | <b>Bixlozone</b>                                                                                                                                        | <b>2,4-dichlorobenzoic acid</b>                                                                                                                       | <b>5'-hydroxy-bixlozone</b>                                                                                                                           |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Matrix effects                                                                    | Matrix effects were investigated and were found to not be significant (<20%). However, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. | Matrix effects were investigated and were found to be significant (>20%). Therefore, matrix matched standards were used for validation of the method. |
| Absence of interference >30% of LOQ in blank sample is demonstrated (yes/no)      | Yes                                                                                                                                                     |                                                                                                                                                       |                                                                                                                                                       |
| Chromatogram of sample spiked at LOQ demonstrates sufficient S/N ration? (yes/no) | Yes                                                                                                                                                     |                                                                                                                                                       |                                                                                                                                                       |
| <b>LOQ</b> (mg/kg)                                                                | 0.01                                                                                                                                                    | 0.01                                                                                                                                                  | 0.01                                                                                                                                                  |

### Final extract stability

Residues of 2,4-dichlorobenzoic acid were shown to be stable in sample extracts of all matrices for up to 7 days when stored at 4 °C.

Residues of bixlozone were shown to be stable in sample extracts of lettuce and wheat for up to 7 days when stored at 4 °C. Residues of bixlozone in dry bean extracts were not shown to be stable over this time period.

Residues of and 5'-hydroxy-bixlozone were shown to be stable in sample extracts of wheat grain for up to 7 days when stored at 4 °C. Residues in lettuce and dry bean extracts were not shown to be stable over this time period.

It is recommended therefore that analysis of bixlozone and 5'-hydroxy-bixlozone occurs within 24 hours of generating the final extract.



### **Extraction efficiency**

Extraction efficiency was sufficiently addressed in the AR (HSE, 2024a) for the methods CAM-0180/001 and CAM-0180/002. The extraction procedures for version 3 are identical to those in version 002 therefore, extraction efficiency has been addressed for CAM-0180/003.

### **Conclusion**

The analytical procedure CAM-0180/003 is considered independently validated in terms of specificity, linearity, precision, accuracy and LOQ, in accordance with SANTE/2020/12830 Rev. 2. Extraction efficiency has been sufficiently addressed.

#### **C.1.1.3 Confirmatory method (if necessary)**

See Appendix C.1.1.1.

#### **C.1.2 Methods for enforcement and monitoring of residues in food and feed of animal origin**

No additional studies submitted.

#### **C.1.3 Methods for risk assessment for residues in food and feed of plant origin**

No additional studies submitted.

#### **C.1.4 Methods for risk assessment for residues in food and feed of animal origin**

No additional studies submitted.

#### **C.1.5 Methods for risk assessment for toxicological studies**

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 Wheat

Reference: Magnitude of the residue of F9600, beflubutamid, cloquintocet-mexyl and their respective metabolites in representative winter wheat raw agricultural commodities after one application of F4215-R007 in northern and southern europe – 2020-2021, [REDACTED] 2023, FMC-55312, 20-00555

Guideline(s): Yes; OECD 509; SANTE 2020/12830, rev. 1

Deviations: No

GLP: Yes

Validity of the study: Valid

#### Materials and methods

Five trials on winter wheat were conducted in Poland, Germany, Northern France and the UK (reflecting the agronomic and climatic conditions in the UK) using 'X8Q85-011' ('Fundatis'), a ZC formulation containing 200 g/L bixlozone (F9600), 125 g/L beflubutamid and 34.5 g/L cloquintocet-mexyl (safener), in the 2020-2021 growing season. It is noted that five additional trials in Southern France, Spain and Italy were conducted however, these will not be considered in this evaluation as they do not reflect the agronomic and climatic conditions in the UK.

'X8Q85-011' was applied as a foliar spray at a rate of 200 g/ha bixlozone in 193.3-304.4 L/ha of water (target dose rate of 1 L product/ha). One application was made at BBCH 11-13 (115-269 days before harvest). The applications were within 25% of the proposed critical GAP (1 x 200 g/ha bixlozone, BBCH 13).

Weather data was reported for the trials and no exceptional events were noted. Three trials were decline trials and two trials were at harvest trials, samples of whole plant were taken at just before application (0 DBA), just after application (0 DAA) and at BBCH 30-31, 51-55 and 75-77. Samples of grain and straw were taken at BBCH 89 (commercial harvest). Samples containing at least 0.5, 0.5 and 1 kg were collected from both treated and control plots for whole plant, straw and grain respectively. It is noted that only 0.15 kg of whole plant was collected from the 0 DAA and 0 DBA plots. It is not considered that this will have a negative impact on the study. Samples were frozen within 12 hours, and stored at  $\leq -18$  °C until analysis. The maximum storage interval between harvest and analysis was 468 days. Data was considered in the AR and a newly submitted study which demonstrates stability of bixlozone, 5'-hydroxy-F9600 and 2,4-dichlorobenzoic acid for this period of time in wheat grain, straw and forage when stored at  $\leq -18$  °C.

Analysis of bixlozone and its metabolites 5'-hydroxy-F9600 and 2,4-dichlorobenzoic acid was performed using LC-MS/MS methods CAM-0154/001 and CAM-0154/002.

## Results and discussions

The analytical method (CAM-0154/001 and CAM-0154/002) was previously validated in the AR (HSE, 2024a) and is satisfactorily validated in accordance with SANTE/2020/12830 rev. 1. The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for bixlozone and metabolites 5'-hydroxy-F9600 and 2,4-dichlorobenzoic acid, using an appropriate number of samples were presented. Fortification levels ranged from 0.01 to 20 mg/kg and mean recoveries of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone in wheat ranged from 79 to 100% (n=3).

No residues were detected in control samples for all trials.

A summary of the residues trials is given in Table C.3.1.2.1-1.

## Conclusion

Five trials on wheat were conducted in NEU, and the trials were within 25% of the proposed critical GAP. Residues of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone in grain and straw were <0.01 mg/kg. Residues in whole plant were <0.01 mg/kg for all analytes except at the 0 DALA. Residues in whole plant at 0 DALA ranged from 4.9 – 19 mg/kg, 0.011 – 0.033 mg/kg and 0.033 – 0.098 mg/kg for bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone respectively.

**Table C.3.1.2.1-1 Residue trials on wheat**

|                              |                                                                                                                                                                                                                                                                                        |                                  |                                                                        |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------------------------------------------------------------|
| Reference:                   | Magnitude of the residue of F9600, beflubutamid, cloquintocet-mexyl and their respective metabolites in representative winter wheat raw agricultural commodities after one application of F4215-R007 in northern and southern europe – 2020-2021, ██████████ 2023, FMC-55312, 20-00555 |                                  |                                                                        |
| GLP:                         | Yes                                                                                                                                                                                                                                                                                    | Sample storage conditions:       | Max. 468 days at ≤-18 °C                                               |
| Crop/crop group:             | Winter wheat                                                                                                                                                                                                                                                                           | Analytical method:               | LC-MS/MS methods CAM-0154/001 (validated) and CAM-0154/002 (validated) |
| Indoor/outdoor:              | Outdoor                                                                                                                                                                                                                                                                                | Limit of Quantification (mg/kg): | 0.01                                                                   |
| Formulation:                 | ZC                                                                                                                                                                                                                                                                                     | Residues calculated as:          | Bixlozone (F9600), 5'-OH-F9600 and 2,4-dichlorobenzoic acid            |
| 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<br>number<br>and last<br>date | 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<br>) | g<br>a.s.<br>/ hL |                                                           |                                         |                     | Bixlozone<br>(F9600) | 5'-OH-F9600 | 2,4-dichlorobenzoic<br>acid |               |         |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                                                                            |                        |                                                                                   |     |     |    |            |         |                                                                            |                                                                      |                                                    |                                                                        |                                      |                                                                                                                |
|----------------------------------------------------------------------------|------------------------|-----------------------------------------------------------------------------------|-----|-----|----|------------|---------|----------------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------|------------------------------------------------------------------------|--------------------------------------|----------------------------------------------------------------------------------------------------------------|
| 20-00555-01<br>Auménancourt le Grand,<br>Grand Est,<br>France<br>2020/2021 | Wheat<br>Tropaz        | 1. 27/10/2020<br>2. 15/06/2021<br>to 19/06/2021<br>3. 20/07/2021                  | 197 | 296 | 67 | 08/01/2021 | BBCH 13 | Whole plant<br>Whole plant<br>Whole plant<br>Whole plant<br>Grain<br>Straw | 19<br><0.01<br><0.01<br><0.01<br><u>&lt;0.01</u><br><u>&lt;0.01</u>  | 0.098<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01 | 0.033<br><0.01<br><0.01<br><0.01<br><u>&lt;0.01</u><br><u>&lt;0.01</u> | 0<br>109<br>151<br>174<br>193<br>193 | Analytical<br>method:<br>CAM-<br>0154/001<br>&/002<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>388 days |
| 20-00555-02<br>Avancon<br>Grand Est,<br>France<br>2020/2021                | Wheat<br>KWS<br>Extase | 1. 12/10/2020<br>2. 10/06/2021<br>to 14/06/2021<br>3. 22/07/2021<br>to 25/07/2021 | 188 | 235 | 80 | 18/11/2020 | BBCH 13 | Whole plant<br>Whole plant<br>Whole plant<br>Whole plant<br>Grain<br>Straw | 4.9<br><0.01<br><0.01<br><0.01<br><u>&lt;0.01</u><br><u>&lt;0.01</u> | 0.033<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01 | 0.016<br><0.01<br><0.01<br><0.01<br><u>&lt;0.01</u><br><u>&lt;0.01</u> | 0<br>127<br>196<br>225<br>248<br>248 | Analytical<br>method:<br>CAM-<br>0154/001<br>&/002<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>439 days |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                                                                     |                        |                                                                                   |     |     |     |            |               |                                                                            |                                                                      |                                                    |                                                                        |                                      |                                                                                                                |
|---------------------------------------------------------------------|------------------------|-----------------------------------------------------------------------------------|-----|-----|-----|------------|---------------|----------------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------|------------------------------------------------------------------------|--------------------------------------|----------------------------------------------------------------------------------------------------------------|
| 20-00555-03<br>Piskorzówek,<br>Dolnośląskie,<br>Poland<br>2020/2021 | Wheat<br>Jocker        | 1. 08/10/2020<br>2. 21/06/2021<br>to 25/06/2021<br>3. 09/08/2021                  | 191 | 287 | 67  | 13/11/2020 | BBCH<br>11-13 | Whole plant<br>Whole plant<br>Whole plant<br>Whole plant<br>Grain<br>Straw | 7.1<br><0.01<br><0.01<br><0.01<br><u>&lt;0.01</u><br><u>&lt;0.01</u> | 0.038<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01 | 0.011<br><0.01<br><0.01<br><0.01<br><u>&lt;0.01</u><br><u>&lt;0.01</u> | 0<br>164<br>217<br>231<br>269<br>269 | Analytical<br>method:<br>CAM-<br>0154/001<br>&/002<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>444 days |
| 20-00555-04<br>Neuruppin,<br>Brandenburg,<br>Germany<br>2020/2021   | Wheat<br>RGT<br>Reform | 1. 01/10/2020<br>2. 07/06/2021<br>to 08/06/2021<br>3. 21/07/2021<br>to 28/07/2021 | 193 | 193 | 100 | 27/10/2020 | BBCH<br>11-12 | Grain<br>Straw                                                             | <u>&lt;0.01</u><br><u>&lt;0.01</u>                                   | <0.01<br><0.01                                     | <u>&lt;0.01</u><br><u>&lt;0.01</u>                                     | 269<br>269                           | Analytical<br>method:<br>CAM-<br>0154/001<br>&/002<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>185 days |



The evaluation of new MRLs for bixlozone in or on barley and wheat

|                                                                 |                   |                                                                                   |     |     |     |            |         |                |                                    |                |                                    |            |                                                                                                                |
|-----------------------------------------------------------------|-------------------|-----------------------------------------------------------------------------------|-----|-----|-----|------------|---------|----------------|------------------------------------|----------------|------------------------------------|------------|----------------------------------------------------------------------------------------------------------------|
| 20-00555-05<br>Wellesbourne<br>Warwickshire,<br>UK<br>2020/2021 | Wheat<br>Costello | 1. 06/11/2020<br>2. 04/06/2021<br>to 30/06/2021<br>3. 25/08/2021<br>to 08/09/2021 | 213 | 213 | 100 | 15/12/2020 | BBCH 12 | Grain<br>Straw | <u>&lt;0.01</u><br><u>&lt;0.01</u> | <0.01<br><0.01 | <u>&lt;0.01</u><br><u>&lt;0.01</u> | 261<br>261 | Analytical<br>method:<br>CAM-<br>0154/001<br>&/002<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>144 days |
|-----------------------------------------------------------------|-------------------|-----------------------------------------------------------------------------------|-----|-----|-----|------------|---------|----------------|------------------------------------|----------------|------------------------------------|------------|----------------------------------------------------------------------------------------------------------------|

#### C.3.1.2.2 Wheat

Reference: Determination of the residue of F9600 metabolite hydroxypivalic acid in winter wheat raw agricultural commodities after one application of F4215-R007 in northern and southern Europe – 2020-2021, [REDACTED] 2022, FMC-80116, S22-05942

Guideline(s): Yes; OECD 509; SANTE 2020/12830, rev. 1

Deviations: No

GLP: Yes

Validity of the study: Valid

#### Materials and methods

The objective of this study was to analyse samples of winter wheat (whole plant, grain and straw) for residues of the bixlozone metabolite hydroxypivalic acid (2,2-dimethyl-3-hydroxy propionic acid). The samples of winter wheat analysed are the same samples from field study FMC-55312. For full trial details please refer to Appendix C.3.1.2.1.

The maximum storage period of samples before extraction was 648 days. Data was considered in the AR (HSE, 2024a) and a newly submitted study which demonstrates stability of hydroxypivalic acid for this period of time in wheat grain, straw and forage when stored at  $\leq -18$  °C. Analysis was performed using LC-MS/MS method CAM-0154/001.

#### Results and discussions

The analytical method (CAM-0154/001) was previously validated in the AR (HSE, 2024). The LOQ of the method is 0.01 mg/kg for whole plant and grain, and 0.05 mg/kg for straw. Acceptable procedural recovery data for hydroxypivalic acid, using an appropriate number of samples were presented. Fortification levels ranged from 0.01 to 0.5 mg/kg and mean recoveries of hydroxypivalic acid in wheat ranged from 78 to 119% (n=3).

Positive residue levels were found in some of the untreated straw samples and one untreated grain sample. Positive levels of hydroxypivalic acid (M118/1) were also found in many of the residue trials considered in the AR (HSE, 2024a). The applicant suggested that M118/1 was found in untreated samples due to the metabolite being ‘naturally’ occurring. A consideration was made in the AR (see section 2.7.4 of Vol. 1) with an overall conclusion stating:

*“Following consideration of the additional position paper and all information submitted during the assessment, HSE has concluded that the residues of M118/1 and M132/1 should not be excluded from the risk assessment considerations, based on the proposal*

*that these might be residues of natural provenance. The reasoning for the presence of residues of M118/1 in untreated control sample material from field trials is uncertain, but volatile transfer of residues (e.g. from application to soil or young plants in neighbouring plots) might be a plausible explanation. Residues of M118/1 were the main residues found in field trials on cereals, and residues of M132/1 were not sought in quantitative trials, but the possible co-presence of M132/1 with M118/1 is suggested from the plant (rice) metabolism data. Currently the residues of M118/1 and M132/1 have been screened as part of an exposure assessment of these metabolites in a TTC consideration. For all future uses a TTC exposure assessment approach or further toxicological assessment should be used to ensure assessment of these residues.”*

A TTC consideration of M118/1 (and M132/1) is being conducted in this evaluation therefore, no further consideration of the positive levels of hydroxypivalic acid in untreated and treated straw samples is required.

A summary of the residues trials is given in Table C.3.1.2.2-1.

## **Conclusion**

Five trials on wheat were conducted in NEU, and the trials were within 25% of the proposed critical GAP. Residues of hydroxypivalic acid in whole plant were <0.01 mg/kg at all time points. Residues of hydroxypivalic acid in grain and straw ranged from <0.01 – 0.017 mg/kg and <0.05 – 0.076 mg/kg respectively.

**Table C.3.1.2.2-1 Residue trials on wheat**

|                              |                                                                                                                                                                                                                                          |                                  |                                                             |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------------------------------------------------------------|
| Reference:                   | Determination of the residue of F9600 metabolite hydroxypivalic acid in winter wheat raw agricultural commodities after one application of F4215-R007 in northern and southern Europe – 2020-2021, [REDACTED] 2022, FMC-80116, S22-05942 |                                  |                                                             |
| GLP:                         | Yes                                                                                                                                                                                                                                      | Sample storage conditions:       | Max. 648 days at ≤-18 °C                                    |
| Crop/crop group:             | Winter wheat                                                                                                                                                                                                                             | Analytical method:               | LC-MS/MS method CAM-0154/001 (validated)                    |
| Indoor/outdoor:              | Outdoor                                                                                                                                                                                                                                  | Limit of Quantification (mg/kg): | 0.01 (whole plant and grain); 0.05 (straw)                  |
| Formulation:                 | ZC                                                                                                                                                                                                                                       | Residues calculated as:          | Hydroxypivalic acid (2,2-dimethyl-3-hydroxy propionic acid) |
| 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 number<br>and last<br>date | 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 |                                                        |                                         |                     | Hydroxypivalic<br>acid (2,2-dimethyl-<br>3-hydroxy<br>propionic acid) |               |         |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                                                                               |                        |                                                                                                  |     |     |    |            |                |                                                                            |                                                             |                                      |                                                                                                       |
|-------------------------------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------------------|-----|-----|----|------------|----------------|----------------------------------------------------------------------------|-------------------------------------------------------------|--------------------------------------|-------------------------------------------------------------------------------------------------------|
| 20-00555-01<br>Auménancourt<br>le Grand,<br>Grand Est,<br>France<br>2020/2021 | Wheat<br>Tropaz        | 1.<br>27/10/2020<br>2.<br>15/06/2021<br>to<br>19/06/2021<br>3.<br>20/07/2021                     | 197 | 296 | 67 | 08/01/2021 | BBCH 13        | Whole plant<br>Whole plant<br>Whole plant<br>Whole plant<br>Grain<br>Straw | <0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.05          | 0<br>109<br>151<br>174<br>193<br>193 | Analytical<br>method:<br>CAM-<br>0154/001<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>596 days |
| 20-00555-02<br>Avancon<br>Grand Est,<br>France<br>2020/2021                   | Wheat<br>KWS<br>Extase | 1.<br>12/10/2020<br>2.<br>10/06/2021<br>to<br>14/06/2021<br>3.<br>22/07/2021<br>to<br>25/07/2021 | 188 | 235 | 80 | 18/11/2020 | BBCH 13        | Whole plant<br>Whole plant<br>Whole plant<br>Whole plant<br>Grain<br>Straw | <0.01<br><0.01<br><0.01<br><0.01<br><0.01<br>0.072 (0.053)* | 0<br>127<br>196<br>225<br>248<br>248 | Analytical<br>method:<br>CAM-<br>0154/001<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>643 days |
| 20-00555-03<br>Piskorzówek,<br>Dolnośląskie,<br>Poland<br>2020/2021           | Wheat<br>Jocker        | 1.<br>08/10/2020<br>2.<br>21/06/2021<br>to<br>25/06/2021<br>3.<br>09/08/2021                     | 191 | 287 | 67 | 13/11/2020 | BBCH 11-<br>13 | Whole plant<br>Whole plant<br>Whole plant<br>Whole plant<br>Grain<br>Straw | <0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.05          | 0<br>164<br>217<br>231<br>269<br>269 | Analytical<br>method:<br>CAM-<br>0154/001<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>648 days |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                                                                   |                        |                                                                                                  |     |     |     |            |                |                |                                  |            |                                                                                                       |
|-------------------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------------------|-----|-----|-----|------------|----------------|----------------|----------------------------------|------------|-------------------------------------------------------------------------------------------------------|
| 20-00555-04<br>Neuruppin,<br>Brandenburg,<br>Germany<br>2020/2021 | Wheat<br>RGT<br>Reform | 1.<br>01/10/2020<br>2.<br>07/06/2021<br>to<br>08/06/2021<br>3.<br>21/07/2021<br>to<br>28/07/2021 | 193 | 193 | 100 | 27/10/2020 | BBCH 11-<br>12 | Grain<br>Straw | 0.017 (0.012)*<br>0.076 (0.087)* | 269<br>269 | Analytical<br>method:<br>CAM-<br>0154/001<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>404 days |
| 20-00555-05<br>Wellesbourne<br>Warwickshire,<br>UK 2020/2021      | Wheat<br>Costello      | 1.<br>06/11/2020<br>2.<br>04/06/2021<br>to<br>30/06/2021<br>3.<br>25/08/2021<br>to<br>08/09/2021 | 213 | 213 | 100 | 15/12/2020 | BBCH 12        | Grain<br>Straw | <0.01<br><0.05                   | 261<br>261 | Analytical<br>method:<br>CAM-<br>0154/001<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>363 days |

\* Positive residue levels found in untreated control samples are shown in brackets

### C.3.1.2.3 Wheat

Reference: Determination of the residue of F9600 metabolite Dimethyl-malonic acid in winter wheat raw agricultural commodities after one application of F4215-R007 in northern and southern Europe – 2020-2021, [REDACTED] 2022, FMC-80117, S22-05940

Guideline(s): Yes; OECD 509; SANTE 2020/12830, rev. 1

Deviations: No

GLP: Yes

Validity of the study: Valid

### Materials and methods

The objective of this study was to analyse samples of winter wheat (whole plant, grain and straw) for residues of the bixlozone metabolite dimethyl-malonic acid (M132/1). The samples of winter wheat analysed are the same samples from field study FMC-55312. For full trial details please refer to Appendix C.3.1.2.1.

The maximum storage period of samples before extraction was 721 days. No data was submitted in the AR (HSE, 2024a) or the newly submitted storage study to address the stability of dimethyl-malonic acid (M132/1). However, the residue levels found in the trials are comparable to the residue levels found of hydroxypivalic acid (M118/1). At active approval, it was suggested that the presence of M118/1 and M132/1 are broadly equal in cereals (based on the metabolism studies). Therefore, for the exposure assessment in the TTC scheme it was considered that levels of M118/1 and M132/1 are equal on a 1-to-1 basis. As the residue levels of M118/1 and M132/1 are comparable within the new trials, it can be assumed, with some uncertainty, that M132/1 is stable for the storage period of 721 days. Analysis was performed using LC-MS/MS method CAM-0180/002.

### Results and discussions

The analytical method (CAM-0180/002) was previously validated in the AR (HSE, 2024a). The LOQ of the method is 0.02 mg/kg. Acceptable procedural recovery data for dimethyl-malonic acid, using an appropriate number of samples were presented. Fortification levels ranged from 0.02 to 0.2 mg/kg and mean recoveries of dimethyl-malonic acid in wheat ranged from 80 to 108% (n=3).

Positive residue levels were found in some of the untreated straw and grain samples. Dimethylmalonic acid (M132/1) was not looked for in the AR trials however, positive levels of hydroxypivalic acid (M118/1) were found in many of the residue trials considered in the AR (HSE, 2024a). As shown in the rice metabolism data, it is assumed that the levels of

M118/1 and M132/1 are present in equal proportions in wheat and barley grain. The applicant suggested that M118/1 was found in untreated samples due to the metabolite being 'naturally' occurring. A consideration was made in the AR (see section 2.7.4 of Vol. 1) with an overall conclusion stating:

*“Following consideration of the additional position paper and all information submitted during the assessment, HSE has concluded that the residues of M118/1 and M132/1 should not be excluded from the risk assessment considerations, based on the proposal that these might be residues of natural provenance. The reasoning for the presence of residues of M118/1 in untreated control sample material from field trials is uncertain, but volatile transfer of residues (e.g. from application to soil or young plants in neighbouring plots) might be a plausible explanation. Residues of M118/1 were the main residues found in field trials on cereals, and residues of M132/1 were not sought in quantitative trials, but the possible co-presence of M132/1 with M118/1 is suggested from the plant (rice) metabolism data. Currently the residues of M118/1 and M132/1 have been screened as part of an exposure assessment of these metabolites in a TTC consideration. For all future uses a TTC exposure assessment approach or further toxicological assessment should be used to ensure assessment of these residues.”*

A combined TTC consideration of M118/1 and M132/1 is being conducted in this evaluation therefore, no further consideration of the positive levels of dimethylmalonic acids in untreated straw and grain samples is required.

A summary of the residues trials is given in Table C.3.1.2.3-1.

## **Conclusion**

Five trials on wheat were conducted in NEU, and the trials were within 25% of the proposed critical GAP. Residues of dimethyl-malonic acid in whole plant, grain and straw were <0.02 – 0.06 mg/kg, <0.02 – 0.05 mg/kg and 0.04 – 0.09 mg/kg respectively.



**Table C.3.1.2.3-1 Residue trials on wheat**

|                              |                                                                                                                                                                                                                                            |                                  |                                          |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------------------------------|
| Reference:                   | Determination of the residue of F9600 metabolite Dimethyl-malonic acid in winter wheat raw agricultural commodities after one application of F4215-R007 in northern and southern Europe – 2020-2021, [REDACTED] 2022, FMC-80117, S22-05940 |                                  |                                          |
| GLP:                         | Yes                                                                                                                                                                                                                                        | Sample storage conditions:       | Max. 721 days at ≤-18 °C                 |
| Crop/crop group:             | Winter wheat                                                                                                                                                                                                                               | Analytical method:               | LC-MS/MS method CAM-0180/002 (validated) |
| Indoor/outdoor:              | Outdoor                                                                                                                                                                                                                                    | Limit of Quantification (mg/kg): | 0.02                                     |
| Formulation:                 | ZC                                                                                                                                                                                                                                         | Residues calculated as:          | Dimethyl-malonic acid                    |
| 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 number<br>and last<br>date | 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 |                                                        |                                         |                     | Dimethyl-malonic<br>acid |               |         |
|                              |                      |                                                                |                                   |                 |                  |                                                        |                                         |                     |                          |               |         |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                                                                               |                        |                                                                                                  |     |     |    |            |                |                                                                            |                                                                 |                                      |                                                                                                       |
|-------------------------------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------------------|-----|-----|----|------------|----------------|----------------------------------------------------------------------------|-----------------------------------------------------------------|--------------------------------------|-------------------------------------------------------------------------------------------------------|
| 20-00555-01<br>Auménancourt<br>le Grand,<br>Grand Est,<br>France<br>2020/2021 | Wheat<br>Tropaz        | 1.<br>27/10/2020<br>2.<br>15/06/2021<br>to<br>19/06/2021<br>3.<br>20/07/2021                     | 197 | 296 | 67 | 08/01/2021 | BBCH 13        | Whole plant<br>Whole plant<br>Whole plant<br>Whole plant<br>Grain<br>Straw | <0.02<br><0.02<br><0.02<br>0.04<br><0.02<br>0.04 (0.03)*        | 0<br>109<br>151<br>174<br>193<br>193 | Analytical<br>method:<br>CAM-<br>0180/002<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>665 days |
| 20-00555-02<br>Avancon<br>Grand Est,<br>France<br>2020/2021                   | Wheat<br>KWS<br>Extase | 1.<br>12/10/2020<br>2.<br>10/06/2021<br>to<br>14/06/2021<br>3.<br>22/07/2021<br>to<br>25/07/2021 | 188 | 235 | 80 | 18/11/2020 | BBCH 13        | Whole plant<br>Whole plant<br>Whole plant<br>Whole plant<br>Grain<br>Straw | <0.02<br><0.02<br><0.02<br>0.06<br>0.05 (0.05)*<br>0.09 (0.06)* | 0<br>127<br>196<br>225<br>248<br>248 | Analytical<br>method:<br>CAM-<br>0180/002<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>716 days |
| 20-00555-03<br>Piskorzówek,<br>Dolnośląskie,<br>Poland<br>2020/2021           | Wheat<br>Jocker        | 1.<br>08/10/2020<br>2.<br>21/06/2021<br>to<br>25/06/2021<br>3.<br>09/08/2021                     | 191 | 287 | 67 | 13/11/2020 | BBCH 11-<br>13 | Whole plant<br>Whole plant<br>Whole plant<br>Whole plant<br>Grain<br>Straw | <0.02<br><0.02<br>0.03<br>0.05<br>0.03 (0.03)*<br>0.04 (0.04)*  | 0<br>164<br>217<br>231<br>269<br>269 | Analytical<br>method:<br>CAM-<br>0180/002<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>721 days |

The evaluation of new MRLs for bixlozone in or on barley and wheat

|                                                                   |                        |                                                                                                  |     |     |     |            |                |                |                              |            |                                                                                                       |
|-------------------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------------------|-----|-----|-----|------------|----------------|----------------|------------------------------|------------|-------------------------------------------------------------------------------------------------------|
| 20-00555-04<br>Neuruppin,<br>Brandenburg,<br>Germany<br>2020/2021 | Wheat<br>RGT<br>Reform | 1.<br>01/10/2020<br>2.<br>07/06/2021<br>to<br>08/06/2021<br>3.<br>21/07/2021<br>to<br>28/07/2021 | 193 | 193 | 100 | 27/10/2020 | BBCH 11-<br>12 | Grain<br>Straw | 0.05 (0.06)*<br>0.09 (0.08)* | 269<br>269 | Analytical<br>method:<br>CAM-<br>0180/002<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>454 days |
| 20-00555-05<br>Wellesbourne<br>Warwickshire,<br>UK 2020/2021      | Wheat<br>Costello      | 1.<br>06/11/2020<br>2.<br>04/06/2021<br>to<br>30/06/2021<br>3.<br>25/08/2021<br>to<br>08/09/2021 | 213 | 213 | 100 | 15/12/2020 | BBCH 12        | Grain<br>Straw | <0.02<br>0.05                | 261<br>261 | Analytical<br>method:<br>CAM-<br>0180/002<br>(LC-<br>MS/MS)<br>Max.<br>frozen<br>storage:<br>413 days |

\* Positive residue levels found in untreated control samples are shown in brackets

## C.3.2 Nature and magnitude of residues in processed commodities

### C.3.2.1 Nature of residues (Standard hydrolysis study)

Reference: Nature of [ $^{14}\text{C}$ ]-2,4-dichlorobenzoic acid residues in process commodities - high temperature hydrolysis, 2024, [REDACTED] FMC-82043

Guideline(s): Yes; OECD 507

Deviations: No

GLP: Yes

Validity of the study:

#### Materials and methods

##### Materials

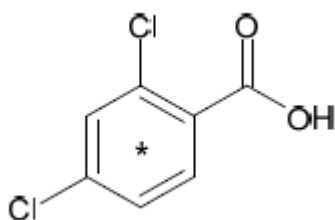
Test Material: [ $^{14}\text{C}$ ]-2,4-dichlorobenzoic acid

Lot/batch No.: 230804

Radiochemical Purity: >99%

Specific Activity: 55 mCi/mmol

**Figure 1:** Structure of radiolabelled 2,4-dichlorobenzoic acid



##### Method

###### Preparation of dose solutions

Dose solutions were prepared in each sterilised buffer solution (pH 4, 5 and 6) on the day of sampling. Aliquots of radiolabelled stock solution were added to a 50 mL volumetric flask and made to volume with the appropriate sterilised buffer solution. The target dose

rate of 2,4-dichlorobenzoic acid was 1 mg/L (the actual dose rates ranged from 0.95 – 1.05 mg/L).

Triplicate aliquots (3 x 15 µL) of the dose solutions were radioassayed by liquid scintillation counting (LSC) before and after dosing to determine the dose rate.

#### *Preparation of test solutions*

Test samples were prepared by transferring aliquots (10 mL by weight) of the dose solutions to sterilised clear glass vials. Four samples were prepared for each pH (two incubates and two controls).

#### *Experimental design*

A range of hydrolytic conditions were employed to simulate common processing practices. These conditions and sampling times are summarised below:

| Temperature (°C) | pH      | Time of Sampling (mins) | Representative Process |
|------------------|---------|-------------------------|------------------------|
| 90 ± 5           | 4 ± 0.1 | 0 and 20                | Pasteurisation         |
| 100 ± 5          | 5 ± 0.1 | 0 and 60                | Baking/brewing/boiling |
| 120 ± 5          | 6 ± 0.1 | 0 and 20                | Sterilisation          |

To achieve the required temperature for each simulated process, the test samples containing the pH 4 buffer were placed in a water bath; the pH 5 buffer samples were placed in an oven; and the test samples containing the pH 6 buffer were placed in an autoclave for the appropriate incubation period. The temperatures of the water bath and oven were measured using a calibrated thermometer. The autoclave temperature was measured using an internal thermometer. The control samples were left to stand in the laboratory and remained at ambient temperature. All test samples and controls were wrapped in aluminium foil to remove the likelihood of degradation as a result of photolysis.

#### *Sampling*

After incubation, the samples were removed from their heat source and cooled to room temperature using water. The pH of all test and control samples was tested and recorded. The contents of each glass vial was transferred to amber jar storage vessels. Test sample vials were rinsed with ethanol and the rinses combined with the test sample in the amber jar.

When not undergoing analysis, all samples were stored frozen (-20°C). All samples were analysed on the same day as sampling.

## ***Analysis***

The radioactive content was determined following the analysis of triplicate aliquots (0.25 mL) by LSC analysis.

Characterisation and identification of the radiolabelled components in the test and control samples was carried out by co-chromatography against a reference standard using HPLC analysis. Quantification of the detected components was conducted using the HPLC data. Additionally, 1D-TLC was used to assist with the confirmation of components.

## **Results and discussion**

### ***Radiochemical purity and stability***

The radiochemical purity of [<sup>14</sup>C]-2,4-dichlorobenzoic acid and stock solution was determined to be ≥98.4% by HPLC analysis.

### ***pH measurements***

The pH of test solutions was measured at the beginning of the experiment, following incubation and following cooling. The pH did not deviate by more than 0.1 pH units in any of the test systems, indicating that the buffering capacity was maintained in the test solutions throughout the duration of the study.

### ***Radioactive recoveries***

The post hydrolysis radioactive recoveries for test solutions ranged from 97.9% to 100.5% across all test systems. This confirms there was no significant loss of radioactivity during the reactions. The control samples also showed no significant loss of radioactivity over the incubation period.

### ***Identification/characterisation***

The majority of the recovered radioactivity was [<sup>14</sup>C]-2,4-dichlorobenzoic acid; accounting for 99.5% and 100.1% TRR in the pH 4 samples, 97.5% and 98.1% TRR in the pH 5 samples and 96.8% and 97.6% TRR in the pH 6 samples. Minor unidentified components were observed in the test samples but no individual component accounted for >0.9% TRR. The amount of [<sup>14</sup>C]-2,4-dichlorobenzoic acid found in the control samples was comparable to the test samples for all test systems.

TLC analysis was used to confirm the peak assignment for 2,4-dichlorobenzoic acid. TLC plates of selected test samples matched the TLC plate of a 2,4-dichlorobenzoic acid

reference standard therefore, confirming that 2,4-dichlorobenzoic acid does not significantly degrade under common processing conditions.

## **Conclusions**

Under conditions representative of pasteurisation (pH 4, 90 °C, 20 min), baking/boiling/brewing (pH 5, 100 °C, 60 min) and sterilisation (pH 6, 120 °C, 20 min) 2,4-dichlorobenzoic acid is found to be hydrolytically stable.

### **C.3.2.2 Magnitude of residues (Processing studies)**

No additional studies submitted.

### C.3.3 Nature and magnitude of residues in rotational crops

#### C.3.3.1 Nature of residue

No additional studies submitted.

#### C.3.3.2 Magnitude of residues (field rotational crop studies)

|                        |                                                                                                                                                                                                                                                         |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Determination of residues of bixlozone (F9600) in rotational crops (radish, spinach, wheat) after one application of F9600-4 on bare soil at 2 sites in Northern Europe and 2 sites in Southern Europe 2020-2023, [REDACTED] 2024, FMC-53729, S20-03164 |
| Guideline(s):          | Yes; OECD 504; OECD 509; SANTE/2020/12830 rev. 1                                                                                                                                                                                                        |
| Deviations:            | Yes; deviations are presented in the results and discussion section below                                                                                                                                                                               |
| GLP:                   | Yes                                                                                                                                                                                                                                                     |
| Validity of the study: | Valid                                                                                                                                                                                                                                                   |

#### Materials and methods

During the growing season of 2020-2021, three outdoor field trials on three rotational crops (wheat, radish and spinach) using the formulated product 'F9600-4', an SC formulation containing 400 g/L bixlozone, were conducted in Germany (NEU zone) and Italy (SEU zone). Additionally, an outdoor field trial was conducted in Spain (SEU zone) during the 2022-2023 growing season using the same trial conditions. The original Spanish trial had to be abandoned after a heavy rainfall event during which crops and soil were washed away before the experimental field phase could be completed. Therefore, the trial was repeated at a later date (2022-2023) and the results of this Spanish trial are included in this evaluation.

The German trials consisted of one control and three treated plots, each divided into 3 sub-plots for the three rotated crops. The Italian trial consisted of two control and six treated plots. Half of the plots were divided into two sub-plots for radish and spinach. Wheat was grown separately on the other half of the plots. The Spanish trial comprised of five untreated and eight treated plots. Five plots were divided into two sub-plots for radish and spinach. Wheat was grown separately on the other eight plots. All plots in all trials were at least 10 m apart.

One application of 'F9600-4' was applied to bare soil at a target rate of 528 g/ha bixlozone in 200-500 L/ha of water (target rate of 1.32 L product/ha). Radish, spinach and wheat were planted at 27-30 days after application, at 61-70 days after application and at 280-



287 days after application. The application dates roughly represent nominal PBIs of 30, 60 and 280 days.

Samples of radish (root and leaves) were taken at BBCH 49 (representative of normal commercial harvest. Immature spinach (leaves) samples were taken at BBCH 41–43 while mature spinach samples were collected at BBCH 49 (normal commercial harvest). Samples of wheat forage and hay were taken at BBCH 51–55 (with an additional drying stage for hay) while grain and straw were collected at BBCH 89 (normal commercial harvest).

Weather data were reported for the trials and no exceptional events were noted. Normal agricultural practice was followed during the field stage. Samples weighing at least 1 kg were collected for mature spinach, radish leaves, wheat grain and whole plant. Samples weighing at least 0.5 kg were collected for immature spinach, wheat hay and straw. Samples of at least 2 kg were collected for radish roots. All samples were taken from an adequate number of places over the plot (12). The same active substance was not applied as a maintenance product during the trials or in the previous season.

Samples were stored frozen at  $\leq -18^{\circ}\text{C}$  within 9.5 hours of harvest and maintained at this temperature until extraction. Samples of the radish, spinach and wheat were stored frozen for up to 338, 322 and 333 days respectively. There is sufficient storage stability data to support this time period of storage for radish, spinach and wheat. Samples were stored for up to 14 days under refrigerated conditions ( $1 - 10^{\circ}\text{C}$ ) between extraction and analysis. The stability of these extracts was confirmed by the procedural recoveries performed in parallel with the field sample analysis. Procedural recovery samples were stored under the same conditions for the same amount of time and gave acceptable results.

Analysis was performed using LC-MS/MS method CAM-0180/001.

## Results and discussions

The analytical method (CAM-0180/001) was previously validated in the AR (HSE, 2024a) and is satisfactorily validated in accordance with SANTE/2020/12830 rev. 1. The LOQ of the method is 0.01 mg/kg for all analytes except dimethyl malonic acid which is 0.02 mg/kg. Acceptable procedural recovery data for active (and metabolites), using an appropriate number of samples were presented.

Some deviations/deficiencies in the study are presented below:

- One control and two treated plots (containing radish and spinach) in the Spanish trial (S20-03164 Trial 5) could not be sampled as the plants did not develop to harvestable stages. These plots were not reported in the study and are not being considered in this evaluation.

- In S20-03164 Trial 5 samples of mature spinach could not be taken as plants did not develop as expected. All available plant material was harvested for samples at BBCH 41-43. However, no retain samples could be taken and weight of ship samples had to be reduced since plants did not develop as expected. No impact is expected as residues in samples taken at BBCH 41-43 were similar to those taken at BBCH 49 in the other three trials. Additionally, sample weights were sufficient for analysis and retain samples were not needed during the analytical phase of the study.
- In S20-03164 Trial 2 the required sample weight of radish roots and leaves were not reached for some plots (ranged from 0.21-0.57 kg). However, the amount of sample that was obtained was sufficient for analysis.

All untreated control samples showed un-quantifiable residue and metabolite levels with the exception of dimethyl malonic acid in wheat. It was proposed by the applicant that dimethyl malonic acid is a 'natural' product in cereals. However, the residues are considered by HSE as being possible real metabolites arising from applications of bixlozone, as they were found as radiolabelled residues in the metabolism studies. For further discussion on the uncertainty regarding the applicant proposal that the residues might be of natural provenance please refer to the end of section 2.7.4 (Vol 1 of the Assessment Report, HSE 2024a).

A TTC consideration of dimethylmalonic acid (M132/1) and 2,2-dimethyl-3-hydroxy propionic acid (M118/1) was conducted in the AR and it was determined that these metabolites did not need to be included in the residue definition for the AR intended uses. However, any extensions to the intended uses (increased application rates, change of application timing or range of crop uses), will require a reconsideration of the residue definition (and recalculation of the exposure assessment versus the TTC for co-exposure of 2,2-dimethyl-3-hydroxy propionic acid and dimethyl malonic acid which are considered to be present in significant amounts in cereal matrices). The proposed uses in this evaluation are within the uses considered in the AR therefore, no further consideration of dimethylmalonic acid (M132/1) or hydroxypivalic acid (M118/1) is required, unless it is considered that there are rotational crop residues of these components that should be taken account of due to the new data/information received on rotational crops based on this new rotational crops study (FMC-53729) submitted. The new rotational crop residues trial evaluated here did not seek residues of hydroxypivalic acid (M118/1) but did determine residues of dimethylmalonic acid (M132/1).

Residues of bixlozone in radish leaves at the 30-day plant-back interval (PBI) were <0.01–0.049 mg/kg. Residues at the 60 and 280-day PBIs were <0.01 mg/kg in trials 01, 03 and 05, but were 0.11 and 0.013 mg/kg, respectively in trial 02. Bixlozone residues in radish roots were <0.01 mg/kg for all samples except the 60-day PBI for trial 02, which was 0.018 mg/kg. Bixlozone residues in immature spinach were <0.01 mg/kg for all samples, except

the 30-day PBI in trial 02, which was 0.013 mg/kg. Residues in mature spinach were <0.01 mg/kg in all samples across all PBIs. Residues in wheat whole plant were <0.01 – 0.014 mg/kg in both the 30- and 60-day PBIs and were <0.01 mg/kg at the 280-day PBI. Residues in wheat grain and straw were <0.01 mg/kg in all samples across all PBIs.

Residues of 2,4-dichlorobenzoic acid were <0.01 mg/kg in all samples except for one sample of wheat straw in trial 01, which was 0.015 mg/kg.

Residues of 5'-hydroxy-F9600 were <0.01 mg/kg in all radish and spinach samples as well as wheat grain. Residues in wheat whole plant at the 30 and 60-day PBI were <0.01 mg/kg except for trial 02 where residues were 0.036 and 0.026 mg/kg, respectively. Residues were <0.01 mg/kg in all trials at the 280-day PBI. Residues in wheat hay ranged from <0.01 – 0.019 mg/kg and <0.01 – 0.020 mg/kg for the 30- and 60-day PBI, respectively. All residues in wheat hay were <0.01 mg/kg at the 280-day PBI. Residues in wheat straw ranged from 0.014 – 0.037 mg/kg and 0.013 – 0.057 mg/kg for the 30 and 60-day PBI, respectively. All residues in wheat straw were <0.01 mg/kg at the 280-day PBI except for trial 03 where residues were 0.012 mg/kg.

Residues of F9600-dimethyl malonamide were <0.01 mg/kg in radish root and all wheat matrices. Residues in radish leaves were <0.01 mg/kg in all samples except for trial 02 at the 60-day PBI, which was 0.019 mg/kg. Residues in immature spinach were <0.01 mg/kg in all samples except for trials 02 and 05. In trial 02 the residues were 0.017 and 0.016 mg/kg at the 30- and 60-day PBI respectively. In trial 05, the residues were 0.021 and 0.013 mg/kg at the 60- and 280-day PBI respectively. Residues in mature spinach ranged from <0.01 – 0.019 mg/kg and <0.01 – 0.022 mg/kg at the 30- and 60-day PBI and <0.01 mg/kg at the 280-day PBI.

Residues of dimethyl malonic acid (M132/1) were below or slightly above the LOQ (<0.02 to 0.026 mg/kg) in radish and spinach matrices. In wheat matrices, residues ranged from <0.02 to 0.13 mg/kg in all matrices across all PBIs.

Residues of F9600-isobutyramide were <0.01 mg/kg in all samples except or one sample of radish leaves from trial 02, which was 0.017 mg/kg at the 60-day PBI.

Each individual trial is summarised in tabular form (see Table C.3.3.2-1 hereafter).

**Table C.3.3.2-1 Residues of bixlozone and it's metabolites in rotational crops (radish, spinach and wheat)**

|                             |                                                                                                                                                                                                                                                         |                                  |                                                                                                                                                   |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:                  | Determination of residues of bixlozone (F9600) in rotational crops (radish, spinach, wheat) after one application of F9600-4 on bare soil at 2 sites in Northern Europe and 2 sites in Southern Europe 2020-2023, [REDACTED] 2024, FMC-53729, S20-03164 |                                  |                                                                                                                                                   |
| GLP:                        | Yes                                                                                                                                                                                                                                                     | Sample storage conditions:       | Max. 338 days at $\leq -18^{\circ}\text{C}$                                                                                                       |
| Primary crop:               | N/A – bare soil treatment                                                                                                                                                                                                                               | Analytical method:               | LC-MS/MS method CAM-0180/001 (validated)                                                                                                          |
| Succeeding crop:            | Radish, spinach and wheat                                                                                                                                                                                                                               | Limit of Quantification (mg/kg): | 0.02 (Dimethylmalonic acid)<br>0.01 (all other analytes)                                                                                          |
| Formulation:                | SC                                                                                                                                                                                                                                                      | Residues calculated as:          | Bixlozone (F9600), 2,4-dichlorobenzoic acid, 5'-hydroxy-bixlozone, F9600-dimethyl malonamide, Dimethyl malonic acid, F9600-hydroxy-isobutyramide- |
| Content of active substance | 400 g/L                                                                                                                                                                                                                                                 |                                  |                                                                                                                                                   |

| Trial No<br>Location<br>Year                                 | Commodity<br>Variety | Application rate per treatment |                          |                          | Growth stage at sampling | Crop Portion analysed | Residues (mg/kg)        |                          |                         |                           |                         |                             | PBI (days)      |
|--------------------------------------------------------------|----------------------|--------------------------------|--------------------------|--------------------------|--------------------------|-----------------------|-------------------------|--------------------------|-------------------------|---------------------------|-------------------------|-----------------------------|-----------------|
|                                                              |                      | g a.s./ha                      | Water (L/ha)             | g a.s./ha                |                          |                       | Bixlozone (F9600)       | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone    | F9600-dimethyl malonamide | Dimethyl malonic acid   | F9600-hydroxy-isobutyramide |                 |
| S20-03164<br>Trial 01<br>Niedersachsen, Germany<br>2020-2021 | Radish/<br>Lucia F1  | T1:<br>530                     | T1:<br>301               | T1:<br>176               | 49                       | Leaves                | 0.019<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>61<br>286 |
|                                                              |                      | T2:<br>524<br>T3:<br>524       | T2:<br>298<br>T3:<br>298 | T2:<br>176<br>T3:<br>176 | 49                       | Roots                 | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>61<br>286 |
|                                                              | Spinach/<br>Sioux    | T1:<br>530                     | T1:<br>301               | T1:<br>176               | 41-43                    | Leaves                | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>61<br>286 |
|                                                              |                      | T2:<br>524<br>T3:<br>524       | T2:<br>298<br>T3:<br>298 | T2:<br>176<br>T3:<br>176 | 49                       | Leaves                | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br>0.011<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>61<br>286 |
|                                                              | Wheat/<br>Quintus    | T1:<br>530                     | T1:<br>301               | T1:<br>176               | 51-55                    | Whole plant           | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>61<br>286 |
|                                                              |                      | T2:<br>524<br>T3:<br>524       | T2:<br>298<br>T3:<br>298 | T2:<br>176<br>T3:<br>176 | 51-55 (after drying)     | Hay                   | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | 0.03<br>0.027<br>0.03   | <0.01<br><0.01<br><0.01     | 27<br>61<br>286 |
|                                                              |                      |                                |                          |                          | 89                       | Grain                 | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>61<br>286 |

| Trial No<br>Location<br>Year | Commodity<br>Variety | Application rate per treatment |              |           | Growth stage at sampling | Crop Portion analysed | Residues (mg/kg)        |                          |                         |                           |                         |                              | PBI (days)      |
|------------------------------|----------------------|--------------------------------|--------------|-----------|--------------------------|-----------------------|-------------------------|--------------------------|-------------------------|---------------------------|-------------------------|------------------------------|-----------------|
|                              |                      | g a.s./ha                      | Water (L/ha) | g a.s./ha |                          |                       | Bixlozone (F9600)       | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone    | F9600-dimethyl malonamide | Dimethyl malonic acid   | F9600-hydroxy-isobutyramide- |                 |
|                              |                      |                                |              |           |                          |                       | <0.01<br><0.01<br><0.01 | <0.01<br>0.015<br><0.01  | 0.018<br>0.015<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01      |                 |
|                              |                      |                                |              |           | 89                       | Straw                 |                         |                          |                         |                           |                         |                              | 27<br>61<br>286 |

T1: Treated plot for the 27 day PBI

T2: Treated plot for the 61 day PBI

T3: Treated plot for the 286 day PBI

| Trial No<br>Location<br>Year                                      | Commodity<br>Variety | Application rate per treatment |              |           | Growth stage at sampling | Crop Portion analysed | Residues (mg/kg)  |                          |                      |                           |                       |                              | PBI (days) |
|-------------------------------------------------------------------|----------------------|--------------------------------|--------------|-----------|--------------------------|-----------------------|-------------------|--------------------------|----------------------|---------------------------|-----------------------|------------------------------|------------|
|                                                                   |                      | g a.s./ha                      | Water (L/ha) | g a.s./ha |                          |                       | Bixlozone (F9600) | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone | F9600-dimethyl malonamide | Dimethyl malonic acid | F9600-hydroxy-isobutyramide- |            |
|                                                                   |                      |                                |              |           |                          |                       |                   |                          |                      |                           |                       |                              |            |
| S20-03164<br>Trial 02<br>Rheinland-Pfalz,<br>Germany<br>2020-2021 | Radish/Raxe          | T1: 538                        | T1: 306      | T1: 176   | 49                       | Leaves                | 0.049             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        | 27         |
|                                                                   |                      | T2: 577                        | T2: 328      | T2: 176   |                          |                       | 0.11              | <0.01                    | <0.01                | 0.019                     | 0.022                 | 0.017                        | 65         |
|                                                                   |                      | T3: 553                        | T3: 314      | T3: 176   |                          |                       | 0.013             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        | 280        |
|                                                                   |                      |                                |              |           | 49                       | Roots                 | <0.01             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        | 27         |
|                                                                   |                      |                                |              |           |                          |                       | 0.018             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        | 65         |
|                                                                   |                      |                                |              |           |                          |                       | <0.01             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        | 280        |
|                                                                   | Spinach/Palco        | T1: 538                        | T1: 306      | T1: 176   | 41-43                    | Leaves                | 0.013             | <0.01                    | <0.01                | 0.017                     | 0.02                  | <0.01                        | 27         |
|                                                                   |                      |                                |              |           |                          |                       | <0.01<br><0.01    | <0.01<br><0.01           | <0.01<br><0.01       | 0.016<br><0.01            | <0.02<br><0.02        | <0.01<br><0.01               | 65<br>280  |

| Trial No<br>Location<br>Year | Commodity<br>Variety | Application rate per treatment |                               |                               | Growth stage at sampling | Crop Portion analysed | Residues (mg/kg)        |                          |                         |                           |                         |                             | PBI (days)      |
|------------------------------|----------------------|--------------------------------|-------------------------------|-------------------------------|--------------------------|-----------------------|-------------------------|--------------------------|-------------------------|---------------------------|-------------------------|-----------------------------|-----------------|
|                              |                      | g a.s./ha                      | Water (L/ha)                  | g a.s./ha                     |                          |                       | Bixlozone (F9600)       | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone    | F9600-dimethyl malonamide | Dimethyl malonic acid   | F9600-hydroxy-isobutyramide |                 |
|                              |                      | T2: 577<br>T3: 553             | T2: 328<br>T3: 314            | T2: 176<br>T3: 176            | 49                       | Leaves                | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | 0.019<br>0.022<br><0.01   | 0.021<br>0.026<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>65<br>280 |
|                              |                      | T1: 538<br>T2: 577<br>T3: 553  | T1: 306<br>T2: 328<br>T3: 314 | T1: 176<br>T2: 176<br>T3: 176 | 51-55                    | Whole plant           | 0.014<br>0.014<br><0.01 | <0.01<br><0.01<br><0.01  | 0.036<br>0.026<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>65<br>280 |
|                              |                      |                                |                               |                               | 51-55 (after drying)     | Hay                   | 0.012<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | 0.014<br>0.011<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>65<br>280 |
|                              | Wheat/<br>Quintus    |                                |                               |                               | 89                       | Grain                 | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>65<br>280 |
|                              |                      |                                |                               |                               | 89                       | Straw                 | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | 0.035<br>0.044<br>0.012 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>65<br>280 |
|                              |                      |                                |                               |                               |                          |                       |                         |                          |                         |                           |                         |                             |                 |
|                              |                      |                                |                               |                               |                          |                       |                         |                          |                         |                           |                         |                             |                 |
|                              |                      |                                |                               |                               |                          |                       |                         |                          |                         |                           |                         |                             |                 |
|                              |                      |                                |                               |                               |                          |                       |                         |                          |                         |                           |                         |                             |                 |
|                              |                      |                                |                               |                               |                          |                       |                         |                          |                         |                           |                         |                             |                 |

T1: Treated plot for the 27 day PBI

T2: Treated plot for the 65 day PBI

T3: Treated plot for the 280 day PBI

| Trial No<br>Location<br>Year                         | Commodity<br>Variety | Application rate per treatment |              |           | Growth stage at sampling | Crop Portion analysed | Residues (mg/kg)        |                          |                         |                           |                         |                             | PBI (days)      |
|------------------------------------------------------|----------------------|--------------------------------|--------------|-----------|--------------------------|-----------------------|-------------------------|--------------------------|-------------------------|---------------------------|-------------------------|-----------------------------|-----------------|
|                                                      |                      | g a.s./ha                      | Water (L/ha) | g a.s./ha |                          |                       | Bixlozone (F9600)       | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone    | F9600-dimethyl malonamide | Dimethyl malonic acid   | F9600-hydroxy-isobutyramide |                 |
| S20-03164<br>Trial 03<br>Bologna, Italy<br>2020-2021 | Radish/<br>Sax       | T4: 526                        | T4: 298      | T4: 177   | 49                       | Leaves                | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 30<br>65<br>280 |
|                                                      |                      | T5: 504                        | T5: 287      | T5: 176   | 49                       | Roots                 | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 30<br>65<br>280 |
|                                                      |                      | T6: 484                        | T6: 275      | T6: 176   |                          |                       |                         |                          |                         |                           |                         |                             |                 |
|                                                      |                      |                                |              |           |                          |                       |                         |                          |                         |                           |                         |                             |                 |
|                                                      | Spinach/<br>Spazio   | T4: 526                        | T4: 298      | T4: 177   | 41-43                    | Leaves                | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 30<br>65<br>280 |
|                                                      |                      | T5: 504                        | T5: 287      | T5: 176   | 49                       | Leaves                | 0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 30<br>65<br>280 |
|                                                      |                      | T6: 484                        | T6: 275      | T6: 176   |                          |                       |                         |                          |                         |                           |                         |                             |                 |
|                                                      |                      |                                |              |           |                          |                       |                         |                          |                         |                           |                         |                             |                 |
|                                                      | Wheat/<br>Palesio    | T1: 546                        | T1: 310      | T1: 176   | 51-55                    | Whole plant           | <0.01<br>0.01<br><0.01  | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>65<br>280 |
|                                                      |                      | T2: 510                        | T2: 290      | T2: 176   | 51-55 (after drying)     | Hay                   | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | 0.019<br>0.02<br><0.01  | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>65<br>280 |
|                                                      |                      | T3: 487                        | T3: 277      | T3: 176   | 89                       | Grain                 | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01     | 27<br>65<br>280 |
|                                                      |                      |                                |              |           |                          |                       |                         |                          |                         |                           |                         |                             |                 |



| Trial No<br>Location<br>Year | Commodity<br>Variety | Application rate per treatment |              |           | Growth stage at sampling | Crop Portion analysed | Residues (mg/kg)        |                          |                         |                           |                         |                              | PBI (days)      |
|------------------------------|----------------------|--------------------------------|--------------|-----------|--------------------------|-----------------------|-------------------------|--------------------------|-------------------------|---------------------------|-------------------------|------------------------------|-----------------|
|                              |                      | g a.s./ha                      | Water (L/ha) | g a.s./ha |                          |                       | Bixlozone (F9600)       | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone    | F9600-dimethyl malonamide | Dimethyl malonic acid   | F9600-hydroxy-isobutyramide- |                 |
|                              |                      |                                |              |           |                          |                       |                         |                          |                         |                           |                         |                              |                 |
|                              |                      |                                |              |           | 89                       | Straw                 | <0.01<br><0.01<br><0.01 | <0.01<br><0.01<br><0.01  | 0.014<br>0.013<br><0.01 | <0.01<br><0.01<br><0.01   | <0.02<br><0.02<br><0.02 | <0.01<br><0.01<br><0.01      | 27<br>65<br>280 |

T1: Treated plot for the 27 day PBI (wheat only)

T2: Treated plot for the 65 day PBI (wheat only)

T3: Treated plot for the 280 day PBI (wheat only)

T4: Treated plot for the 30 day PBI (spinach and radish)

T5: Treated plot for the 65 day PBI (spinach and radish)

T6: Treated plot for the 280 day PBI (spinach and radish)

| Trial No<br>Location<br>Year                          | Commodity<br>Variety | Application rate per treatment |              |           | Growth stage at sampling | Crop Portion analysed | Residues (mg/kg)  |                          |                      |                           |                       |                              | PBI (days)      |
|-------------------------------------------------------|----------------------|--------------------------------|--------------|-----------|--------------------------|-----------------------|-------------------|--------------------------|----------------------|---------------------------|-----------------------|------------------------------|-----------------|
|                                                       |                      | g a.s./ha                      | Water (L/ha) | g a.s./ha |                          |                       | Bixlozone (F9600) | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone | F9600-dimethyl malonamide | Dimethyl malonic acid | F9600-hydroxy-isobutyramide- |                 |
|                                                       |                      |                                |              |           |                          |                       |                   |                          |                      |                           |                       |                              |                 |
| S20-03164<br>Trial 05<br>Allueva,<br>Aragon,<br>Spain | Radish/<br>Redondo   | T6:                            | T6:          | T6:       | 49                       | Leaves                | <0.01             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        | 28<br>61<br>287 |
|                                                       |                      | 516                            | 196          | 263       |                          |                       | <0.01             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        |                 |
|                                                       |                      | T9:                            | T9:          | T9:       |                          |                       | <0.01             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        |                 |
|                                                       |                      | 501                            | 190          | 264       | 49                       | Roots                 | <0.01             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        | 28<br>61<br>287 |
|                                                       |                      | T10:                           | T10:         | T10:      |                          |                       | <0.01             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        |                 |
|                                                       |                      | 536                            | 203          | 264       |                          |                       | <0.01             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                        |                 |

| Trial No<br>Location<br>Year | Commodity<br>Variety            | Application rate per treatment |              |             | Growth stage at sampling | Crop Portion analysed | Residues (mg/kg)  |                          |                      |                           |                       |                             | PBI (days)      |
|------------------------------|---------------------------------|--------------------------------|--------------|-------------|--------------------------|-----------------------|-------------------|--------------------------|----------------------|---------------------------|-----------------------|-----------------------------|-----------------|
|                              |                                 | g a.s./ha                      | Water (L/ha) | g a.s./ha   |                          |                       | Bixlozone (F9600) | 2,4-dichlorobenzoic acid | 5'-hydroxy-bixlozone | F9600-dimethyl malonamide | Dimethyl malonic acid | F9600-hydroxy-isobutyramide |                 |
| 2022-2023                    | Spinach/<br>Monstruosa Viroflay | T6:<br>516                     | T6:<br>196   | T6:<br>263  | 41-43                    | Leaves                | <0.01             | <0.01                    | <0.01                | <0.01                     | <0.02                 | <0.01                       | 28<br>61<br>287 |
|                              |                                 | T9:<br>501                     | T9:<br>190   | T9:<br>264  |                          |                       | <0.01             | <0.01                    | <0.01                | 0.021                     | <0.02                 | <0.01                       |                 |
|                              |                                 | T10:<br>536                    | T10:<br>203  | T10:<br>264 |                          |                       | <0.01             | <0.01                    | <0.01                | 0.013                     | <0.02                 | <0.01                       |                 |
|                              |                                 |                                |              |             |                          |                       |                   |                          |                      |                           |                       |                             |                 |
|                              | Wheat/<br>Chambo                | T5:<br>505                     | T5:<br>192   | T5:<br>263  | 51-55                    | Whole plant           | <0.01             | <0.01                    | <0.01                | <0.01                     | 0.03                  | <0.01                       | 28<br>70<br>289 |
|                              |                                 | T7:<br>526                     | T7:<br>299   | T7:<br>176  | 51-55<br>(after drying)  | Hay                   | <0.01             | <0.01                    | <0.01                | <0.01                     | 0.044                 | <0.01                       |                 |
|                              |                                 | T8:<br>537                     | T8:<br>203   | T8:<br>265  |                          |                       | <0.01             | <0.01                    | <0.01                | <0.01                     | 0.038                 | <0.01                       | 28<br>70<br>289 |
|                              |                                 |                                |              |             | 89                       | Grain                 | <0.01             | <0.01                    | <0.01                | <0.01                     | 0.13                  | <0.01                       |                 |
|                              |                                 |                                |              |             |                          |                       | <0.01             | <0.01                    | <0.01                | <0.01                     | 0.12                  | <0.01                       |                 |
|                              |                                 |                                |              |             | 89                       | Straw                 | <0.01             | <0.01                    | 0.037                | <0.01                     | 0.086                 | <0.01                       | 28<br>70<br>289 |
|                              |                                 |                                |              |             |                          |                       | <0.01             | <0.01                    | 0.057                | <0.01                     | 0.076                 | <0.01                       |                 |
|                              |                                 |                                |              |             |                          |                       | <0.01             | <0.01                    | <0.01                | <0.01                     | 0.049                 | <0.01                       |                 |

T5: Treated plot for the 28 day PBI (wheat only)

T6: Treated plot for the 28 day PBI (spinach and radish)

T7: Treated plot for the 70 day PBI (wheat only)

T8: Treated plot for the 289 day PBI (wheat only)

T9: Treated plot for the 61 day PBI (spinach and radish)

T10: Treated plot for the 287 day PBI (spinach and radish)

### **C.3.4 Nature and magnitude of residues in livestock**

No additional studies submitted.

### **C.3.5 Residues in honey**

No additional studies submitted.

## C.3.6 Storage stability

### C.3.6.1 Storage stability of residues in plant products

|                        |                                                                                                                                                                                                                            |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference:             | Storage stability of F9600 and its metabolites 2,4-dichlorobenzoic acid, 5'-hydroxy-F9600 and 2,2-dimethyl-3-hydroxy propionic acid in wheat and beans under deep frozen conditions, [REDACTED] 2022, FMC-53694, S19-23627 |
| Guideline(s):          | Yes; OECD 506; SANTE/2020/12830 rev. 1                                                                                                                                                                                     |
| Deviations:            | No                                                                                                                                                                                                                         |
| GLP:                   | Yes                                                                                                                                                                                                                        |
| Validity of the study: | Valid                                                                                                                                                                                                                      |

#### Materials and methods

The frozen storage of bixlozone and its metabolites 2,4-dichlorobenzoic acid, 5'-hydroxy-bixlozone and hydroxypivalic acid (2,2-dimethyl-3-hydroxy propionic acid) was studied in wheat (forage and grain) and dry beans for 24 months.

Untreated homogenate wheat and dry bean sample matrices (2.5g) were jointly fortified with bixlozone, 2,4-dichlorobenzoic acid, 5'-hydroxy-bixlozone and hydroxypivalic acid at a level of 0.1 mg/kg for all analytes except hydroxypivalic acid that was fortified at 0.5 mg/kg. As stated in OECD 506, joint fortification is not recommended:

*“Where the residue definitions contain more than one component studies need to be designed to demonstrate stability of each component. Consequently, the use of mixed spiking solutions is not recommended as it could mask potential transformations from one compound to another. Therefore, the freezer storage stability study should be conducted with separate samples of each commodity under investigation spiked with the individual components of the residue definitions.”*

However, the available studies have enabled each component to be studied therefore, it is acceptable in this case even though it is not recommended.

5 samples (4 fortified (2 procedural recovery and 2 storage samples) and 1 non-fortified control sample) per commodity matrix were kept in a sample tube at  $\leq -18^{\circ}\text{C}$  in the dark for up to 24 months. Additionally, 4 samples (3 fortified procedural recovery samples and 1 non-fortified control sample) per commodity matrix were prepared for day 0 testing. After time intervals of approximately 3, 6, 9, 12, 18 and 24 months, samples were removed from storage and were analysed for bixlozone, 2,4-dichlorobenzoic acid, 5'-hydroxy-bixlozone

and hydroxypivalic acid. Procedural (fresh) recoveries were undertaken concurrently on samples fortified at 0.1 mg/kg (bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone) or 0.5 mg/kg (hydroxypivalic acid).

Analysis was performed using LC-MS/MS method (CAM-0180/001).

## Results and discussions

The recoveries of bixlozone, 2,4-dichlorobenzoic acid, 5'-hydroxy-bixlozone and hydroxypivalic acid from wheat (forage and grain) and dry bean matrices after the various storage periods are summarised by the applicant in Tables C.3.6.1-1 to C.3.6.1-4 below.

Residues of bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone remained stable over the whole storage period of at least 24 months in wheat (forage and grain) and dry beans. Additionally, residues of hydroxypivalic acid remained stable for at least 24 months in wheat forage and grain. It is noted that at the 12 month time point for wheat forage the mean recovery was 69%; dropping below the acceptable decline limit of 70%. However, the procedural recovery sample was also low (65%). There are acceptable mean recoveries at the following timepoints of 18 and 24 months with good procedural recoveries. Therefore, there is sufficient confidence that hydroxypivalic acid remains stable across the whole storage period of 24 months in wheat forage.

Residues of hydroxypivalic acid were only demonstrated to be stable for up to 18 months in dry bean. The mean recovery in dry bean at time points after 18 months was 69% compared to 95% in the procedural recovery samples.

The LC-MS/MS analytical method (CAM-0180/001) was previously validated in the AR (HSE, 2024a) and is satisfactorily validated in accordance with SANTE/2020/12830 rev. 1. The LOQ of the method is 0.01 mg/kg for bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone; and 0.05 mg/kg for hydroxypivalic acid. The procedural recoveries (freshly spiked samples at 0.1 mg/kg) were in the acceptable range of 70 and 120%. It is noted that one 5'-hydroxy-bixlozone sample at the 24 month timepoint is slightly outside the limit at 121%. The procedural recoveries (freshly spiked samples at 0.5 mg/kg) were mostly in the acceptable range of 70 and 110% for hydroxypivalic acid. At the 12 month time point the mean procedural recoveries were 65%, 68% and 63% for wheat forage, wheat grain and dry beans respectively. The mean procedural recoveries for hydroxypivalic acid at the following 18 and 24 month timepoints are within the acceptable range.

**Table C.3.6.1-1 Stability of bixlozone residues following storage at  $\leq -18^{\circ}\text{C}$** 

| Commodity    | Level (mg/kg) | Storage interval (months) | Fresh recovery (mean, %) | Residues after storage (mg/kg) |       | Recovery (% of nominal fortification level) |
|--------------|---------------|---------------------------|--------------------------|--------------------------------|-------|---------------------------------------------|
|              |               |                           |                          | Individual values              | Mean  |                                             |
| Wheat forage | 0.1           | 0                         | 82                       | 0.08, 0.08, 0.85               | 0.082 | 82                                          |
|              |               | 3                         | 88                       | 0.088, 0.079                   | 0.084 | 84                                          |
|              |               | 6                         | 85                       | 0.082, 0.083                   | 0.083 | 83                                          |
|              |               | 9                         | 92                       | 0.087, 0.103                   | 0.095 | 95                                          |
|              |               | 12                        | 82                       | 0.079, 0.066                   | 0.073 | 73                                          |
|              |               | 18                        | 106                      | 0.099, 0.096                   | 0.098 | 98                                          |
|              |               | 24                        | 104                      | 0.104, 0.099                   | 0.102 | 102                                         |
| Wheat grain  | 0.1           | 0                         | 82                       | 0.083, 0.091, 0.072            | 0.082 | 82                                          |
|              |               | 3                         | 77                       | 0.066, 0.079                   | 0.073 | 73                                          |
|              |               | 6                         | 79                       | 0.077, 0.075                   | 0.076 | 76                                          |
|              |               | 9                         | 81                       | 0.073, 0.071                   | 0.072 | 72                                          |
|              |               | 12                        | 70                       | 0.073, 0.078                   | 0.076 | 76                                          |
|              |               | 18                        | 110                      | 0.107, 0.105                   | 0.106 | 106                                         |
|              |               | 24                        | 94                       | 0.109, 0.102                   | 0.106 | 106                                         |
| Dry beans    | 0.1           | 0                         | 80                       | 0.086, 0.084, 0.069            | 0.080 | 80                                          |
|              |               | 3                         | 76                       | 0.080, 0.080                   | 0.080 | 80                                          |
|              |               | 6                         | 89                       | 0.093, 0.077                   | 0.085 | 85                                          |
|              |               | 9                         | 77                       | 0.077, 0.076                   | 0.077 | 77                                          |
|              |               | 12                        | 73                       | 0.078, 0.075                   | 0.077 | 77                                          |
|              |               | 18                        | 108                      | 0.107, 0.098                   | 0.103 | 103                                         |
|              |               | 24                        | 108                      | 0.091, 0.121                   | 0.106 | 106                                         |



**Table C.3.6.1-2 Stability of 2,4-dichlorobenzoic acid residues following storage at ≤-18°C**

| Commodity    | Level (mg/kg) | Storage interval (months) | Fresh recovery (mean, %) | Residues after storage (mg/kg) |       | Recovery (% of nominal fortification level) |
|--------------|---------------|---------------------------|--------------------------|--------------------------------|-------|---------------------------------------------|
|              |               |                           |                          | Individual values              | Mean  |                                             |
| Wheat forage | 0.1           | 0                         | 95                       | 0.094, 0.092, 0.100            | 0.095 | 95                                          |
|              |               | 3                         | 98                       | 0.086, 0.092                   | 0.089 | 89                                          |
|              |               | 6                         | 107                      | 0.115, 0.106                   | 0.111 | 111                                         |
|              |               | 9                         | 92                       | 0.090, 0.087                   | 0.089 | 89                                          |
|              |               | 12                        | 79                       | 0.086, 0.076                   | 0.081 | 81                                          |
|              |               | 18                        | 106                      | 0.107, 0.107                   | 0.107 | 107                                         |
|              |               | 24                        | 118                      | 0.112, 0.115                   | 0.114 | 114                                         |
| Wheat grain  | 0.1           | 0                         | 96                       | 0.093, 0.100, 0.095            | 0.096 | 96                                          |
|              |               | 3                         | 89                       | 0.085, 0.084                   | 0.085 | 85                                          |
|              |               | 6                         | 86                       | 0.095, 0.098                   | 0.097 | 97                                          |
|              |               | 9                         | 89                       | 0.080, 0.083                   | 0.082 | 82                                          |
|              |               | 12                        | 83                       | 0.088, 0.089                   | 0.089 | 89                                          |
|              |               | 18                        | 100                      | 0.110, 0.109                   | 0.110 | 110                                         |
|              |               | 24                        | 106                      | 0.101, 0.113                   | 0.107 | 107                                         |
| Dry beans    | 0.1           | 0                         | 96                       | 0.091, 0.097, 0.100            | 0.096 | 96                                          |
|              |               | 3                         | 100                      | 0.096, 0.093                   | 0.095 | 95                                          |
|              |               | 6                         | 74                       | 0.079, 0.082                   | 0.081 | 81                                          |
|              |               | 9                         | 87                       | 0.090, 0.087                   | 0.089 | 89                                          |
|              |               | 12                        | 79                       | 0.092, 0.083                   | 0.088 | 88                                          |
|              |               | 18                        | 110                      | 0.110, 0.104                   | 0.107 | 107                                         |
|              |               | 24                        | 109                      | 0.090, 0.115                   | 0.103 | 103                                         |

**Table C.3.6.1-3 Stability of 5'-hydroxy-bixlozone residues following storage at ≤-18°C**

| Commodity    | Level (mg/kg) | Storage interval (months) | Fresh recovery (mean, %) | Residues after storage (mg/kg) |       | Recovery (% of nominal fortification level) |
|--------------|---------------|---------------------------|--------------------------|--------------------------------|-------|---------------------------------------------|
|              |               |                           |                          | Individual values              | Mean  |                                             |
| Wheat forage | 0.1           | 0                         | 91                       | 0.097, 0.089, 0.087            | 0.091 | 91                                          |
|              |               | 3                         | 93                       | 0.089, 0.084                   | 0.087 | 87                                          |
|              |               | 6                         | 106                      | 0.102, 0.107                   | 0.105 | 105                                         |
|              |               | 9                         | 86                       | 0.087, 0.089                   | 0.088 | 88                                          |
|              |               | 12                        | 95                       | 0.089, 0.077                   | 0.083 | 83                                          |
|              |               | 18                        | 107                      | 0.108, 0.100                   | 0.104 | 104                                         |
|              |               | 24                        | 121                      | 0.107, 0.100                   | 0.104 | 104                                         |
| Wheat grain  | 0.1           | 0                         | 96                       | 0.097, 0.101, 0.090            | 0.096 | 96                                          |
|              |               | 3                         | 89                       | 0.082, 0.091                   | 0.087 | 87                                          |
|              |               | 6                         | 81                       | 0.077, 0.081                   | 0.079 | 79                                          |
|              |               | 9                         | 88                       | 0.085, 0.085                   | 0.085 | 85                                          |
|              |               | 12                        | 83                       | 0.082, 0.091                   | 0.087 | 87                                          |
|              |               | 18                        | 105                      | 0.109, 0.112                   | 0.111 | 111                                         |
|              |               | 24                        | 100                      | 0.096, 0.106                   | 0.101 | 101                                         |
| Dry beans    | 0.1           | 0                         | 98                       | 0.091, 0.104, 0.100            | 0.098 | 98                                          |
|              |               | 3                         | 89                       | 0.093, 0.092                   | 0.093 | 93                                          |
|              |               | 6                         | 93                       | 0.096, 0.084                   | 0.090 | 90                                          |
|              |               | 9                         | 84                       | 0.090, 0.086                   | 0.088 | 88                                          |
|              |               | 12                        | 83                       | 0.095, 0.086                   | 0.091 | 91                                          |
|              |               | 18                        | 108                      | 0.114, 0.105                   | 0.110 | 110                                         |
|              |               | 24                        | 108                      | 0.083, 0.103                   | 0.093 | 93                                          |

**Table C.3.6.1-4 Stability of hydroxypivalic acid residues following storage at  $\leq -18^{\circ}\text{C}$** 

| Commodity    | Level (mg/kg) | Storage interval (months) | Fresh recovery (mean, %) | Residues after storage (mg/kg) |       | Recovery (% of nominal fortification level) |
|--------------|---------------|---------------------------|--------------------------|--------------------------------|-------|---------------------------------------------|
|              |               |                           |                          | Individual values              | Mean  |                                             |
| Wheat forage | 0.5           | 0                         | 77                       | 0.389, 0.364, 0.406            | 0.386 | 77                                          |
|              |               | 3                         | 73                       | 0.382, 0.350                   | 0.366 | 73                                          |
|              |               | 6                         | 77                       | 0.409, 0.440                   | 0.425 | 85                                          |
|              |               | 9                         | 74                       | 0.387, 0.370                   | 0.379 | 76                                          |
|              |               | 12                        | 65                       | 0.353, 0.337                   | 0.345 | 69                                          |
|              |               | 18                        | 71                       | 0.374, 0.364                   | 0.369 | 74                                          |
|              |               | 24                        | 92                       | 0.357, 0.353                   | 0.355 | 71                                          |
| Wheat grain  | 0.5           | 0                         | 77                       | 0.373, 0.394, 0.390            | 0.386 | 77                                          |
|              |               | 3                         | 72                       | 0.334, 0.365                   | 0.350 | 70                                          |
|              |               | 6                         | 77                       | 0.376, 0.404                   | 0.390 | 78                                          |
|              |               | 9                         | 72                       | 0.345, 0.366                   | 0.356 | 71                                          |
|              |               | 12                        | 68                       | 0.361, 0.362                   | 0.362 | 72                                          |
|              |               | 18                        | 87                       | 0.458, 0.485                   | 0.472 | 94                                          |
|              |               | 24                        | 93                       | 0.354, 0.345                   | 0.350 | 70                                          |
| Dry beans    | 0.5           | 0                         | 80                       | 0.378, 0.408, 0.418            | 0.401 | 80                                          |
|              |               | 3                         | 76                       | 0.400, 0.408                   | 0.404 | 81                                          |
|              |               | 6                         | 82                       | 0.436, 0.376                   | 0.406 | 81                                          |
|              |               | 9                         | 70                       | 0.371, 0.370                   | 0.371 | 74                                          |
|              |               | 12                        | 63                       | 0.397, 0.352                   | 0.375 | 75                                          |
|              |               | 18                        | 91                       | 0.519, 0.480                   | 0.500 | 100                                         |
|              |               | 24                        | 95                       | 0.348, 0.346                   | 0.347 | 69                                          |

## Conclusion

Bixlozone, 2,4-dichlorobenzoic acid and 5'-hydroxy-bixlozone have demonstrated to be stable in wheat forage (high water group), wheat grain (high starch group) and dry bean (high protein group) for at least 24 months when stored at  $\leq -18^{\circ}\text{C}$  in the dark.

Hydroxypivalic acid has been demonstrated to be stable in wheat forage (high water group) and wheat grain (high starch group) for at least 24 months, and up to 18 months in dry beans (high protein group), when stored at  $\leq -18^{\circ}\text{C}$  in the dark.

### C.3.6.2 Storage stability of residues in animal products

[No additional studies submitted.]

#### **C.3.6.3 Storage stability in honey**

No additional studies submitted.

## Appendix D – List of endpoints

The endpoints outlined in Tables D.1 to D.5 have been derived as a result of this assessment. All other endpoints remained unchanged. The list of endpoints for the representative uses considered in the assessment report is outlined in GB LoEP (HSE, 2024c).

**Table D.1 Nature of the residue on processing**

| Conditions                                                                              | Stability | Comment                                                                  |
|-----------------------------------------------------------------------------------------|-----------|--------------------------------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4)                                                     | Stable    | For new study assessing stability of metabolite 2,4-dichlorobenzoic acid |
| Baking, brewing and boiling (60 min, 100°C, pH 5)                                       | Stable    |                                                                          |
| Sterilisation (20 min, 120°C, pH 6)                                                     | Stable    |                                                                          |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes       |                                                                          |

**Table D.2 Stability of residues in plants**

| Plant product (category) | Commodity    | Temperature (°C) | Stability (months) | Comment/ analyte                      |
|--------------------------|--------------|------------------|--------------------|---------------------------------------|
| High starch              | Wheat grain  | <-18             | 24                 | Bixlozone                             |
| High starch              | Wheat grain  | <-18             | 24                 | 2,4-dichlorobenzoic acid              |
| High starch              | Wheat grain  | <-18             | 24                 | 2,2-dimethyl-3-hydroxy propionic acid |
| High starch              | Wheat grain  | <-18             | 24                 | 5'-hydroxy-bixlozone                  |
| High water               | Wheat forage | <-18             | 24                 | Bixlozone                             |
| High water               | Wheat forage | <-18             | 24                 | 2,4-dichlorobenzoic acid              |

| <b>Plant product (category)</b> | <b>Commodity</b> | <b>Temperature (°C)</b> | <b>Stability (months)</b> | <b>Comment/ analyte</b>               |
|---------------------------------|------------------|-------------------------|---------------------------|---------------------------------------|
| High water                      | Wheat forage     | <-18                    | 24                        | 2,2-dimethyl-3-hydroxy propionic acid |
| High water                      | Wheat forage     | <-18                    | 24                        | 5'-hydroxy-bixlozone                  |
| High protein                    | Dry beans        | <-18                    | 24                        | Bixlozone                             |
| High protein                    | Dry beans        | <-18                    | 18                        | 2,4-dichlorbenozic acid               |
| High protein                    | Dry beans        | <-18                    | 24                        | 2,2-dimethyl-3-hydroxy propionic acid |
| High protein                    | Dry beans        | <-18                    | 24                        | 5'-hydroxy-bixlozone                  |

**Table D.3 Residues in primary crops**

|                              |                                                                                                                                                                                                                                                  |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| New residues trials on wheat | <p>Five new trials on wheat with residues of bixlozone and 2,4-dichlorobenzoic acid in grain and straw all &lt;0.01 mg/kg.</p> <p>No change to the STMR and HR already assessed (GB LoEP (HSE, 2024c)) for wheat and barley grain and straw.</p> |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Table D.4 Residues in rotational crops**

|                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Residues in rotational or succeeding crops expected based on confined rotational crop study?</p> | <p>Yes</p> <p>Based on the CRC study it was considered likely that metabolites would not be expected to occur, although some residues of bixlozone (e.g. in leafy crops) could be found. The new rotational crop field study (see below) indicates that depending on application rate, residues of metabolites could be found in rotational crops, as well as parent bixlozone. For the current time a replant restriction is proposed to limit residues (see below). However if new rotational crops studies are generated in the future then the possibility of finding metabolites as well as parent bixlozone should be considered (see below where HSE recommends the OECD recommended super crop group approach).</p> <p>As the new data demonstrates that positive residues of various metabolites may be found in rotational crops, additional data and information are likely to be required to establish suitable residue definitions for rotational crops.</p> |
|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Residues in rotational or succeeding crops expected based on field rotational crop trials?</p> | <p>Yes, a new rotational crop field trials study was submitted enabling a more extensive assessment of the potential formation of metabolites and parent bixlozone. The replant restriction has now been amended to avoid residues of parent bixlozone or metabolites being found in various rotational crops.</p> <p>The required label restriction:<br/> <i>“All rotational crops, except cereals (including maize), oilseeds and pulses (dry seed), must not be planted until at least 9 months after application of bixlozone”.</i></p> <p>Since residues of parent and metabolites have been detected in the rotational crop field trials, HSE recommends that any new field rotational crop residues trials for future extensions of uses or to further refine the replant restriction must cover parent and metabolites, and also consider a wider range of commodities, as per the Tier 3 ‘super crop group’ approach (as recommended in OECD Guidance on Residues in Rotational Crops, 2018).</p> |
|---------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



**Table D.5 Methods for monitoring/enforcement**

|                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Methods of analysis for monitoring/enforcement of residues (analytical technique, crop groups, LOQs)</p> | <p>The new method CAM-0180/003 (version 3 of the method considered for monitoring at active approval), and ILV, is validated and acceptable for the monitoring of bixlozone in high water, high starch (dry commodities) and high protein.</p> <p>To conclude, the HPLC-MS/MS method CAM-0180 is validated for the high acid, high water, high starch (dry), high protein and high oil matrix groups and cereal straw (no group) with an LOQ of 0.01 mg/kg. Acceptable ILV data were provided.</p> |
|-------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## Appendix E – Import Tolerances

Not applicable.

## 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        |
|------------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| ██████████ | 2024 | Nature of [ <sup>14</sup> C]-2,4-dichlorobenzoic acid residues in process commodities - high temperature hydrolysis ██████████<br>██████████ Report No. FMC-82043, GLP                                                                                                                    | FMC Agro Limited |
| ██████████ | 2023 | Bixlozone - Validation of the Analytical Method CAM-0180 for the Determination of Bixlozone (F9600) and Metabolites 2,4-dichlorobenzoic acid and 5'-hydroxy-F9600 in Lettuce, Wheat Grain and Dried Beans by LC-MS/MS, ██████████<br>██████████ FMC-81447, GLP                            | FMC Agro Limited |
| ██████████ | 2023 | Independent Laboratory Validation of an Analytical Method for the Determination of Bixlozone (F9600) and Metabolites 2,4-dichlorobenzoic acid and 5'-hydroxy-F9600 in Lettuce, Wheat Grain and Dried Bean, ██████████<br>██████████ FMC-81446, GLP                                        | FMC Agro Limited |
| ██████████ | 2023 | Magnitude of the residue of F9600, beflubutamid, cloquintocet-mexyl and their respective metabolites in representative winter wheat raw agricultural commodities after one application of F4215-R007 in northern and southern europe – 2020-2021, ██████████<br>██████████ FMC-55312, GLP | FMC Agro Limited |
| ██████████ | 2022 | Determination of the residue of F9600 metabolite hydroxypivalic acid in winter wheat raw agricultural commodities after one application of F4215-R007 in northern and southern Europe – 2020-2021, ██████████<br>██████████ FMC-80116, GLP                                                | FMC Agro Limited |

| Author(s)  | Year | Title/Testing Facility/Report No/GLP or GEP Status/Published or not                                                                                                                                                                            | Submitter        |
|------------|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| [REDACTED] | 2022 | Determination of the residue of F9600 metabolite Dimethyl-malonic acid in winter wheat raw agricultural commodities after one application of F4215-R007 in northern and southern Europe – 2020-2021, [REDACTED]<br>[REDACTED] FMC-80117, GLP   | FMC Agro Limited |
| [REDACTED] | 2024 | Determination of residues of bixlozone (F9600) in rotational crops (radish, spinach, wheat) after one application of F9600-4 on bare soil at 2 sites in Northern Europe and 2 sites in Southern Europe 2020-2023, [REDACTED]<br>FMC-53729, GLP | FMC Agro Limited |
| [REDACTED] | 2022 | Storage stability of F9600 and its metabolites 2,4-dichlorobenzoic acid, 5'-hydroxy-F9600 and 2,2-dimethyl-3-hydroxy propionic acid in wheat and beans under deep frozen conditions, [REDACTED]<br>[REDACTED] FMC-53694, GLP                   | FMC Agro Limited |





