

The review of the MRLs for apples and pears and CXLs for dithianon

UK Competent Authority Draft Evaluation Report and Reasoned Opinion

- Prepared under Article 6(3) of Assimilated Regulation 396/2005 and Data Requirements of Assimilated Regulation 544/2011
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Summary

This assessment is a draft only and outlines proposed recommendations for the MRLs in or on apples and pears and all existing CXLs for the active substance dithianon.

According to Article 6 (3) of the assimilated regulation 396/2005,¹ HSE considered the need to review the MRL for dithianon in or on apples and pears.

HSE identified an acute intake concern arising from the current MRLs for dithianon in or on apples and pears of 3 mg/kg. The highest UK NESTI was 154.3% of the ARfD (infant/apples). The highest PRIMo IESTI was 218% of the ARfD (NL toddler/pears). Therefore, an acute intake concern has been identified for the current MRL on apples and pears. HSE considered the potential adoption of the lower CXL for pome fruits for adoption as a GB MRL.

HSE noted that a number of the current substantive MRLs were not supported by residue trials data and that there were chronic intake concerns. Therefore, HSE evaluated the potential adoption of other CXLs, supported by trials data, as GB MRLs. This was to ensure that the UK's appropriate level of protection was met.

Based on the review of the MRLs, HSE prepared a Reasoned Opinion (RO). HSE took into account the assessment report and EFSA conclusion prepared under Regulation (EC) 1107/2009, whilst the UK was an EU MS, for the approval of the active substance. HSE also took into account previous Reasoned Opinions related to MRL decisions adopted prior to 1 January 2021.

Sufficiently validated analytical methods for the determination of dithianon in plant commodities, in line with the enforcement residue definition for products of plant origin, are available to support the crop group under consideration in the review of the MRL for apples and pears.

Toxicological reference values were established for the approval of the active substance: an ADI of 0.01 mg/kg bw/day and an ARfD of 0.12 mg/kg bw.

Metabolism in primary crops was investigated following foliar spray treatment in apple, orange, spinach and wheat for the approval of the active substance (DAR, 2006). As a consistent metabolic pathway was observed across crops from three crop groups, the

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

available data are sufficient to support all crop groups. The application type in the studies is foliar spray, which is the same as the application type for the use supporting the MRL being reviewed. On this basis the MRLs in or on apples and pears are supported by the available metabolism data.

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

- Dithianon

The residue definition for enforcement (RD-Enf) in plants in the GB MRL Statutory Register is currently:

- Dithianon

Multiple GAPs are authorised for the use of dithianon on apples and pears in GB. Sixteen trials are available to support the cGAP and an MRL of 0.8 mg/kg is required. There is a CXL available for all pome fruits (1 mg/kg), as this is greater than the required MRL of 0.8 mg/kg, the CXL was considered in the consumer risk assessment.

Hydrolysis of dithianon under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrates that dithianon is not stable across the standard conditions. Additional data was evaluated in an amendment to the DAR which investigated the stability of dithianon during hydrolysis in apple juice, rather than standard buffer solutions.

In apple juice, dithianon was the predominant residue formed on pasteurisation (up to 47.3 % TAR). However, under conditions representing baking/brewing/boiling and sterilisation, dithianon was degraded into multiple components.

A specific residue definition for processed commodities was not established for the approval of the active substance. However, specific active substance confirmatory data to address the storage stability and nature of the residues on processing was set for the approval of the active substance, and these data will be considered separately.

The MRLs which are recommended for adoption as GB MRLs are the CXLs for which it is considered that a further consideration of processing is not required at this time as it is covered as part of the assessment undertaken by the JMPR to establish the international food standards.

No consideration of residues in rotational crops is required, as the authorised use is on crops which are considered to be permanent/semi-permanent and there are no concerns from potential accumulation.

The maximum livestock dietary burden exceeded the trigger value for further assessment (0.1 mg/kg DM and AR) for all livestock species. Metabolism of dithianon 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. Based on the results of the livestock metabolism studies and the calculated dietary burdens, residues of dithianon above the LOQ of 0.01 mg/kg are not expected in ruminant, swine and poultry matrices.

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

- Dithianon

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

- Dithianon

For the current MRLs for apple and pear, the highest UK NESTI was 154.3% of the ARfD (infant/apples). The highest PRIMo IESTI was 218% of the ARfD (NL toddler/pears).

As a result of the acute intake concerns identified for the current MRLs on apples and pears, HSE recommends that the current GB MRLs are not retained. As a first step the exposure assessments relating to the lower CXL for pome fruits (for apple and pear) was considered. HSE also identified a chronic risk to some population subgroups for the current GB MRLs and therefore several different scenarios had to be considered in the consumer risk assessments as outlined below:

- **Scenario 1** acute risk assessment for the current MRLs on apples and pears, followed by consideration of the CXL for pome fruits (1.0 mg/kg).
- **Scenario 2** is a consideration of all relevant CXLs (as detailed in table 0.3) for both chronic and acute intakes, as well as consideration of chronic intakes for all existing MRLs.
- **Scenario 3** as a chronic risk was identified from all uses considered in scenario 2, refinements were made. The highest contributors to the chronic exposures were removed where there was no UK use, with no data currently available to support the MRL, and no CXL. Lower CXLs available for dithianon were considered in the consumer risk assessments.

Scenario 1

The scenario 1 risk assessment was undertaken for the HR values for the current GB MRL on apples and pears.

For the current MRL on apples and pears:

The highest UK NESTI was 154.3% of the ARfD (infant/ apples). The highest PRIMo IESTI was 218% of the ARfD (NL toddler/ pears). Therefore, an acute intake concern has been identified for the current MRLs for apples and pears.

The CXL was identified as a 'fallback' option for apples and pears and it accommodates the current GB authorisation on apples and pears (see section 3).

For the CXL on apples and pears:

The highest UK NESTI was 53.1% of the ARfD (infant/ apples). The highest PRIMo IESTI was 75.0% of the ARfD (NL toddler/ pears). Therefore, no acute intake concerns were identified.

HSE concludes that harmful effects on human health cannot be excluded for residues dithianon occurring in apples and pears arising from the current GB MRL. The CXL of 1.0 mg/kg did not result in acute intake concerns. Therefore, the CXL for pome fruits (which includes apples and pears) is recommended for adoption in GB for apples and pears. For other pome fruits the current GB MRL of 3 mg/kg does not result in acute intake concerns for UK consumers, and therefore HSE recommends that the higher GB MRL is retained.

Scenario 2

Under Scenario 2, the following was considered in the chronic assessment:

- Currently established GB MRLs
- Additional CXLs (which are higher than the current GB MRL) considered for adoption as GB MRLs; in cases where the GB MRL and CXL are equivalent, but for which no STMR is available for the current MRL (e.g. cherries), the CXL has been considered for adoption given it is supported by data
- STMR for CXL for Apple and pear input

For scenario 2, the highest UK NEDI was 388% of the ADI (toddler). The highest PRIMo IEDI was 120% of the ADI (NL toddler). Therefore, a chronic intake concern has been identified from exposure to dithianon from all dietary sources.

The highest UK NESTI was 73.4% of the ARfD (toddler/ peaches). The highest PRIMo IESTI was 127% of the ARfD (NL toddler/ peaches). Therefore, acute intake concerns were identified for peaches; HSE recommends that the CXL for stone fruits of 2 mg/kg is considered for adoption in GB MRL for all commodities in the stone fruit group (MRL code 0140000) except for peaches. For peaches (MRL code 0140030) the current MRL of 0.5 should be retained. The current MRL of 0.5 mg/kg for peaches does not result in acute intake concerns for UK consumers.

An acute intake concern was not identified for any other commodity.

Scenario 3

As the NEDIs and IEDIs in scenario 2 exceeded the ADI for some population subgroups, refinement of the chronic exposures was undertaken. The refinement was undertaken in a

stepwise approach removing the highest contributors to the overall chronic exposures, for which there are no authorisations in GB and no CXLs, until there were no exposures that exceeded the ADI. Additionally, as residues in products of animal origin are expected to be negligible (see section 4.2), the input for all animal commodities have been set to zero.

Following this stepwise approach the inputs for citrus fruits and raspberries were lowered to the LOQ of 0.01* mg/kg. For currants (black, red and white) the STMR for the lower CXL, compared to the current GB MRL, was used as the input.

After the final step, the highest UK NEDI was 99.5% of the ADI (toddler) and the highest PRIMo IEDI was 84% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with dithianon.

Based on the chronic and acute risk assessments from scenario 2 and 3, no health effects are expected. All relevant CXLs can be adopted except the CXL for peaches.

HSE recommends that the MRLs outlined in Table 0.1 are adopted.

Table 0.1 MRLs recommended by HSE

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
Enforcement residue definition for products of plant origin: Dithianon				
0110000 (except 0110050)	Citrus fruits (except mandarins)	1.0	0.01*	The current MRL results in chronic intake concerns. No fallback options, or CXLs, are available, the MRL should be lowered to the LOQ. No health effects are expected.
0110050	Mandarins	3.0	0.01*	The current MRL results in chronic intake concerns. No fallback options, or CXLs, are available, the MRL should be lowered to the LOQ. No health effects are expected.

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
0130010	Apples	3.0	1.0	The current MRL results in acute intake concerns. The new MRL is based on the CXL. No health effects are expected.
0130020	Pears	3.0	1.0	The current MRL results in acute intake concerns. The new MRL is based on the CXL. No health effects are expected.
0140010	Apricots	0.5	2.0	The MRL is based on the CXL. No health effects are expected.
0140040	Plums	0.5	2.0	The MRL is based on the CXL. No health effects are expected.
0151020	Wine grapes	3.0	5.0	The MRL is based on the CXL. No health effects are expected
0153030	Raspberries (red and yellow)	3.0	0.01*	The current MRL results in chronic intake concerns. No fallback options, or CXLs, are available, the MRL should be lowered to the LOQ. No health effects are expected.

Product code	Product	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)	Comments
0154030	Currants (red, black and white)	3.0	2.0	The current MRL results in chronic intake concerns. A CXL of 2 mg/kg is available and was considered for adoption as a 'fallback' MRL. No health effects are expected.
0700000	Hops	100.0	300.0	The MRL is based on the CXL. No health effects are expected.

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

The full list of all MRLs recommended for adoption are summarised in Table 8.1.

Proposed Recommendations

Based on the risk assessment conducted, HSE concludes that harmful effects on human health cannot be excluded for residues of dithianon occurring in or on apples and pears based on the current GB MRLs for dithianon. As the required level of protection has not been met based on the current MRL, HSE proposes that the MRL for apples and pears is modified from 3 mg/kg to the CXL of 1 mg/kg.

HSE also reviewed all current CXLs available for dithianon. The full list of the MRLs recommended for adoption are outlined in Table 8.1. The MRLs should be established on the basis of the following residue definition for enforcement (RD-Enf) in plants and animals:

- Dithianon

Notification of the proposed MRL

To meet the UK's international trade obligations, the measures have been notified to the World Trade Organization (WTO). The WTO/SPS notification can be found at the following link and searching for dithianon and United Kingdom as the notifying member:

<http://spsims.wto.org/en/Notifications/Search>

- There may be a delay between publication of this draft RO and the notification appearing in the Sanitary and Phytosanitary Information Management System.
- The notification includes the proposed date of adoption/publication and the proposed date of entry in force of the new MRL.

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Background

HSE identified an acute intake concern arising from the current MRL of 3 mg/kg for dithianon in or on apples and pears. The highest UK NESTI was 154% of the ARfD (infants/apples). The highest PRIMo IESTI was 218% of the ARfD (NL toddler/pears).

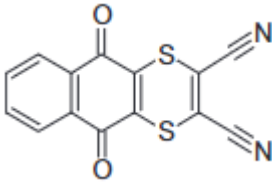
As a result of the acute intake concerns identified, HSE considered the need to review the MRLs for apples and pears in accordance with Article 6 (3) of Assimilated Regulation 396/2005 and compile and evaluate additional information in accordance with Article 7, including the CXL for pome fruits of 1 mg/kg.

In addition, a lack of trials data and chronic intake concerns were identified for the current MRLs. Therefore, HSE considered the potential adoption of other CXLs for dithianon to ensure the UK's appropriate level of protection was met.

The active substance and its use pattern

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

Table 0.2 Information on the active substance

Common name (ISO)	Dithianon
Chemical name (IUPAC)	5,10-dihydro-5,10-dioxonaphtho[2,3-b]-1,4-dithiine-2,3-dicarbonitrile
CAS number	3347-22-6
Structural formula	
Molecular formula	C ₁₄ H ₄ N ₂ O ₂ S ₂
Molecular mass	296.32 g/mol

Dithianon is an approved substance in GB. An EFSA conclusion is available (EFSA, 2010). The MRLs for dithianon have not yet been reviewed under Article 12 of Assimilated Regulation 396/2005 in GB. MRLs are established for dithianon in Part 3 of the GB MRL Statutory Register. Dithianon is used as a protectant dicarbonitrile fungicide for control of scab and other foliar diseases (excluding powdery mildew).

Appendix A outlines the GAPs (Good Agricultural Practices) relevant to the MRL under review. The GAP table only includes apples and pears as these are the commodities that triggered this review. The GAP relates to the critical use in GB for apples and pears and hence the use on which the MRL would need to be based in the absence of an IT based MRL or a CXL. There is a CXL for pome fruits that is relevant to the review of the GB MRLs for apples and pears.

As there are chronic consumer risks associated with the current MRLs and all the STMRs are not available (see section 7), all the currently available CXLs were also considered in this review. The CXLs available are outlined in the Codex Pesticide Residues in food online database and outlined below in Table 0.3.

Table 0.3 CXLs relevant to the proposed uses

Commodity	CXL (mg/kg)	Comments	Year of adoption
Almonds	0.05	The CXL is equal to the current GB MRL and therefore no further consideration is required.	2014
Pome fruits (group)	1.0	The CXL is lower than the current GB MRL. The current GB MRLs for apples and pears are being lowered to the CXL due to identified acute intake concerns. The CXL accommodates the currently authorised use of dithianon on apples and pears in GB. No health effects are expected based on the CXL, and therefore the CXL can be adopted for apples and pears. The current GB MRL for all other pome fruits is greater than the CXL, therefore no further consideration is required.	2014
Stone fruits (group)	2.0	The CXL is greater than or equal to the current GB MRL. The underlying data for the current GB MRL is unavailable, hence the CXL was considered. No health effects are expected for stone fruits, except for peaches, therefore the CXL can be adopted for these commodities. For peaches, the CXL results in acute intake concerns, the CXL cannot be adopted for peaches. Note for cherries the GB MRL is already 2 mg/kg.	2014
Table grapes	2.0	The CXL is lower than the current GB MRL and therefore no further consideration is required; the current GB MRL of 3 mg/kg is retained.	2014
Wine grapes	5.0	The CXL is greater than the current GB MRL. No health effects are expected and therefore the CXL can be adopted.	2014

Currants (red, black and white)	2.0	The current GB MRL contributes to chronic exposures that exceed the ADI, as such, the current GB MRL is to be lowered. The CXL is lower than the current GB MRL and therefore was considered for adoption as a 'fallback' MRL. No health effects are expected and therefore the CXL can be adopted.	2014
Hops	300.0	The CXL is greater than the current GB MRL. No health effects are expected therefore the CXL can be adopted	2014
Meat (from mammals other than marine mammals)	0.01*	The CXL is equal to the current GB MRL and therefore no further consideration is required	2014
Edible offal (mammalian)	0.01*	The CXL is equal to the current GB MRL and therefore no further consideration is required	2014
Milks	0.01*	The CXL is equal to the current GB MRL and therefore no further consideration is required	2014
Poultry meat	0.01*	The CXL is equal to the current GB MRL and therefore no further consideration is required	2014
Poultry, edible offal of	0.01*	The CXL is equal to the current GB MRL and therefore no further consideration is required	2014
Eggs	0.01*	The CXL is equal to the current GB MRL and therefore no further consideration is required	2014

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

Assessment

1 Methods of analysis

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

Analytical methods for the determination of dithianon in plant commodities, in line with the enforcement residue definition for products of plant origin, were assessed for the approval of the active substance (EFSA conclusion, 2010).

The available method is validated for the high water, high acid, high starch and high oil commodity groups with an LOQ of 0.01 mg/kg. Acceptable ILV data were provided.

The crops under a specific consideration in this MRL review (apple and pear) belong to the high water commodity group, and are therefore, covered by the analytical methods available. The other MRLs being adopted are CXLs and the JMPR concluded sufficient methods are available for the monitoring of residues.

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

Not required as the review does not require the amendment of MRLs in products of animal origin.

2 Mammalian toxicology

The toxicological end points established for the approval of the active substance are summarised in a tabular form as proposed below.

Table 2.1 Overview of the toxicological reference values for dithianon

TRVs	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA	2010	0.01	Long-term toxicity/ carcinogenicity study in rat	100
ARfD	EFSA	2010	0.12	7-day & 28-day oral toxicity in rat	100

3 Residues in plants

3.1 Nature of residues in primary crops

Metabolism in primary crops was investigated following foliar spray treatment in apple, orange, spinach and wheat for the approval of the active substance (DAR, 2006).

The following summary is presented in the EFSA conclusion (EFSA, 2010):

“The metabolism of dithianon has been investigated in fruit crops (apple and orange), leafy vegetables (spinach) and cereals (wheat). In fruit crops and for all the sampling intervals, the major part of the radioactivity was found in the surface rinse as unchanged parent dithianon, while the remaining radioactive residues in the extracts of apple and orange peel and pulp consisted of a large number of mostly polar compounds. A similar metabolic pattern was observed in wheat and spinach with further characterisation of the metabolites CL 231509, CL 902200 and phthalic acid, all recovered in negligible amounts. The residue definition for monitoring and risk assessment is proposed to include the parent compound only.”

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	RTI ^(a) days	DAT ^(b) (days)
Fruit	Apple	Foliar treatment: 4-5 100 µL droplets of a formulation containing dithianon at a concentration between 0.07% and 0.1%	14	0, 21 days after 4 th application, 15 days after 5 th application
	Orange	Foliar, 3 x 1870 g a.s./ha	28	14, 28
Leafy crops	Spinach	Foliar, 3 x 1000 g a.s./ha, BBCH 16-18	10-13	0 after each application, 20 after 3 rd application
Cereals/grass crops	Wheat	Foliar, 2 x 1500 g a.s./ha, BBCH 59-61	14	Stem and ears: 0, 20

(a) Re-treatment interval

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

As a consistent metabolic pathway was observed across crops from three crop groups, the available data are sufficient to support all crop groups. The application type in the studies is foliar spray, which is the same as the application type for the use supporting the MRL

being reviewed. On this basis the MRLs in or on apples and pears are supported by the available metabolism data.

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

- Dithianon

The residue definition for enforcement (RD-Enf) in plants in the GB MRL Statutory Register is currently:

- Dithianon

These residue definitions are the same as those endorsed by the JMPR and are also applicable to the CXLs being adopted.

3.2 Magnitude of residues in primary crops

No new residue trials have been assessed as part of this review of the MRL for dithianon in or on apples and pears.

The current GB MRLs for apples and pears were set during the approval of the active substance (EFSA, 2010). The GAP (SEU and NEU) for the approval of the active substance was 12 x 525 g a.s./ha, minimum RTI of 7 days and a PHI of 21 days. The MRL derived for the approval was 3 mg/kg; this was not based on the OECD calculator, the required MRL based on the OECD calculator is 4 mg/kg.

The MRL was based on the combined dataset of apples and pears from NEU and SEU; the STMR and HR were 0.62 mg/kg and 1.89 mg/kg, respectively.

Residue trials

0130010 Apples
0130020 Pears

There are currently a number of products authorised for use on apples and pears in GB and NI. The authorised GAPs are covered by the following use patterns:

- 'Dithianon WG' (COP 2013/01119; HSE internal reference.: W001648294), 6 x 350 g a.s./ha with an RTI of 5 days and a PHI of 42 days.
- 'Delan Pro' (COP 2014/00918, HSE int. reference.: W001688651), 6 x 312.5 g a.s./ha with an RTI of 5 days and a PHI of 35 days.

A full analysis of the trials conducted for both products can be found in section D.3.1.2.

Eight trials were available to support the authorised GAP for 'Dithianon WG' in the product evaluation considered under COP 2013/01119. These trials were conducted at 6x350 g a.s./ha, PHI 42 days. All trials were decline trials and also contained residue results at a PHI of 35 days. The trials were conducted with a WG formulation.

Eight different trials were available to support the authorised GAP for 'Delan Pro' in the product evaluation considered under COP 2014/00918. These trials were conducted at 6x312.5 g a.s./ha, PHI 35 days. All trials were decline trials and also contained residue results at a PHI of 42 days. The trials were conducted with a SC formulation.

All the residue trials were conducted in accordance with the relevant guidance documents (including the GB Extrapolation Guidance, 2024), and no significant deviations were noted in the trials.

On considering the 25% rule, the extrapolation between trials conducted with a WG and SC formulation is possible and that for both sets of trials, data are available covering a PHI of 35 and 42 days, the following can be stated:

- The trials for 'Dithianon WG', conducted at 6 x 350 g a.s./ha with an RTI of 5 days, also support the GAP for 'Delan Pro' with an application rate of 6 x 312.5 g a.s./ha with an RTI of 5 days.
- Trials for 'Delan Pro', conducted at an application rate of 6 x 312.5 g a.s./ha with an RTI of 5 days, also support the GAP for 'Dithianon WG' with an application rate of 6 x 350 g a.s./ha with an RTI of 5 days.

Therefore:

- Sixteen trials are available to support the GAP for 'Dithianon WG': 6 x 350 g a.s./ha with an RTI of 5 days and a PHI of 42 days
- Sixteen trials are available to support the GAP for 'Delan Pro': 6 x 312.5 g a.s./ha with an RTI of 5 days and a PHI of 35 days

For both GAPs the MRL derived is 0.8 mg/kg, and the HR is 0.52 mg/kg. As the STMR for the 'Delan Pro' GAP is higher this can be regarded as the cGAP in GB.

A CXL is available for pome fruits (1 mg/kg); the CXL has been considered for adoption as a first step, given it accommodates the GB authorisation. The HR for the CXL is 0.65 mg/kg, compared to the HR of 0.52 mg/kg for the GB GAP. However, it is noted that the STMR for the GB cGAP is 0.24 mg/kg, which is higher than the STMR of 0.15 mg/kg for the CXL. Therefore, for the livestock dietary burden and the chronic consumer risk assessment, the value of 0.24 mg/kg has been used.

Storage stability

Sufficient storage stability in high water commodities is available from the approval of dithianon to support the maximum storage period of 200 days for apples.

Storage stability of dithianon in high water commodities was demonstrated for at least 12 months at <-20°C.

Analytical methods

Analysis for residues of dithianon was completed using LC-MS/MS method L0152/01 (see COP 2012/01846). The analytical method was satisfactorily validated in accordance with SANCO 3029/99 rev. 4. Extraction efficiency was not addressed for the method and is in principle required, however, this is unlikely to affect the outcome of the consumer risk assessment or the derived MRL, as such, no further information is required at this stage.

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Table 3.2 Overview of the available residue trials data

Commodity	Region/ (GAP) (a)	Residue levels (mg/kg) observed in the trials representative for the intended GAPs (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Apples → apples and pears	NEU / 6 x 350 g a.s./ha, 42 d PHI (Dithianon WG trials)	0.04, 0.09, 0.12, 0.13, 2 x 0.16, 0.19, 0.40	MR _{LOECD} : 0.590 (unrounded MRL)	0.6	0.40	0.145
Apples → apples and pears	NEU / 6 x 312.5 g a.s./ha, 35 d PHI (Delan Pro trials)	0.17, 0.24, 0.25, 0.31, 0.33, 0.42, 0.43, 0.52	MR _{LOECD} : 1.001 (unrounded MRL)	1.0	0.52	0.32
Apples → apples and pears	NEU / combined trials - 35 d PHI (Delan Pro GAP)	0.04, 0.12, 0.15, 0.16, 0.17, 0.18, 0.20, 2 x 0.24, 0.25, 0.31, 0.33, 0.40, 0.42, 0.43, 0.52	Sixteen trials on apples (whole fruit) were conducted in NEU and extrapolated to cover pears. MR _{LOECD} : 0.785 (unrounded MRL)	0.8	0.52	0.24
Apples → apples and pears	NEU / combined trials - 42 d PHI	0.04, 0.09, 0.10, 0.12, 0.13, 4x0.16, 0.19, 0.21, 0.31, 0.32, 0.40, 0.42, 0.52	Sixteen trials on apples (whole fruit) were conducted in NEU and extrapolated to cover pears. MR _{LOECD} : 0.762 (unrounded MRL)	0.8	0.52	0.16

Commodity	Region/ (GAP) (a)	Residue levels (mg/kg) observed in the trials representative for the intended GAPs (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
	(Dithianon WG GAP)					
Pome fruits	CXL	-	-	1.0	0.65	0.15

(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})

3.3 Effect of industrial processing and/or household preparation

3.3.1 Nature of the residues in processed commodities

Hydrolysis of dithianon under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance (DAR, 2006). Dithianon was found to be stable under pasteurisation conditions while it was degraded into multiple degradation products under conditions of baking/ brewing/ boiling and sterilisation. Under pasteurisation conditions, degradation of dithianon into numerous uncharacterised metabolites was observed in apple juice.

A specific residue definition for processed commodities was not established for the approval of the active substance. However, a data gap was identified by EFSA for additional hydrolysis studies for dithianon in the presence of apple or grape juice, rather than buffer solutions (EFSA, 2010). This data gap was set as a specific active confirmatory data requirement to be addressed:

The storage stability and the nature of residues in processed products

The consideration of the data to address this active confirmatory data requirement will be considered separately.

3.3.2 Magnitude of the residues in processed commodities

For the adoption of CXLs a consideration of processing is not required as it is covered as part of the assessment undertaken by the JMPR to establish the international food standards.

It is noted that a processing factor was derived for wine/wine grapes by the JMPR (JMPR, 2013); $pf < 0.003$. This pf has been applied in the consumer risk assessment.

3.4 Rotational crops

No consideration of residues in rotational crops is required, as the authorised use is on crops which are considered to be permanent/semi-permanent and there are no concerns from potential accumulation.

4 Residues in livestock

The crops under consideration in this MRL review are fed to livestock and therefore residues in products of animal origin have been considered further.

4.1 Dietary burden

The dietary burden calculation has been undertaken using the EFSA animal model 2017.

The following assumptions have been made:

- 1) 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.
- 2) 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
- 3) There is no loss of residue during transport, storage, preparation of feed prior to consumption.
- 4) Default processing factors as set out in the EFSA Animal Model 2017 have been used unless other specific processing factors are available or residues

Input values covering the MRLs recommended for adoption are summarised in Table 4.1-1 and the highest and median calculated animal intakes are reports in Table 4.1-2.

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment	residue	definition: dithianon		
Apple pomace, wet	1.2	STMR (0.24) x Pf (5)	1.2	STMR (0.24) x Pf (5)
Potato, culls	0.1	MRL	0.1	MRL
Carrot, culls	0.05	MRL	0.05	MRL
Wheat grain	0.05	MRL	0.05	MRL
Distillers grain, dried	0.17	MRL x default pf (3.3)	0.17	MRL x default pf (3.3)
Potato, process waste	2	MRL x pf (20) [†]	2	MRL x pf (20) [†]

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment	residue	definition: dithianon		
Potato, dried pulp	3.8	MRL x pf (38)	3.8	MRL x pf (38)
Wheat gluten, meal	0.09	MRL x default pf (1.8)	0.09	MRL x default pf (1.8)
Wheat, milled by-products	0.35	MRL x default pf (7)	0.35	MRL x default pf (7)

Table 4.1-4 Estimated animal intakes

Animal	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	>0.1 mg/kg DM (Y/N)	Maximum burden (mg/kg DM)	Highest contributing commodity^(a)
Cattle (all diets)	0.199	0.199	Y	6.83	Potato process waste
Cattle (dairy only)	0.199	0.199	Y	5.17	Potato process waste
Sheep (all diets)	0.228	0.228	Y	6.83	Potato process waste
Sheep (ewe only)	0.228	0.228	Y	6.83	Potato process waste
Swine (all diets)	0.083	0.083	Y	3.60	Potato process waste
Poultry (all diets)	0.067	0.067	Y	0.95	Potato dried pulp
Poultry (layer only)	0.050	0.050	Y	0.74	Potato dried pulp

(a) Considering the maximum dietary animal burden

Dietary burden of the tentative GAP exceed the trigger of 0.1 mg/kg DM in all animals. Therefore, further consideration of residues in these groups is required.

4.2 Nature of residues (Animal metabolism studies)

Metabolism in livestock was investigated in lactating goats (ruminants) and laying hens (poultry) for the approval of the active substance (DAR, 2006). Metabolism in rat was also considered for approval of the active.

A summary of the available livestock metabolism data is presented below (EFSA, 2010):

“The metabolism of dithianon has been investigated in lactating goats and laying hens. The major part of the radioactivity was excreted (80%) and unchanged dithianon was recovered at a very low level in all the matrices when expressed on a 1N rate basis. The residue definition for monitoring and risk assessment is proposed as the parent compound alone. Considering the metabolism studies, and the potential exposure of ruminants through consumption of apple pomace, the residues of the parent compound and any metabolite are expected to be recovered at a trace level and no MRLs for livestock matrices are proposed.”

Animal	Dosing rate	Duration	Comment
Poultry	1.41-14.1 mg/kg bw/d	5 days	21 – 210N
Goat	0.07-0.8 mg/kg bw/d	5 days	0.31 – 3.5N
Pig	Not required	-	Rat and ruminant metabolism similar

As acceptable livestock metabolism data is presented for poultry and ruminants, and as the dose rate in the metabolism studies is greater than the calculated dietary burden in each case (21-210N for poultry and 0.31-3.5N for ruminants), it is considered that the results of these studies are applicable to the dithianon GAP.

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

- Dithianon

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

- Dithianon

4.3 Magnitude of residues

No consideration of livestock feeding studies are required, as residues in the metabolism studies on poultry and ruminants were <0.01 mg/kg when dosed at $\geq 21N$ for poultry and up to $3.5N$ for ruminants.

It should be noted that the livestock dietary burden calculated is very conservative; the MRL inputs have been used for a number of animal feed items, including for processed fractions for which the STMR is a more appropriate reflection of the residue that will be in feed items. Noting this, and the fact that the overdosed metabolism studies demonstrate that residues will be < 0.01 mg/kg, then for the chronic risk assessment (see section 7) it would be overly conservative to include a residue of 0.01 mg/kg for all products of animal origin. Residues in products of animal origin are expected to be negligible.

It should also be noted that all CXLs for products of animal origin are set at 0.01^* mg/kg.

4.4 Conversion factor for risk assessment for products of animal origin

As the residue definitions for enforcement (RD-Enf) and risk assessment (RD-RA) are equivalent, conversion factors (CFs) for enforcement to risk assessment are not required.

DRAFT

5 Residues in honey

No consideration of residues in honey is required, as the application is to 'old' data requirements set out under Assimilated Regulation 544/2011.

DRAFT

6 MRLs for products not covered in Sections 3 and 4

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

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

7 Consumer risk assessment

7.1 Dietary exposure

Consumer intake calculations have been performed using the UK chronic and acute dietary exposure models and the EFSA PRIMo.

The chronic risk assessments have been estimated based on the uses of dithianon considered in this application, the uses considered in previous assessments supporting existing GB MRLs and, for the remaining commodities, the existing MRLs established in the GB MRL Statutory Register.

As a result of chronic and acute intake concerns for the current GB MRLs, several different scenarios have also need to be presented for the consumer risk assessments.

Information covering the general approach to the consumer risk assessments, as well as the details for the different scenarios, is outlined below.

UK NEDIs and NESTIs

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

- For the NESTIs, upper range of normal (97.5th 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 97.5th percentile intakes and the mean intakes for all remaining commodities.
- All produce eaten which may have been treated has been treated and contains residues at the levels given in the tables below.
- There is no loss of residue during transport or storage, or processing of foods prior to consumption.

PRIMo

The PRIMo IEDIs and IESTIs for the active substance and commodities listed in the tables below have been calculated using PRIMo revision 3.1 – Pesticide Residues Intake Model.

The following assumptions have been made:

- All produce eaten which may have been treated, has been treated and contains residues at the levels as given in the tables below.

- There is no loss of residue during transport or storage, or processing of foods prior to consumption.

Consumer risk assessment scenarios

Several different scenarios have been presented for the consumer risk assessments to find a combination of commodities which do not result in exposures that exceed the TRVs and hence present a risk to UK consumers:

- **Scenario 1** acute risk assessment for the current MRLs on apples and pears, followed by consideration of the CXL for pome fruits (1.0 mg/kg).
- **Scenario 2** is a consideration of all relevant CXLs (as detailed in table 0.3) for both chronic and acute intakes, as well as consideration of chronic intake for all existing MRLs.
- **Scenario 3** as a chronic risk was identified from all uses considered in scenario 2, refinements were made. The highest contributors to the chronic exposures were removed where there was no UK use, with no data currently available to support the MRL, and no CXL. Lower CXLs available for dithianon were considered in the consumer risk assessments.

Current GB MRLs

It is noted that for a number of the current MRLs there are no identifiable supporting trials and hence associated STMRs and HRs. All current substantive MRLs are detailed below:

Table 7.1-1 Substantive existing GB MRLs for dithianon

Product Code	Product	MRL (mg/kg)	Comment
0110000 (except 0110050)	Citrus fruits (except mandarins)	1	No available trials for existing MRL/ no supporting STMR and HR
0110050	Mandarins	3	No available trials for existing MRL/ no supporting STMR and HR
0120010	Almonds	0.05	No available trials for existing MRL/ no supporting STMR and HR
0120110	Walnuts	0.05	No available trials for existing MRL/ no supporting STMR and HR
0130010	Apples	3	Supporting trials available (EFSA, 2010). Acute intake concern with current MRL

Product Code	Product	MRL (mg/kg)	Comment
0130020	Pears	3	Supporting trials available (EFSA, 2010). Acute intake concern with current MRL
0130030, 0130040, 0130050 and 0130990	Quinces, medlars, Loquats/Japanese medlars, others – pome fruits	3	Derived by extrapolation of trials which support apple and pear (EFSA, 2010) – no acute intake concern
0140010	Apricots	0.5	No available trials for existing MRL/ no supporting STMR and HR
0140020	Cherries	2	No available trials for existing MRL/ no supporting STMR and HR
0140030	Peaches	0.5	No available trials for existing MRL/ no supporting STMR and HR
0140040	Plums	0.5	No available trials for existing MRL/ no supporting STMR and HR
0140990	Others – stone fruits	2	No available trials for existing MRL/ no supporting STMR and HR
0151010	Table grapes	3	Trials available (EFSA, 2010)
0151020	Wine grapes	3	Trials available (EFSA, 2010)
0153010	Blackberries	0.5	No available trials for existing MRL/ no supporting STMR and HR
0153020	Dewberries	0.5	No available trials for existing MRL/ no supporting STMR and HR
0153030	Raspberries	3.0	No available trials for existing MRL/ no supporting STMR and HR
0154020	Cranberries	3.0	No available trials for existing MRL/ no supporting STMR and HR
0154030	Currants	3.0	No available trials for existing MRL/ no supporting STMR and HR
0154040	Gooseberries	3.0	No available trials for existing MRL/ no supporting STMR and HR

Product Code	Product	MRL (mg/kg)	Comment
0211000	Potatoes	0.1	No available trials for existing MRL/ no supporting STMR and HR
0231010	Tomatoes	0.6	No available trials for existing MRL/ no supporting STMR and HR
0231020	Sweet peppers/ bell peppers	0.6	No available trials for existing MRL/ no supporting STMR and HR
0252010	Spinaches	0.6	No available trials for existing MRL/ no supporting STMR and HR
0253000	Grape leaves and similar species	0.1	No available trials for existing MRL/ no supporting STMR and HR
0260040	Peas (without pods)	0.6	No available trials for existing MRL/ no supporting STMR and HR
0401000	Oilseeds	0.02	No available trials for existing MRL/ no supporting STMR and HR
0500060	Rice	0.05	No available trials for existing MRL/ no supporting STMR and HR
0500090	Wheat	0.05	No available trials for existing MRL/ no supporting STMR and HR
0700000	Hops	100	No available trials for existing MRL/ no supporting STMR and HR

For the commodities not supported by STMRs and HRs, the MRL value was used in the initial consumer risk assessments. There are chronic consumer risks associated with the current MRLs (see below). As all the STMRs are not available, other CXLs were also considered for adoption as GB MRLs, in addition to the CXL for pome fruits (covering apples and pears).

7.1.1 Scenario 1 - UK NESTIs and PRIMo IESTIs for the current MRLs on apples and pears, and fallback CXL for apples and pears

7.1.1.1 Current GB MRLs

The acute risk assessments have been undertaken using the HR of 1.89 mg/kg, which supports the current MRL for pome fruits (DAR, 2006 and EFSA, 2010).

Model outputs for the UK acute model version 1.2 and PRIMo revision 3.1 are presented in Appendix C.

Table 7.1.1-1 Input values for the UK and PRIMo acute consumer risk assessments

Commodity	Acute risk assessment	
	Input (mg/kg)	Comment
Risk assessment residue	definition: dithianon	
Apple	1.89	HR (current MRL, DAR, 2006)
Pear	1.89	HR (current MRL, DAR, 2006)

The highest UK NESTI was 154.3% of the ARfD (infant/ apples). The highest PRIMo IESTI was 218% of the ARfD (NL toddler/ pears). Therefore, an acute intake concern has been identified for the current MRLs on apples and pears.

The current MRL on apples and pears results in consumer exposures exceeding the ARfD. Therefore, further acute consumer risk assessments have been performed for a fall-back MRL for apples and pears.

7.1.1.2 Consideration of CXL for apples and pears

Due to the exceedances of the ARfD, a fall-back MRL was considered. As a first step, a CXL of 1 mg/kg is available for the pome fruit group (JMPR, 2013). This is higher than the MRL required to support current GB authorisations. Inputs for the consumer risk assessment are detailed in Table 7.1.1-2.

The CXL is set for 'Pome fruits' – in GB, this applies to all pome fruit included in commodity group 0130000. In scenario 1, the CXL has only been considered for apples and pears.

Table 7.1.1-2 Input values for the UK and PRIMo acute consumer risk assessments

Commodity	Acute risk assessment	
	Input (mg/kg)	Comment
Risk assessment residue	definition: dithianon	
Apple	0.65	HR (JMPR, 2013)
Pear	0.65	HR (JMPR, 2013)

The highest UK NESTI was 53.1% of the ARfD (infant/ apples). The highest PRIMo IESTI was 75.0% of the ARfD (NL toddler/ pears). Therefore, no acute intake concerns were identified.

As no acute risk was identified for apples and pears based on the CXL, a further consideration of the CXL with regards to the impact on the chronic risk assessment is considered in scenario 2.

Note the CXL is for pome fruits (GB MRL Code 0130000). The current GB MRL of 3 mg/kg for all other pome fruits, except apples and pears, does not result in harmful effects on human health. Therefore, the GB MRL of 3 mg/kg for these pome fruits does not need to be lowered to the CXL of 1 mg/kg.

7.1.2 Scenario 2 - UK NEDIs and NESTIs and PRIMo IEDIs and IESTIs for the current MRLs on apples and pears, including CXLs not currently adopted

In the scenario 2 risk assessments the following has been considered for the chronic risk assessment:

- Currently established GB MRLs
- Additional CXLs considered for adoption as GB MRLs
 - The additional CXLs considered were for stone fruits, wine grapes and hops.
 - In cases where the GB MRL and CXL are equivalent, but for which no STMR is available for the current MRL (e.g. cherries), the CXL has been considered for adoption given it is supported by data
- Apple and pear input as the CXL-STMR

The following additional points are noted:

- The CXL for stone fruits of 2 mg/kg (HR is 1.6 mg/kg) resulted in an acute intake concern for peaches (see below). Therefore, in the chronic risk assessment the input was the current GB MRL for peaches of 0.5 mg/kg; for all other stone fruits the input was the STMR supporting the CXL of 2 mg/kg.
- There are CXLs available for other crops and these have not been considered in scenario 2 for the following reasons:
 - The CXL for almonds is equivalent to the GB MRL (0.05 mg/kg).
 - The CXL for table grapes of 2 mg/kg is lower than the current GB MRL of 3 mg/kg; therefore, the current GB MRL has been considered in scenario 2.
 - The CXL for currants of 2 mg/kg is lower than the current GB MRL of 3 mg/kg; therefore, the current GB MRL has been considered in scenario 2.
 - The CXLs for products of animal origin are all at 0.01* mg/kg and are equivalent to the current GB MRLs.

The inputs for the chronic risk assessment are shown in Table 7.1.2-1.

Table 7.1.2-1 Input values for the UK and PRIMo consumer risk assessment – chronic

Commodity	Chronic risk assessment	
	Input (mg/kg)	Comment
Risk assessment residue	definition: dithianon	
Apples and pears[¥]	0.24	STMR taken from this assessment for GB GAP
Stone fruits (except peaches[§])	0.43	STMR (JMPR, 2013)
Wine grapes	0.0021	STMR (0.69) x Pf (0.003) (JMPR, 2013)
Hops	64	STMR (JMPR, 2013)
Table grapes	1.01	STMR (EFSA, 2010)
All other commodities	MRL	MRL [†]

* indicates residues at the LOQ

† GB MRL Statutory Register and Regulation (EU) 839/2008

¥ The STMR for the CXL of 1 mg/kg is 0.15 mg/kg. The data for the GB use results in a lower MRL of 0.8 mg/kg, but the STMR is higher at 0.24 mg/kg. The STMR for the GB use has therefore been used in the chronic risk assessment.

§ As the CXL for stone fruits results in an exceedance of the ARfD for peaches, the input for peaches was the current GB MRL of 0.5 mg/kg

In bold inputs for the CXLs, all other inputs are based on the current GB MRLs

The acute consumer risk assessments for the additional CXLs that have been considered for adoption have also been undertaken. The inputs for the acute risk assessment are shown in Table 7.1.2-2.

Table 7.1.2-2 Input values for the UK and PRIMo consumer risk assessment – acute

Commodity	Acute risk assessment	
	Input (mg/kg)	Comment
Risk assessment residue	definition: dithianon	
Stone fruits	1.6	HR (JMPR, 2013)
Wine grapes	0.0138	HR (4.6) x Pf (0.003) (JMPR, 2013)
Hops	242	HR (JMPR, 2013)

* indicates residues at the LOQ

For scenario 2, the NEDIs ranged from 68 to 388% of the ADI. The highest IEDI was 120% of the ADI for the NL toddler.

The highest UK NESTI was 73.4% of the ARfD (toddler/ peaches). The highest PRIMo IESTI was 127% of the ARfD (NL toddler/ peaches). Therefore, acute intake concerns were identified for peaches. An acute intake concern was not identified for any other commodity.

Model outputs for the UK chronic and acute models (versions 1.1 and 1.2 respectively) are presented in Appendix C. Model outputs for EFSA PRIMo revision 3.1 are also presented in Appendix C.

Based on the chronic risk assessments it is not possible to exclude harmful effects to human health. A refinement of the chronic risk assessment is required, and this is considered in scenario 3.

7.1.3 Scenario 3 - NEDIs and IEDIs with GB MRLs which contribute significantly to chronic exposure removed

The chronic risk assessments in scenario 2 have been calculated using the current GB MRLs and the following CXLs: pome fruit (apples and pears only), stone fruit (whole group, except peaches), wine grapes and hops.

The chronic exceedance observed in scenario 2 is driven by GB MRLs for which no supporting trials data is available. In addition, no GB authorisations exist for these commodities (relevant commodities listed below). The highest contributors to the exceedance were removed in a stepwise manner until no exceedances of the ADI were observed. Additionally, as residues in products of animal origin are expected to be negligible (see section 4.2), the input for all animal commodities have been set to zero.

Citrus fruits

The largest contributor to the chronic exceedance without a UK authorised GAP is citrus fruits. There is no CXL for citrus fruit. As a result, citrus fruit inputs have been set to 0.01 mg/kg for the calculation of the NEDI and IEDI.

With citrus fruit inputs lowered to 0.01 mg/kg, the highest UK NEDI was 148% of the ADI (toddler). The highest PRIMo IEDI was 99% of the ADI (NL toddler). Therefore, chronic intake concerns were identified in the UK chronic model from exposure to dithianon from all dietary sources.

Therefore, the 2nd highest contribution to the chronic exceedance was considered:

Raspberries

The next largest contributor to the chronic exceedance without an existing UK authorisation was raspberries. There is no CXL for raspberries. Raspberry inputs have been set to 0.01 mg/kg for the calculation of the NEDI and IEDI.

With citrus fruit and raspberries inputs lowered to 0.01 mg/kg, the highest UK NEDI was 122% of the ADI (toddler). The highest PRIMo IEDI was 94% of the ADI (NL toddler).

Therefore, chronic intake concerns continue to be identified in the UK chronic model and PRIMo 3.1 from exposure to dithianon from all dietary sources.

The 3rd highest contribution to the chronic exceedance was considered:

Currants (black, red and white)

The next largest contributor to the chronic exceedance without an existing UK authorisation was currants (black, red and white). There is a CXL for currants (2 mg/kg); this was considered as a 'fallback' MRL as a first step.

The highest UK NEDI was 99.5% of the ADI (toddler). The highest PRIMo IEDI was 84% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with dithianon.

The acute consumer risk assessments for the 'fallback' CXL for currants (black, red and white) has also been undertaken, inputs are detailed in table 7.1.2-3.

Table 7.1.2-3 Input values for the UK and PRIMo consumer risk assessment – acute

Commodity	Acute risk assessment	
	Input (mg/kg)	Comment
Risk assessment residue definition:	dithianon	
Currants (black, red and white)	0.89	HR (JMPR, 2013)

* indicates residues at the LOQ

The highest UK NESTI was 3.7 of the ARfD (4-6 year olds/ blackcurrants). The highest PRIMo IESTI was 6% of the ARfD (NL toddler/currants (black, red and white)). Therefore, acute intake concerns were not identified for the CXL on currants.

The inputs used in the final step of the chronic assessments in the UK model and PRIMo are recorded in Table 7.1.2-4. Model outputs for each step are presented in Appendix C.

Table 7.1.2-4 Updated input values for the UK and PRIMo consumer risk assessment – chronic final step

Commodity	Chronic risk assessment	
	Input (mg/kg)	Comment
Risk assessment residue	definition: dithianon	
Apples and pears	0.24	STMR taken from this assessment for GB GAP
Stone fruits (except peaches)	0.43	STMR (JMPR, 2013)
Wine grapes	0.0021	STMR (0.69) x Pf (0.003) (JMPR, 2013)
Hops	64	STMR (JMPR, 2013)
Currants (black, red and white)	0.105	STMR (JMPR, 2013)
Table grapes	1.01	STMR (EFSA, 2010)
Citrus fruits	0.01	MRL
Raspberry	0.01	MRL
All other commodities	MRL	MRL [†]

* indicates residues at the LOQ

† GB MRL Statutory Register and Regulation (EU) 839/2008

In bold inputs for the CXLs

The NEDIs ranged from 45-99.5% of the ADI. The highest IEDI of 84% occurred for toddlers.

Based on the chronic and acute risk assessments from scenario 2 and 3, no health effects are expected. HSE recommends that the CXL for stone fruits of 2 mg/kg is adopted as a GB MRL for all commodities in the stone fruit group (MRL code 0140000) except for peaches. For peaches (MRL code 0140030) the current MRL of 0.5 mg/kg should be retained. All relevant CXLs can be adopted except the CXL for peaches.

7.2 Other routes of exposure

Not applicable

7.3 Conclusion on dietary exposure

In scenario 1, (current MRLs for apple and pear), the NESTI and IESTIs exceeded the ARfD and hence health effects as a result of acute exposure could not be excluded. Based on the 'fallback' MRL (the CXL) considered in scenario 1, no health effects as a result of acute exposure are expected.

The consumer risk assessments undertaken in scenario 2 have identified chronic exposures that exceed the ADI. In addition, an acute intake concern was identified for the CXL for stone fruits with respect to peaches; the CXL for stone fruits should therefore only be adopted for stone fruits except peaches.

With respect to the chronic intakes in scenario 2, a large proportion of the inputs were the MRLs, as no supporting trials (and hence no STMRs) were available. Therefore, HSE refined the consumer risk assessments, lowering a number of unsupported MRLs, for which there were also no CXLs, to the LOQ (citrus and raspberries). Inputs for animal commodities were also lowered to zero, as residues in products of animal origin are likely to be negligible. In the case of currants (black, red and white), a lower CXL is available which does not result in chronic intake concerns.

For the final scenario, as the NEDI/ IEDIs are below the ADI and the NESTIs/ IESTIs are below the ARfD, no health effects are expected. The UK's appropriate level of protection has been met.

8 The draft conclusion of the competent authority

This assessment is a draft only and outlines proposed recommendations for the MRLs in or on apples and pears and all existing CXLs for the active substance dithianon.

According to Article 6 (3) of the assimilated regulation 396/2005, HSE considered the need to review the MRL for dithianon in or on apples and pears.

HSE identified an acute intake concern arising from the current MRLs for dithianon in or on apples and pears of 3 mg/kg. The highest UK NESTI was 154.3% of the ARfD (infant/apples). The highest PRIMo IESTI was 218% of the ARfD (NL toddler/pears). Therefore, an acute intake concern has been identified for the current MRL on apples and pears. HSE considered the potential adoption of the lower CXL for pome fruits for adoption as a GB MRL.

HSE noted that a number of the current substantive MRLs were not supported by residue trials data and that there were chronic intake concerns. Therefore, HSE evaluated the potential adoption of other CXLs, supported by trials data, as GB MRLs. This was to ensure that the UK's appropriate level of protection was met.

Based on the review of the MRLs, HSE prepared a Reasoned Opinion (RO). HSE took into account the assessment report and EFSA conclusion prepared under Regulation (EC) 1107/2009, whilst the UK was an EU MS, for the approval of the active substance. HSE also took into account previous Reasoned Opinions related to MRL decisions adopted prior to 1 January 2021.

Sufficiently validated analytical methods for the determination of dithianon in plant commodities, in line with the enforcement residue definition for products of plant origin, are available to support the crop group under consideration in the review of the MRL for apples and pears.

Toxicological reference values were established for the approval of the active substance: an ADI of 0.01 mg/kg bw/day and an ARfD of 0.12 mg/kg bw.

Metabolism in primary crops was investigated following foliar spray treatment in apple, orange, spinach and wheat for the approval of the active substance (DAR, 2006). As a consistent metabolic pathway was observed across crops from three crop groups, the available data are sufficient to support all crop groups. The application type in the studies is foliar spray, which is the same as the application type for the use supporting the MRL

being reviewed. On this basis the MRLs in or on apples and pears are supported by the available metabolism data.

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

- Dithianon

The residue definition for enforcement (RD-Enf) in plants in the GB MRL Statutory Register is currently:

- Dithianon

Multiple GAPs are authorised for the use of dithianon on apples and pears in GB. Sixteen trials are available to support the cGAP and an MRL of 0.8 mg/kg is required. There is a CXL available for all pome fruits (1 mg/kg), as this is greater than the required MRL of 0.8 mg/kg, the CXL was considered in the consumer risk assessment.

Hydrolysis of dithianon under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrates that dithianon is not stable across the standard conditions. Additional data was evaluated in an amendment to the DAR which investigated the stability of dithianon during hydrolysis in apple juice, rather than standard buffer solutions.

In apple juice, dithianon was the predominant residue formed on pasteurisation (up to 47.3 % TAR). However, under conditions representing baking/brewing/boiling and sterilisation, dithianon was degraded into multiple components.

A specific residue definition for processed commodities was not established for the approval of the active substance. However, specific active substance confirmatory data to address the storage stability and nature of the residues on processing was set for the approval of the active substance, and these data will be considered separately.

The MRLs which are recommended for adoption as GB MRLs are the CXLs for which it is considered that a further consideration of processing is not required at this time as it is covered as part of the assessment undertaken by the JMPR to establish the international food standards.

No consideration of residues in rotational crops is required, as the authorised use is on crops which are considered to be permanent/semi-permanent and there are no concerns from potential accumulation.

The maximum livestock dietary burden exceeded the trigger value for further assessment (0.1 mg/kg DM and AR) for all livestock species. Metabolism of dithianon 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. Based on the results of the livestock metabolism studies and the calculated dietary burdens, residues of dithianon above the LOQ of 0.01 mg/kg are not expected in ruminant, swine and poultry matrices.

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

- Dithianon

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

- Dithianon

For the current MRLs for apple and pear, the highest UK NESTI was 154.3% of the ARfD (infant/apples). The highest PRIMo IESTI was 218% of the ARfD (NL toddler/pears).

As a result of the acute intake concerns identified for the current MRLs on apples and pears, HSE recommends that the current GB MRLs are not retained. As a first step the exposure assessments relating to the lower CXL for pome fruits (for apple and pear) was considered. HSE also identified a chronic risk to some population subgroups for the current GB MRLs and therefore several different scenarios had to be considered in the consumer risk assessments as outlined below:

- **Scenario 1** acute risk assessment for the current MRLs on apples and pears, followed by consideration of the CXL for pome fruits (1.0 mg/kg).
- **Scenario 2** is a consideration of all relevant CXLs (as detailed in table 0.3) for both chronic and acute intakes, as well as consideration of chronic intakes for all existing MRLs.
- **Scenario 3** as a chronic risk was identified from all uses considered in scenario 2, refinements were made. The highest contributors to the chronic exposures were removed where there was no UK use, with no data currently available to support the MRL, and no CXL. Lower CXLs available for dithianon were considered in the consumer risk assessments.

Scenario 1

The scenario 1 risk assessment was undertaken for the HR values for the current GB MRL on apples and pears.

For the current MRL on apples and pears:

The highest UK NESTI was 154.3% of the ARfD (infant/ apples). The highest PRIMo IESTI was 218% of the ARfD (NL toddler/ pears). Therefore, an acute intake concern has been identified for the current MRLs for apples and pears.

The CXL was identified as a 'fallback' option for apples and pears and it accommodates the current GB authorisation on apples and pears (see section 3).

For the CXL on apples and pears:

The highest UK NESTI was 53.1% of the ARfD (infant/ apples). The highest PRIMo IESTI was 75.0% of the ARfD (NL toddler/ pears). Therefore, no acute intake concerns were identified.

HSE concludes that harmful effects on human health cannot be excluded for residues dithianon occurring in apples and pears arising from the current GB MRL. The CXL of 1.0 mg/kg did not result in acute intake concerns. Therefore, the CXL for pome fruits (which includes apples and pears) is recommended for adoption in GB for apples and pears. For other pome fruits the current GB MRL of 3 mg/kg does not result in acute intake concerns for UK consumers, and therefore HSE recommends that the higher GB MRL is retained.

Scenario 2

Under Scenario 2, the following was considered in the chronic assessment:

- Currently established GB MRLs
- Additional CXLs (which are higher than the current GB MRL) considered for adoption as GB MRLs; in cases where the GB MRL and CXL are equivalent, but for which no STMR is available for the current MRL (e.g. cherries), the CXL has been considered for adoption given it is supported by data
- Apple and pear input as the CXL

For scenario 2, the highest UK NEDI was 388% of the ADI (toddler). The highest PRIMo IEDI was 120% of the ADI (NL toddler). Therefore, a chronic intake concern has been identified from exposure to dithianon from all dietary sources.

The highest UK NESTI was 73.4% of the ARfD (toddler/ peaches). The highest PRIMo IESTI was 127% of the ARfD (NL toddler/ peaches). Therefore, acute intake concerns were identified for peaches; HSE recommends that the CXL for stone fruits of 2 mg/kg is considered for adoption in GB MRL for all commodities in the stone fruit group (MRL code 0140000) except for peaches. For peaches (MRL code 0140030) the current MRL of 0.5 should be retained. The current MRL of 0.5 mg/kg for peaches does not result in acute intake concerns for UK consumers.

An acute intake concern was not identified for any other commodity.

Scenario 3

As the NEDIs and IEDIs in scenario 2 exceeded the ADI for some population subgroups, refinement of the chronic exposures was undertaken. The refinement was undertaken in a stepwise approach removing the highest contributors to the overall chronic exposures, for which there are no authorisations in GB and no CXLs, until there were no exposures that

exceeded the ADI. Additionally, as residues in products of animal origin are expected to be negligible (see section 4.2), the input for all animal commodities have been set to zero.

Following this stepwise approach the inputs for citrus fruits and raspberries were lowered to the LOQ of 0.01* mg/kg. For currants (black, red and white) the STMR for the lower CXL, compared to the current GB MRL, was used as the input.

After the final step, the highest UK NEDI was 99.5% of the ADI (toddler) and the highest PRIMo IEDI was 84% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with dithianon.

Based on the chronic and acute risk assessments from scenario 2 and 3, no health effects are expected. All relevant CXLs can be adopted except the CXL for peaches.

The MRLs proposed by HSE are outlined in Table 8.1.

Table 8.1 MRLs proposed by HSE for dithianon

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
Enforcement residue	definition for products of plant	origin: dithianon	
0100000	FRUITS, FRESH or FROZEN; TREE NUTS		
0110000	Citrus fruits		
0110010	Grapefruits	1.0	0.01*
0110020	Oranges	1.0	0.01*
0110030	Lemons	1.0	0.01*
0110040	Limes	1.0	0.01*
0110050	Mandarins	3.0	0.01*
0110990	Others - Citrus Fruit	1.0	0.01*
0120000	Tree Nuts		
0120010	Almonds	0.05	0.05
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*
0120080	Pecans	0.01*	0.01*
0120090	Pine nut kernels	0.01*	0.01*
0120100	Pistachios	0.01*	0.01*
0120110	Walnuts	0.05	0.05
0120990	Others - Tree nuts	0.01*	0.01*
0130000	Pome fruits		
0130010	Apples	3.0	1.0
0130020	Pears	3.0	1.0
0130030	Quinces	3.0	3.0
0130040	Medlars	3.0	3.0
0130050	Loquats/Japanese medlars	3.0	3.0
0130990	Others - Pome fruit	3.0	3.0
0140000	Stone fruits		

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0140010	Apricots	0.5	2.0
0140020	Cherries (sweet)	2.0	2.0
0140030	Peaches	0.5	0.5
0140040	Plums	0.5	2.0
0140990	Others - Stone fruit	2.0	2.0
0150000	Berries and small fruits		
0151000	Grapes		
0151010	Table grapes	3.0	3.0
0151020	Wine grapes	3.0	5.0
0152000	Strawberries		
0152000	Strawberries	0.01*	0.01*
0153000	Cane fruits		
0153010	Blackberries	0.5	0.5
0153020	Dewberries	0.5	0.5
0153030	Raspberries (red and yellow)	3.0	0.01*
0153990	Others - Cane fruit	0.01*	0.01*
0154000	Other small fruits and berries		
0154010	Blueberries	0.01*	0.01*
0154020	Cranberries	3.0	3.0
0154030	Currants (black, red and white)	3.0	2.0
0154040	Gooseberries (green, red and yellow)	3.0	3.0
0154050	Rose hips	0.01*	0.01*
0154060	Mulberries (black and white)	0.01*	0.01*
0154070	Azaroles/Mediterranean medlars	0.01*	0.01*
0154080	Elderberries	0.01*	0.01*
0154990	Others - Other small fruit and berries	0.01*	0.01*
0160000	Miscellaneous fruits with		
0161000	Edible peel		
0161010	Dates	0.01*	0.01*
0161020	Figs	0.01*	0.01*
0161030	Table olives	0.01*	0.01*

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0161040	Kumquats	0.01*	0.01*
0161050	Carambolas	0.01*	0.01*
0161060	Kaki/Japanese persimmons	0.01*	0.01*
0161070	Jambuls/jambolans	0.01*	0.01*
0161990	Others - Edible peel	0.01*	0.01*
0162000	Inedible peel, small		
0162010	Kiwi fruits (green, red, yellow)	0.01*	0.01*
0162020	Litchis/lychees	0.01*	0.01*
0162030	Passionfruits/maracujas	0.01*	0.01*
0162040	Prickly pears/cactus fruits	0.01*	0.01*
0162050	Star apples/cainitos	0.01*	0.01*
0162060	American persimmons/Virginia kaki	0.01*	0.01*
0162990	Others - Inedible peel, small	0.01*	0.01*
0163000	Inedible peel, large		
0163010	Avocados	0.01*	0.01*
0163020	Bananas	0.01*	0.01*
0163030	Mangoes	0.01*	0.01*
0163040	Papayas	0.01*	0.01*
0163050	Granate apples/pomegranates	0.01*	0.01*
0163060	Cherimoyas	0.01*	0.01*
0163070	Guavas	0.01*	0.01*
0163080	Pineapples	0.01*	0.01*
0163090	Breadfruits	0.01*	0.01*
0163100	Durians	0.01*	0.01*
0163110	Soursops/guanabanas	0.01*	0.01*
0163990	Others - Inedible peel, large	0.01*	0.01*
0200000	VEGETABLES, FRESH or FROZEN		
0210000	Root and tuber vegetables		
0211000	Potatoes	0.1	0.1
0212000	Tropical root and tuber vegetables		

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0212010	Cassava roots/manioc	0.01*	0.01*
0212020	Sweet potatoes	0.01*	0.01*
0212030	Yams	0.01*	0.01*
0212040	Arrowroots	0.01*	0.01*
0212990	Others - Tropical root and tuber vegetables	0.01*	0.01*
0213000	Other root and tuber vegetables except sugar beets		
0213010	Beetroots	0.01*	0.01*
0213020	Carrots	0.5	0.5
0213030	Celeriacs/turnip rooted celeries	0.01*	0.01*
0213040	Horseradishes	0.01*	0.01*
0213050	Jerusalem artichokes	0.01*	0.01*
0213060	Parsnips	0.01*	0.01*
0213070	Parsley roots/Hamburg roots parsley	0.01*	0.01*
0213080	Radishes	0.01*	0.01*
0213090	Salsifies	0.01*	0.01*
0213100	Swedes/rutabagas	0.01*	0.01*
0213110	Turnips	0.01*	0.01*
0213990	Others - Other root and tuber vegetables except sugar beet	0.01*	0.01*
0220000	Bulb vegetables		
0220010	Garlic	0.01*	0.01*
0220020	Onions	0.01*	0.01*
0220030	Shallots	0.01*	0.01*
0220040	Spring onions/green onions and Welsh onions	0.01*	0.01*
0220990	Others - bulb vegetables	0.01*	0.01*
0230000	Fruiting vegetables		
0231000	Solanaceae and Malvaceae		
0231010	Tomatoes	0.6	0.6

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0231020	Sweet peppers/bell peppers	0.6	0.6
0231030	Aubergines/eggplants	0.01*	0.01*
0231040	Okra/lady's fingers	0.01*	0.01*
0231990	Others - Solanacea	0.01*	0.01*
0232000	Cucurbits with edible peel		
0232010	Cucumbers	0.01*	0.01*
0232020	Gherkins	0.01*	0.01*
0232030	Courgettes	0.01*	0.01*
0232990	Others - Cucurbits-edible peel	0.01*	0.01*
0233000	Cucurbits with inedible peel		
0233010	Melons	0.01*	0.01*
0233020	Pumpkins	0.01*	0.01*
0233030	Watermelons	0.01*	0.01*
0233990	Others - Cucurbits - inedible peel	0.01*	0.01*
0234000	Sweet corn	0.01*	0.01*
0239000	Other fruiting vegetables	0.01*	0.01*
0240000	Brassica vegetables (excluding	brassica roots and brassica	baby leaf crops)
0241000	Flowering brassica		
0241010	Broccoli	0.01*	0.01*
0241020	Cauliflowers	0.01*	0.01*
0241990	Others - Flowering Brassicas	0.01*	0.01*
0242000	Head brassica		
0242010	Brussels sprouts	0.01*	0.01*
0242020	Head cabbages	0.01*	0.01*
0242990	Others - Head Brassicas	0.01*	0.01*
0243000	Leafy brassica		
0243010	Chinese cabbages/pe-tsai	0.01*	0.01*
0243020	Kales	0.01*	0.01*
0243990	Others - Leafy Brassicas	0.01*	0.01*
0244000	Kohlrabies	0.01*	0.01*
0250000	Leaf vegetables, herbs and edible	flowers	

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0251000	Lettuces and salad plants		
0251010	Lamb's lettuces/corn salads	0.01*	0.01*
0251020	Lettuces	0.01*	0.01*
0251030	Escaroles/broad-leaved endives	0.01*	0.01*
0251040	Cresses and other sprouts and shoots	0.01*	0.01*
0251050	Land cresses	0.01*	0.01*
0251060	Roman rocket/rucola	0.01*	0.01*
0251070	Red mustards	0.01*	0.01*
0251080	Baby leaf crops (including brassica species)	0.01*	0.01*
0251990	Others - Lettuce and other salad plants including brassica	0.01*	0.01*
0252000	Spinaches and similar leaves		
0252010	Spinaches	0.6	0.6
0252020	Purslanes	0.01*	0.01*
0252030	Chards/beet leaves	0.01*	0.01*
0252990	Others - Spinach and similar (leaves)	0.01*	0.01*
0253000	Grape leaves and similar species	0.1	0.1
0254000	Watercresses	0.01*	0.01*
0255000	Witloofs/Belgian endives	0.01*	0.01*
0256000	Herbs and edible flowers		
0256010	Chervil	0.01*	0.01*
0256020	Chives	0.01*	0.01*
0256030	Celery leaves	0.01*	0.01*
0256040	Parsley	0.01*	0.01*
0256050	Sage	0.01*	0.01*
0256060	Rosemary	0.01*	0.01*
0256070	Thyme	0.01*	0.01*
0256080	Basil and edible flowers	0.01*	0.01*
0256090	Laurel/bay leaves	0.01*	0.01*

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0256100	Tarragon	0.01*	0.01*
0256990	Others - Herbs	0.01*	0.01*
0260000	Legume vegetables		
0260010	Beans (with pods)	0.01*	0.01*
0260020	Beans (without pods)	0.01*	0.01*
0260030	Peas (with pods)	0.01*	0.01*
0260040	Peas (without pods)	0.6	0.6
0260050	Lentils	0.01*	0.01*
0260990	Others - Legume vegetables (fresh)	0.01*	0.01*
0270000	Stem vegetables		
0270010	Asparagus	0.01*	0.01*
0270020	Cardoons	0.01*	0.01*
0270030	Celeries	0.01*	0.01*
0270040	Florence fennels	0.01*	0.01*
0270050	Globe artichokes	0.01*	0.01*
0270060	Leeks	0.01*	0.01*
0270070	Rhubarbs	0.01*	0.01*
0270080	Bamboo shoots	0.01*	0.01*
0270090	Palm hearts	0.01*	0.01*
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*
0300000	PULSES, DRY		
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*

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0400000	OILSEEDS AND OIL FRUITS		
0401000	Oilseeds		
0401010	Linseeds	0.02	0.02
0401020	Peanuts/groundnuts	0.02	0.02
0401030	Poppy seeds	0.02	0.02
0401040	Sesame seeds	0.02	0.02
0401050	Sunflower seeds	0.02	0.02
0401060	Rapeseeds/canola seeds	0.02	0.02
0401070	Soyabeans	0.02	0.02
0401080	Mustard seeds	0.02	0.02
0401090	Cotton seeds	0.02	0.02
0401100	Pumpkin seeds	0.02	0.02
0401110	Safflower seeds	0.02	0.02
0401120	Borage seeds	0.02	0.02
0401130	Gold of pleasure seeds	0.02	0.02
0401140	Hemp seeds	0.02	0.02
0401150	Castor beans	0.02	0.02
0401990	Others - Oilseeds	0.02	0.02
0402000	Oil fruits		
0402010	Olives for oil production	0.01*	0.01*
0402020	Oil palms kernels	0.01*	0.01*
0402030	Oil palms fruits	0.01*	0.01*
0402040	Kapok	0.01*	0.01*
0402990	Others - Oilfruits	0.01*	0.01*
0500000	CEREALS		
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	0.05	0.05

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0500070	Rye	0.01*	0.01*
0500080	Sorghum	0.01*	0.01*
0500090	Wheat	0.05	0.05
0500990	Others - cereals	0.01*	0.01*
0600000	TEAS, COFFEE, HERBAL	INFUSIONS, COCOA AND	CAROBS
0610000	Teas	0.01*	0.01*
0620000	Coffee beans	0.01*	0.01*
0630000	Herbal infusions from Dried product		
0631000	Flowers		
0631010	Chamomile	0.01*	0.01*
0631020	Hibiscus/roselle	0.01*	0.01*
0631030	Rose	0.01*	0.01*
0631040	Jasmine	0.01*	0.01*
0631050	Lime/linden	0.01*	0.01*
0631990	Others - Flowers	0.01*	0.01*
0632000	Leaves and herbs		
0632010	Strawberry	0.01*	0.01*
0632020	Rooibos	0.01*	0.01*
0632030	Mate	0.01*	0.01*
0632990	Others - Herbal infusions (leaves and herbs)	0.01*	0.01*
0633000	Roots		
0633010	Valerian	0.01*	0.01*
0633020	Ginseng	0.01*	0.01*
0633990	Others - Roots	0.01*	0.01*
0639000	Other herbal Infusions - Parts of the	plant other than flowers, leaves	and herbs, and roots
0639000	Any other parts of the plant	0.01*	0.01*
0640000	Cocoa beans	0.01*	0.01*
0650000	Carobs/Saint John's breads	0.01*	0.01*
0700000	Hops	100	300

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0800000	SPICES		
0810000	Seed spices		
0810010	Anise/aniseed	0.01*	0.01*
0810020	Black caraway/black cumin	0.01*	0.01*
0810030	Celery seed	0.01*	0.01*
0810040	Coriander seed	0.01*	0.01*
0810050	Cumin seed	0.01*	0.01*
0810060	Dill seed	0.01*	0.01*
0810070	Fennel seed	0.01*	0.01*
0810080	Fenugreek	0.01*	0.01*
0810090	Nutmeg	0.01*	0.01*
0810990	Others - Seeds	0.01*	0.01*
0820000	Fruit spices		
0820010	Allspice/pimento	0.01*	0.01*
0820020	Sichuan pepper	0.01*	0.01*
0820030	Caraway	0.01*	0.01*
0820040	Cardamom	0.01*	0.01*
0820050	Juniper berry	0.01*	0.01*
0820060	Peppercorn (black, green and white)	0.01*	0.01*
0820070	Vanilla	0.01*	0.01*
0820080	Tamarind	0.01*	0.01*
0820990	Others - Fruit spices	0.01*	0.01*
0830000	Bark spices	0.01*	0.01*
0830010	Cinnamon	0.01*	0.01*
0830990	Others - Bark	0.01*	0.01*
0840000	Root and rhizome spices		
0840010	Liquorice	0.01*	0.01*
0840020	Ginger	0.01*	0.01*
0840030	Turmeric/curcuma	0.01*	0.01*
0840040	Horseradish	0.01*	0.01*

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0840990	Others - Roots or rhizome	0.01*	0.01*
0850000	Bud spices		
0850010	Cloves	0.01*	0.01*
0850020	Capers	0.01*	0.01*
0850990	Others - Buds	0.01*	0.01*
0860000	Flower pistil spices		
0860010	Saffron	0.01*	0.01*
0860990	Others - Flower pistil spices	0.01*	0.01*
0870000	Aril spices		
0870010	Mace	0.01*	0.01*
0870990	Others - Aril spices	0.01*	0.01*
0900000	SUGAR PLANTS		
0900010	Sugar beet roots	0.01*	0.01*
0900020	Sugar canes	0.01*	0.01*
0900030	Chicory roots	0.01*	0.01*
0900990	Others - Sugar plants	0.01*	0.01*
1000000	PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL	ANIMALS	
Enforcement definition	residue for products of animal origin:	dithianon	
1010000	Products of animal origin – terrestrial	animals	
1011000	Swine	0.01*	0.01*
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*

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1012020	Fat - bovine	0.01*	0.01*
1012030	Liver - bovine	0.01*	0.01*
1012040	Kidney - bovine	0.01*	0.01*
1012050	Edible offals (other than liver and kidney) - bovine	0.01*	0.01*
1012990	Others - bovine	0.01*	0.01*
1013000	Sheep		
1013010	Muscle - sheep	0.01*	0.01*
1013020	Fat - sheep	0.01*	0.01*
1013030	Liver - sheep	0.01*	0.01*
1013040	Kidney - sheep	0.01*	0.01*
1013050	Edible offals (other than liver and kidney) - sheep	0.01*	0.01*
1013990	Others - sheep	0.01*	0.01*
1014000	Goat		
1014010	Muscle - goat	0.01*	0.01*
1014020	Fat - goat	0.01*	0.01*
1014030	Liver - goat	0.01*	0.01*
1014040	Kidney - goat	0.01*	0.01*
1014050	Edible offals (other than liver and kidney) - goat	0.01*	0.01*
1014990	Others - goat	0.01*	0.01*
1015000	Equine		
1015010	Muscle - equine	0.01*	0.01*
1015020	Fat - equine	0.01*	0.01*
1015030	Liver - equine	0.01*	0.01*
1015040	Kidney - equine	0.01*	0.01*
1015050	Edible offals (other than liver and kidney) - equine	0.01*	0.01*
1015990	Others - equine	0.01*	0.01*
1016000	Poultry		

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1016010	Muscle - poultry	0.01*	0.01*
1016020	Fat - poultry	0.01*	0.01*
1016030	Liver - poultry	0.01*	0.01*
1016040	Kidney - poultry	0.01*	0.01*
1016050	Edible offals (other than liver and kidney) - poultry	0.01*	0.01*
1016990	Others - poultry	0.01*	0.01*
1017000	Other farmed terrestrial animals		
1017010	Muscle - other farmed terrestrial animals	0.01*	0.01*
1017020	Fat - other farmed terrestrial animals	0.01*	0.01*
1017030	Liver - other farmed terrestrial animals	0.01*	0.01*
1017040	Kidney - other farmed terrestrial animals	0.01*	0.01*
1017050	Edible offals (other than liver and kidney) - other farmed terrestrial animals	0.01*	0.01*
1017990	Others - Other farm animals	0.01*	0.01*
1020000	Milk		
1020010	Cattle - milk	0.01*	0.01*
1020020	Sheep - milk	0.01*	0.01*
1020030	Goat - milk	0.01*	0.01*
1020040	Horse - milk	0.01*	0.01*
1020990	Others - Milk and cream	0.01*	0.01*
1030000	Birds eggs		
1030010	Chicken - eggs	0.01*	0.01*
1030020	Duck - eggs	0.01*	0.01*
1030030	Geese - eggs	0.01*	0.01*
1030040	Quail - eggs	0.01*	0.01*
1030990	Others - Birds' eggs	0.01*	0.01*

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1040000	Honey and other apiculture products	0.01*	0.01*
1050000	Amphibians and reptiles	0.01*	0.01*
1060000	Terrestrial invertebrate animals	0.01*	0.01*
1070000	Wild terrestrial vertebrate animals	0.01*	0.01*

* denotes an MRL at the limit of determination / quantification

Changes are highlighted in **bold**

References

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance dithianon, EFSA Journal 2010;8(11):1904

Greece, 2006. Draft Assessment Report (DAR) on the active substance dithianon, prepared by the rapporteur Member State Greece in Annex I of Council Directive 91/414/EEC, October 2006

FAO (Food and Agriculture Organization of the United Nations), 2014. Dithianon. In: Pesticide residues in food - 2013. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 219

Appendix A – Authorised GAP for apple and pears in GB

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)		
Apples and pears	GB	Dithianon WG	F	<i>Venturia inaequalis</i> (VENTIN) <i>Venturia pyrina</i> (VENTPI)	WG	700 g/kg Dithianon	Foliar spray (high/ low volume spray)	BBCH 53-79	6	5 days	-	200-1000	350	42	-
Apples and pears	GB	Delan Pro	F	<i>Venturia inaequalis</i> (VENTIN) <i>Venturia pyrina</i> (VENTPI)	SC	125 g/L Dithianon 561 g/L Potassium phosphonates	Broadcast spray	BBCH 53-81	6	5 days	-	200-800	312.5 Dithianon 1403 Potassium phosphonates	35	-

(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) (b) State if the use is outdoor, field use (F) or glasshouse (G) or indoor use (I). (c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(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. benthialdicarb-isopropyl). (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 (k) Indicate the minimum and maximum number of applications possible under practical conditions of use (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) (m) PHI - minimum pre-harvest interval
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Appendix B – Consumer risk assessments

Approach to the consumer risk assessments

Scenario 1

The consumer risk assessments under scenario 1 focus on the current GB MRLs for apples and pears, as detailed in the GB Statutory Register.

The HRs used are taken from previous assessments., The highest UK NESTI was 154.3% of the ARfD (infant/ apples). The highest PRIMo IESTI was 218% of the ARfD (NL toddler/ pears). As there are exposures that exceed the ARfD, , further acute consumer risk assessments have been performed for the CXL available for apples and pears.

For the CXL, the highest UK NESTI was 53.1% of the ARfD (infant/ apples). The highest PRIMo IESTI was 75.0% of the ARfD (NL toddler/ pears). Therefore, no acute intake concerns were identified for the CXL.

Scenario 2

Scenario 2 comprises a chronic risk assessment including all current MRLs, and any CXLs which are higher than the current GB MRLs in force. In the scenario 2 risk assessments the following has been considered for the chronic risk assessment:

- Currently established GB MRLs
- Additional CXLs considered for adoption as GB MRLs
 - The additional CXL considered were for stone fruits, wine grapes and hops.
 - In cases where the GB MRL and CXL are equivalent, but for which no STMR is available for the current MRL (e.g. cherries), the CXL has been considered for adoption given it is supported by data
- Apple and pear input as the CXL

The following additional points are noted:

- The CXL for stone fruits of 2 mg/kg (HR is 1.6 mg/kg) resulted in an acute intake concern for peaches (see below). Therefore, in the chronic risk assessment the input was the current GB MRL for peaches of 0.5 mg/kg; for all other stone fruits the input was the STMR supporting the CXL of 2 mg/kg.

- There are CXLs available for other crops and these have not been considered in scenario 2 for the following reasons:
 - The CXL for almonds is equivalent to the GB MRL (0.05 mg/kg).
 - The CXL for table grapes of 2 mg/kg is lower than the current GB MRL of 3 mg/kg; therefore the current GB MRL has been considered in scenario 2.
 - The CXL for currants of 2 mg/kg is lower than the current GB MRL of 3 mg/kg; therefore the current GB MRL has been considered in scenario 2.
 - The CXLs for products of animal origin are all at 0.01* mg/kg and are equivalent to the current GB MRLs.

The highest UK NEDI was 388% of the ADI (toddler). The highest PRIMo IEDI was 120% of the ADI (NL toddler).

Therefore, a chronic intake concern was identified from exposure to dithianon from all dietary sources.

The highest UK NESTI was 73.4% of the ARfD (toddler/ peaches). The highest PRIMo IESTI was 127% of the ARfD (NL toddler/ peaches). Therefore, acute intake concerns were identified for peaches; HSE recommends that the CXL for stone fruits of 2 mg/kg is considered in GB for all commodities in the stone fruit group (MRL code 0140000) except for peaches. For peaches (MRL code 0140030) the current MRL of 0.5 should be retained.

An acute intake concern was not identified for any other commodity.

Scenario 3

As the NEDIs and IEDIs in scenario 2 exceeded the ADI for some population subgroups, refinement of the chronic exposures was undertaken. The refinement was undertaken in a stepwise approach removing the highest contributors to the overall chronic exposures, for which there are no authorisations in GB and no CXLs, until there were no exposures that exceeded the ADI. Additionally, as residues in products of animal origin are expected to be negligible (see section 4.2), the input for all animal commodities have been set to zero.

Following this stepwise approach the inputs for citrus and raspberries were lowered to the LOQ of 0.01* mg/kg. For currants (black, red and white) the STMR for the CXL was used as the input.

After the final step, the highest UK NEDI was 99.5% of the ADI (toddler) and the highest PRIMo IEDI was 84% of the ADI (NL toddler). Therefore, no health effects due to chronic exposure are expected from the consumption of commodities treated with dithianon.

Based on the chronic and acute risk assessments from scenario 2 and 3, no health effects are expected. All relevant CXLs can be adopted except the CXL for peaches.

DRAFT

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

Table C.1 Scenario 1 - Acute risk assessment undertaken using UK model version 1.2 for the current apple and pear MRLs

Acute Intakes (97.5th percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Apples	1.89		0.02826	23.6	0.18515	154.3	0.13616	113.5	0.10536	87.8	0.07769	64.7
Pears	1.89		0.03337	27.8	0.13686	114.1	0.16043	133.7	0.11368	94.7	0.07552	62.9

			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
Apples	1.89		0.04875	40.6	0.03997	33.3	0.03346	27.9	0.02516	21.0	0.02500	20.8
Pears	1.89		0.04965	41.4	0.03801	31.7	0.03745	31.2	0.03490	29.1	0.03436	28.6

Table C.2 Scenario 1 - Acute risk assessment undertaken using PRIMo revision 3.1 for the current apple and pear MRLs

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): 2				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
	IESTI				IESTI			
	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)
	218.12%	Pears	3 / 1.89	261.75				
	169.76%	Apples	3 / 1.89	203.71				
	Expand/collapse list							
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 5							

Table C.3 Scenario 1 - Acute risk assessment undertaken using UK model version 1.2 for the CXL available for apples and pears

Acute Intakes
(97.5th
percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Apples	0.65		0.00972	8.1	0.06368	53.1	0.04683	39.0	0.03624	30.2	0.02672	22.3
Pears	0.65		0.01148	9.6	0.04707	39.2	0.05517	46.0	0.03910	32.6	0.02597	21.6

			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
Apples	0.65		0.01677	14.0	0.01375	11.5	0.01151	9.6	0.00865	7.2	0.00860	7.2
Pears	0.65		0.01707	14.2	0.01307	10.9	0.01288	10.7	0.01200	10.0	0.01182	9.8

Table C.4 Scenario 1 - Acute risk assessment undertaken using PRIMo revision 3.1 for the CXL available for apples and pears

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
			MRL / input for RA	Exposure			MRL / input for RA	Exposure
	Highest % of ARfD/ADI	Commodities	(mg/kg)	(µg/kg bw)	Highest % of ARfD/ADI	Commodities	(mg/kg)	(µg/kg bw)
	75.02%	Pears	0 / 0.65	90.02	16.54%	Pears	0 / 0.65	19.85
	58.38%	Apples	0 / 0.65	70.06	15.21%	Apples	0 / 0.65	18.25
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

Table C.5 Scenario 2 - Chronic risk assessment undertaken using UK model version 1.1 for the available CXLs and current GB MRLs

Active substance:

ADI: 0.01 mg/kg bw/day

Source: Dithianon

	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	0.00983	0.01667	0.038829	0.025428	0.02409	0.01405	0.01299	0.00974	0.01014	0.00683
% of ADI	98%	167%	388%	254%	241%	140%	130%	97%	101%	68%

STMR		P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
Grapefruit	1		0.00193	0.00160	0.00581	0.00528	0.01152	0.00210	0.00146	0.00234	0.00240	0.00194
Lemons	1		0.00013	0.00069	0.00032	0.00013	0.00009	0.00008	0.00014	0.00022	0.00033	0.00007
Limes	1		0.00028	L/C	0.00163	0.00022	0.00016	0.00016	0.00024	0.00028	0.00034	0.00053
Mandarins	3		0.00420	L/C	0.01918	0.01084	0.00882	0.00455	0.00501	0.00354	0.00471	0.00201
Oranges	1		0.00386	0.01074	0.01639	0.01121	0.00836	0.00798	0.00662	0.00457	0.00357	0.00273
Almonds	0.05		0.00000	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	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
Cashew nuts	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	L/C
Coconuts	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Hazelnuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.01		0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.05		0.00001	L/C	0.00002	0.00000	0.00000	0.00000	0.00001	0.00001	0.00001	0.00000

The review of the MRLs for apples and pears and CXLs for dithianon - proposed MRLs

Peanuts	0.01	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000
Apples	0.24	0.00064	0.00202	0.00357	0.00226	0.00181	0.00098	0.00086	0.00080	0.00053	0.00026
Pears	0.24	0.00034	0.00061	0.00157	0.00087	0.00053	0.00044	0.00035	0.00045	0.00055	0.00029
Apricots	0.43	0.00016	0.00058	0.00044	0.00027	0.00018	0.00016	0.00010	0.00033	0.00019	0.00016
Peaches	0.5	0.00068	0.00067	0.00157	0.00079	0.00059	0.00038	0.00022	0.00047	0.00047	0.00022
Plums	0.43	0.00039	0.00021	0.00093	0.00058	0.00034	0.00012	0.00011	0.00030	0.00028	0.00009
Cherries	0.43	0.00020	0.00061	0.00045	0.00065	0.00024	0.00031	0.00025	0.00022	0.00015	0.00003
Table grapes	1.01	0.00133	0.00167	0.00474	0.00218	0.00261	0.00112	0.00064	0.00206	0.00134	0.00047
Wine grapes	0.0021	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00002	0.00001	0.00000
Strawberries	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Blackberries	0.5	0.00006	L/C	0.00097	0.00003	0.00017	0.00013	0.00005	0.00016	0.00013	0.00002
Loganberries	0.5	0.00004	0.00030	0.00057	0.00008	0.00025	0.00013	0.00008	0.00011	0.00008	0.00005
Raspberries	3	0.00124	L/C	0.00714	0.00196	0.00302	0.00079	0.00021	0.00120	0.00250	0.00113
Gooseberries	3	0.00074	0.00155	0.00197	0.00073	0.00071	0.00071	0.00055	0.00217	0.00247	0.00071
Blackcurrants	3	0.001721	0.00355	0.005379	0.005385	0.00415	0.003075	0.003362	0.001066	0.001614	0.000838
Red currants	3	0.00022	L/C	0.00236	L/C	0.00017	0.00036	0.00013	0.00012	0.00101	L/C
White currants	3	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.01	0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000	0.00001	0.00001	L/C
Bananas	0.01	0.00002	0.00007	0.00007	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002
Dates	0.01	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00001	0.00000
Figs	0.01	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Kiwi fruit	0.01	0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000
Lychees	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Mangoes	0.01	0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004	0.00001	0.00000	L/C
Olives	0.01	0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C	0.00000	0.00000	L/C
Passion fruit	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C

The review of the MRLs for apples and pears and CXLs for dithianon – proposed MRLs

Pineapples	0.01	0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Pomegranates	0.01	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000	0.00001	0.00001	0.00001
Beetroot	0.01	0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Carrots	0.05	0.00004	0.00018	0.00012	0.00010	0.00006	0.00004	0.00005	0.00004	0.00005	0.00004
Celeriac	0.01	0.00000	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C
Horseradish	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Jerusalem artichokes	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Parsnips	0.01	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.01	0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	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	0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01	0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01	0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.01	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Spring onions	0.01	0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Tomatoes	0.6	0.00083	0.00110	0.00158	0.00115	0.00110	0.00065	0.00080	0.00106	0.00087	0.00080
Peppers	0.6	0.00022	L/C	0.00048	0.00025	0.00041	0.00019	0.00017	0.00036	0.00034	0.00011
Aubergines	0.01	0.00000	L/C	0.00002	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000	L/C
Marrows	0.01	0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001
Cucumbers	0.01	0.00000	0.00000	0.00002	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000
Gourd	0.01	0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.01	0.00000	0.00001	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Melons	0.01	0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00003	0.00003	0.00003	0.00001
Sweet corn	0.01	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.01	0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000

The review of the MRLs for apples and pears and CXLs for dithianon - proposed MRLs

Cauliflower	0.01	0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Brussels sprouts	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Head cabbage	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Chinese cabbage	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00000	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	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	0.01	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Spinach	0.6	0.00032	0.00060	0.00094	0.00052	0.00053	0.00038	0.00021	0.00041	0.00034	0.00021
Watercress	0.01	0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Chicory	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Parsley	0.01	0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Beans with pods	0.01	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000
Runner Beans	0.01	0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01	0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01	0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.6	0.00046	0.00144	0.00122	0.00084	0.00062	0.00044	0.00055	0.00052	0.00060	0.00044
Beansprouts	0.01	0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01	0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.01	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Fennel	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Globe artichokes	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Leeks	0.01	0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Rhubarb	0.01	0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.01	0.00002	0.00006	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001

The review of the MRLs for apples and pears and CXLs for dithianon – proposed MRLs

Lentils	0.01	0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.01	0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Oilseeds	0.02	0.00006	0.00013	0.00014	0.00014	0.00011	0.00008	0.00007	0.00009	0.00006	0.00008
Potatoes	0.1	0.00033	0.00111	0.00092	0.00083	0.00070	0.00053	0.00046	0.00035	0.00033	0.00032
Tea (dried leaves)	0.01	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Hops (dried 0.25% of beer)	64	0.00396	L/C	L/C	L/C	L/C	0.00040	0.00351	0.00336	0.00398	0.00301
Oats	0.01	0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01	0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
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
Maize	0.01	0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.05	0.00018	0.00014	0.00042	0.00044	0.00034	0.00025	0.00020	0.00021	0.00016	0.00017
Rice	0.05	0.00011	0.00014	0.00024	0.00019	0.00025	0.00020	0.00013	0.00010	0.00006	0.00002
Rye	0.01	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.01	0.00002	0.00002	0.00003	0.00003	0.00002	0.00002	0.00002	0.00002	0.00002	0.00001
Meat fat	0.01	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0.01	0.00002	0.00004	0.00004	0.00003	0.00003	0.00002	0.00002	0.00000	0.00002	0.00002
All types of kidney	0.01	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
All types of Liver	0.01	0.00000	0.00002	0.00002	0.00000	0.00000	0.00001	0.00000	L/C	0.00001	0.00000
Other types of offal	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001
Eggs	0.01	0.00001	0.00005	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Milk	0.01	0.00008	0.00098	0.00056	0.00029	0.00018	0.00012	0.00009	0.00010	0.00009	0.00012
Sugar beet	0.01	0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015

Table C.6 Scenario 2 - Chronic risk assessment undertaken using PRIMo revision 3.1 for the available CXLs and current GB MRLs

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
			No of diets exceeding the ADI :								Exposure resulting from
TMDI/NEDI/IEDI calculation (based on average food)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	119.8%	NL toddler	11.98	25.9%	Apples	22.4%	Oranges	12.7%	Mandarins	8.9%	
	116.9%	DE child	11.69	40.2%	Oranges	30.0%	Apples	12.3%	Mandarins	3.0%	
	83.3%	NL child	8.33	19.4%	Mandarins	14.2%	Oranges	13.9%	Apples	4.4%	
	64.5%	GEMS/Food G06	6.45	21.5%	Tomatoes	10.0%	Oranges	9.7%	Mandarins	1.6%	
	64.3%	FR child 3 15 yr	6.43	34.1%	Oranges	5.0%	Tomatoes	4.9%	Mandarins	3.8%	
	62.7%	FR toddler 2 3 yr	6.27	23.5%	Mandarins	14.3%	Oranges	7.6%	Apples	4.1%	
	60.0%	IE adult	6.00	15.4%	Mandarins	10.4%	Oranges	8.6%	Wine grapes	2.0%	
	55.8%	UK toddler	5.58	19.8%	Oranges	8.4%	Mandarins	4.1%	Apples	3.0%	
	55.1%	GEMS/Food G07	5.51	13.9%	Oranges	10.2%	Wine grapes	6.5%	Tomatoes	1.9%	
	53.8%	DE women 14-50 yr	5.38	19.1%	Oranges	6.2%	Apples	5.8%	Wine grapes	2.3%	
	50.9%	DE general	5.09	15.6%	Oranges	5.8%	Apples	5.7%	Wine grapes	2.3%	
	49.8%	GEMS/Food G15	4.98	7.2%	Tomatoes	6.9%	Wine grapes	6.7%	Oranges	1.9%	
	49.4%	GEMS/Food G10	4.94	11.3%	Oranges	8.2%	Tomatoes	5.4%	Mandarins	1.8%	
	48.8%	PT general	4.88	17.2%	Wine grapes	6.1%	Oranges	5.4%	Tomatoes	0.3%	
	48.6%	GEMS/Food G08	4.86	7.5%	Mandarins	7.2%	Wine grapes	6.8%	Tomatoes	1.9%	

The review of the MRLs for apples and pears and CXLs for dithianon – proposed MRLs

48.5%	GEMS/Food G11	4.85	7.3%	Oranges	7.0%	Wine grapes	5.5%	Tomatoes	2.1%
47.9%	ES child	4.79	21.7%	Oranges	5.9%	Tomatoes	5.0%	Mandarins	2.3%
46.9%	RO general	4.69	11.6%	Tomatoes	11.6%	Wine grapes	3.7%	Potatoes	2.1%
45.0%	SE general	4.50	13.3%	Mandarins	7.5%	Oranges	4.6%	Tomatoes	2.5%
37.7%	UK infant	3.77	13.0%	Oranges	3.9%	Milk: Cattle	3.8%	Apples	4.8%
36.6%	FI 3 yr	3.66	11.7%	Mandarins	5.6%	Raspberries (red and yellow)	4.7%	Potatoes	0.6%
36.5%	NL general	3.65	10.1%	Oranges	5.1%	Mandarins	4.1%	Wine grapes	1.8%
35.0%	FR adult	3.50	16.0%	Wine grapes	5.9%	Oranges	2.8%	Tomatoes	1.1%
34.9%	ES adult	3.49	12.9%	Oranges	4.7%	Tomatoes	4.2%	Mandarins	1.2%
32.4%	IT toddler	3.24	8.6%	Tomatoes	6.3%	Mandarins	4.8%	Oranges	0.4%
30.6%	UK vegetarian	3.06	8.7%	Oranges	5.6%	Wine grapes	3.7%	Tomatoes	0.7%
28.9%	UK adult	2.89	7.5%	Wine grapes	5.6%	Oranges	4.2%	HOPS (dried)	0.7%
28.6%	FI 6 yr	2.86	9.8%	Mandarins	4.0%	Raspberries (red and yellow)	3.9%	Potatoes	0.5%
26.2%	IT adult	2.62	7.0%	Tomatoes	4.8%	Mandarins	3.7%	Oranges	0.3%
26.0%	DK child	2.60	5.6%	Apples	3.2%	Tomatoes	2.7%	Mandarins	2.8%
23.0%	DK adult	2.30	6.6%	Wine grapes	3.2%	Mandarins	3.1%	Tomatoes	1.0%
21.0%	FI adult	2.10	4.2%	Mandarins	4.1%	Oranges	3.3%	Tomatoes	0.8%
20.6%	FR infant	2.06	4.3%	Mandarins	4.0%	Apples	2.4%	Oranges	2.2%
20.1%	PL general	2.01	5.3%	Tomatoes	4.9%	Apples	3.4%	Potatoes	0.2%
16.1%	LT adult	1.61	4.5%	Apples	3.7%	Tomatoes	3.2%	Potatoes	0.9%
5.4%	IE child	0.54	1.0%	Currants (red, black and white)	0.8%	Oranges	0.8%	Apples	0.5%

Table C.7 Scenario 2 - Acute risk assessment undertaken using UK model version 1.2 for the existing CXLs

Acute Intakes
(97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Apricots	1.60		0.01120	9.3	0.03090	25.7	0.03329	27.7	0.03742	31.2	0.02485	20.7
Peaches	1.60		0.01962	16.4	0.05510	45.9	0.08807	73.4	0.06142	51.2	0.04107	34.2
Plums	1.60		0.01167	9.7	0.03463	28.9	0.04729	39.4	0.03540	29.5	0.02255	18.8
Cherries	1.60		0.00303	2.5	0.00441	3.7	0.00711	5.9	0.00867	7.2	0.00597	5.0
Wine grapes	0.01		0.00033	0.3	0.00011	0.1	0.00006	0.1	0.00009	0.1	0.00003	0.0
Hops (dried 0.25% of beer)	242.00		0.04114	34.3	0.00000	0.0	0.00501	4.2	0.00472	3.9	0.00157	1.3

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Apricots	1.60		0.00873	7.3	0.01205	10.0	0.01209	10.1	0.01121	9.3	0.01247	10.4
Peaches	1.60		0.02963	24.7	0.02158	18.0	0.02035	17.0	0.01861	15.5	0.01833	15.3
Plums	1.60		0.01392	11.6	0.01042	8.7	0.01265	10.5	0.01013	8.4	0.00860	7.2
Cherries	1.60		0.00798	6.6	0.00441	3.7	0.00385	3.2	0.00222	1.9	0.00040	0.3
Wine grapes	0.01		0.00010	0.1	0.00026	0.2	0.00030	0.2	0.00018	0.2	0.00005	0.0
Hops (dried 0.25% of beer)	242.00		0.01008	8.4	0.03869	32.2	0.04426	36.9	0.02393	19.9	0.01846	15.4

Table C.8 Scenario 2 - Acute risk assessment undertaken using PRIMo revision 3.1 for the existing CXLs

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	1				---			
	IESTI				IESTI			
	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)
	126.71%	Peaches	0 / 1.6	152.05	36.89%	HOPS (dried)	0 / 242	44.26
	56.18%	Plums	0 / 1.6	67.41	24.97%	Peaches	0 / 1.6	29.97
	46.63%	Apricots	0 / 1.6	55.96	23.75%	Plums	0 / 1.6	28.50
Processed commodities	16.30%	Cherries (sweet)	0 / 1.6	19.56	14.50%	Apricots	0 / 1.6	17.40
	8.40%	HOPS (dried)	0 / 242	10.08	13.33%	Cherries (sweet)	0 / 1.6	16.00
	0.84%	Table grapes	0 / 0.01	1.01	0.39%	Table grapes	0 / 0.01	0.47
	Expand/collapse list							
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							
	1							
Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	34.7%	Peaches / canned	0 / 1.6	41.61	10.9%	Peaches / canned	0 / 1.6	13.08

Table C.9 Scenario 3 - Chronic risk assessment undertaken using UK model version 1.1 – Citrus inputs set to LOQ

Active substance:

ADI: 0.01 mg/kg bw/day

Source: Dithianon

	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	0.00662	0.00713	0.014815	0.009415	0.00892	0.00529	0.00783	0.00679	0.00731	0.00495
% of ADI	66%	71%	148%	94%	89%	53%	78%	68%	73%	50%

STMR		P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
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	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.05		0.00000	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	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
Cashew nuts	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	L/C
Coconuts	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Hazelnuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.01		0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.05		0.00001	L/C	0.00002	0.00000	0.00000	0.00000	0.00001	0.00001	0.00001	0.00000
Peanuts	0.01		0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000

The review of the MRLs for apples and pears and CXLs for dithianon – proposed MRLs

Apples	0.24	0.00064	0.00202	0.00357	0.00226	0.00181	0.00098	0.00086	0.00080	0.00053	0.00026
Pears	0.24	0.00034	0.00061	0.00157	0.00087	0.00053	0.00044	0.00035	0.00045	0.00055	0.00029
Apricots	0.43	0.00016	0.00058	0.00044	0.00027	0.00018	0.00016	0.00010	0.00033	0.00019	0.00016
Peaches	0.5	0.00068	0.00067	0.00157	0.00079	0.00059	0.00038	0.00022	0.00047	0.00047	0.00022
Plums	0.43	0.00039	0.00021	0.00093	0.00058	0.00034	0.00012	0.00011	0.00030	0.00028	0.00009
Cherries	0.43	0.00020	0.00061	0.00045	0.00065	0.00024	0.00031	0.00025	0.00022	0.00015	0.00003
Table grapes	1.01	0.00133	0.00167	0.00474	0.00218	0.00261	0.00112	0.00064	0.00206	0.00134	0.00047
Wine grapes	0.0021	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00002	0.00001	0.00000
Strawberries	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Blackberries	0.5	0.00006	L/C	0.00097	0.00003	0.00017	0.00013	0.00005	0.00016	0.00013	0.00002
Loganberries	0.5	0.00004	0.00030	0.00057	0.00008	0.00025	0.00013	0.00008	0.00011	0.00008	0.00005
Raspberries	3	0.00124	L/C	0.00714	0.00196	0.00302	0.00079	0.00021	0.00120	0.00250	0.00113
Gooseberries	3	0.00074	0.00155	0.00197	0.00073	0.00071	0.00071	0.00055	0.00217	0.00247	0.00071
Blackcurrants	3	0.00172	0.00355	0.00538	0.00539	0.00415	0.00308	0.00336	0.00107	0.00161	0.00084
Red currants	3	0.00022	L/C	0.00236	L/C	0.00017	0.00036	0.00013	0.00012	0.00101	L/C
White currants	3	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.01	0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000	0.00001	0.00001	L/C
Bananas	0.01	0.00002	0.00007	0.00007	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002
Dates	0.01	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00001	0.00000
Figs	0.01	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Kiwi fruit	0.01	0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000
Lychees	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Mangoes	0.01	0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004	0.00001	0.00000	L/C
Olives	0.01	0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C	0.00000	0.00000	L/C
Passion fruit	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Pineapples	0.01	0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001

The review of the MRLs for apples and pears and CXLs for dithianon - proposed MRLs

Pomegranates	0.01	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000	0.00001	0.00001	0.00001
Beetroot	0.01	0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Carrots	0.05	0.00004	0.00018	0.00012	0.00010	0.00006	0.00004	0.00005	0.00004	0.00005	0.00004
Celeriac	0.01	0.00000	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C
Horseradish	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Jerusalem artichokes	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Parsnips	0.01	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.01	0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	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	0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01	0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01	0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.01	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Spring onions	0.01	0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Tomatoes	0.6	0.00083	0.00110	0.00158	0.00115	0.00110	0.00065	0.00080	0.00106	0.00087	0.00080
Peppers	0.6	0.00022	L/C	0.00048	0.00025	0.00041	0.00019	0.00017	0.00036	0.00034	0.00011
Aubergines	0.01	0.00000	L/C	0.00002	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000	L/C
Marrows	0.01	0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001
Cucumbers	0.01	0.00000	0.00000	0.00002	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000
Gourd	0.01	0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.01	0.00000	0.00001	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Melons	0.01	0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00003	0.00003	0.00003	0.00001
Sweet corn	0.01	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.01	0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Cauliflower	0.01	0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001

The review of the MRLs for apples and pears and CXLs for dithianon – proposed MRLs

Brussels sprouts	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Head cabbage	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Chinese cabbage	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00000	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		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	0.01		0.00001	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Spinach	0.6		0.00032	0.00060	0.00094	0.00052	0.00053	0.00038	0.00021	0.00041	0.00034	0.00021
Watercress	0.01		0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Chicory	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Parsley	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Beans with pods	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000
Runner Beans	0.01		0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01		0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.6		0.00046	0.00144	0.00122	0.00084	0.00062	0.00044	0.00055	0.00052	0.00060	0.00044
Beansprouts	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Fennel	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Globe artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Leeks	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Rhubarb	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.01		0.00002	0.00006	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001
Lentils	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000

The review of the MRLs for apples and pears and CXLs for dithianon - proposed MRLs

dried Peas	0.01	0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Oilseeds	0.02	0.00006	0.00013	0.00014	0.00014	0.00011	0.00008	0.00007	0.00009	0.00006	0.00008
Potatoes	0.1	0.00033	0.00111	0.00092	0.00083	0.00070	0.00053	0.00046	0.00035	0.00033	0.00032
Hops (dried 0.25% of beer)	64	0.00396	L/C	L/C	L/C	L/C	0.00040	0.00351	0.00336	0.00398	0.00301
Oats	0.01	0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01	0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
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
Maize	0.01	0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.05	0.00018	0.00014	0.00042	0.00044	0.00034	0.00025	0.00020	0.00021	0.00016	0.00017
Rice	0.05	0.00011	0.00014	0.00024	0.00019	0.00025	0.00020	0.00013	0.00010	0.00006	0.00002
Rye	0.01	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat fat	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
All types of kidney	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
All types of Liver	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
Other types of offal	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Eggs	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Milk	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Sugar beet	0.01	0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015

Table C.10 Scenario 3 - Chronic risk assessment undertaken using PRIMo revision 3.1 – Citrus inputs set to LOQ

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
			No of diets exceeding the ADI : -- -								Exposure resulting from
TMDI/NEDI/IEDI calculation (based on average food)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	98.7%	NL toddler	9.87	25.9%	Apples	15.6%	Table grapes	10.4%	Pears	2.9%	
	74.8%	DE child	7.48	30.0%	Apples	13.8%	Table grapes	5.9%	Tomatoes	1.3%	
	57.5%	NL child	5.75	13.9%	Apples	10.4%	Table grapes	7.5%	Currants (red, black and white)	1.8%	
	52.0%	GEMS/Food G06	5.20	21.5%	Tomatoes	10.6%	Table grapes	3.6%	Wheat	1.4%	
	33.6%	GEMS/Food G15	3.36	7.2%	Tomatoes	3.6%	Potatoes	3.4%	Table grapes	1.0%	
	31.9%	RO general	3.19	11.6%	Tomatoes	3.7%	Potatoes	3.4%	Apples	0.7%	
	29.9%	GEMS/Food G10	2.99	8.2%	Tomatoes	3.0%	Table grapes	3.0%	Potatoes	1.1%	
	29.6%	UK toddler	2.96	4.1%	Apples	3.9%	Currants (red, black and white)	3.5%	Tomatoes	0.9%	
	29.5%	GEMS/Food G08	2.95	6.8%	Tomatoes	3.9%	Potatoes	3.4%	Table grapes	1.1%	
	26.9%	DE general	2.69	5.8%	Apples	4.2%	HOPS (dried)	3.9%	Tomatoes	1.0%	
	26.5%	GEMS/Food G11	2.65	5.5%	Tomatoes	4.2%	Table grapes	3.9%	Potatoes	1.1%	
	26.3%	FR child 3 15 yr	2.63	5.0%	Tomatoes	4.0%	Apples	3.6%	Table grapes	1.3%	
	26.0%	DE women 14-50 yr	2.60	6.2%	Apples	4.4%	Tomatoes	3.0%	Table grapes	1.1%	
	25.5%	FI 3 yr	2.55	5.6%	Raspberries (red and yellow)	4.7%	Potatoes	3.4%	Tomatoes	0.7%	
	25.2%	PT general	2.52	5.4%	Tomatoes	5.3%	Potatoes	2.8%	Table grapes	0.4%	

The review of the MRLs for apples and pears and CXLs for dithianon - proposed MRLs

25.2%	GEMS/Food G07	2.52	6.5%	Tomatoes	3.8%	Potatoes	3.4%	Table grapes	1.0%
24.5%	UK infant	2.45	3.9%	Milk: Cattle	3.8%	Apples	3.4%	Peas (without pods)	0.8%
22.9%	DK child	2.29	5.6%	Apples	3.2%	Tomatoes	2.4%	Potatoes	1.0%
22.6%	FR toddler 2 3 yr	2.26	7.6%	Apples	2.9%	Milk: Cattle	2.9%	Tomatoes	1.0%
22.4%	SE general	2.24	4.6%	Tomatoes	4.2%	Potatoes	2.5%	Apples	0.8%
21.9%	IT toddler	2.19	8.6%	Tomatoes	3.3%	Wheat	2.1%	Apples	0.5%
21.6%	ES child	2.16	5.9%	Tomatoes	2.7%	Apples	2.2%	Wheat	0.7%
21.4%	PL general	2.14	5.3%	Tomatoes	4.9%	Apples	3.4%	Potatoes	0.2%
20.5%	IE adult	2.05	2.6%	Table grapes	2.4%	Tomatoes	2.3%	Potatoes	1.6%
19.0%	NL general	1.90	3.5%	Apples	2.5%	Table grapes	2.5%	Tomatoes	0.9%
19.0%	FI 6 yr	1.90	4.0%	Raspberries (red and yellow)	3.9%	Potatoes	2.6%	Tomatoes	0.5%
18.6%	IT adult	1.86	7.0%	Tomatoes	2.1%	Wheat	1.9%	Apples	0.4%
15.3%	ES adult	1.53	4.7%	Tomatoes	1.8%	Apples	1.2%	Wheat	0.5%
14.9%	LT adult	1.49	4.5%	Apples	3.7%	Tomatoes	3.2%	Potatoes	0.3%
14.4%	UK vegetarian	1.44	3.7%	Tomatoes	1.9%	HOPS (dried)	1.4%	Apples	0.4%
14.0%	UK adult	1.40	4.2%	HOPS (dried)	2.6%	Tomatoes	1.4%	Potatoes	0.3%
13.3%	DK adult	1.33	3.1%	Tomatoes	2.3%	Apples	1.7%	Table grapes	0.2%
13.3%	FR infant	1.33	4.0%	Apples	1.9%	Potatoes	1.7%	Milk: Cattle	0.5%
11.7%	FR adult	1.17	2.8%	Tomatoes	1.8%	Apples	1.1%	Table grapes	0.5%
11.3%	FI adult	1.13	3.3%	Tomatoes	1.4%	Apples	1.3%	Raspberries (red and yellow)	0.9%
5.0%	IE child	0.50	1.0%	Currants (red, black and white)	0.8%	Apples	0.6%	Potatoes	0.1%

Table C.11 Scenario 3 - Chronic risk assessment undertaken using UK model version 1.1 – Citrus and Raspberries input set to LOQ

Active substance:

ADI: 0.01 mg/kg bw/day

Source: Dithianon

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	0.00660	0.00713	0.012171	0.009401	0.00838	0.00529	0.00782	0.00676	0.00727	0.00464
% of ADI	66%	71%	122%	94%	84%	53%	78%	68%	73%	46%

STMR		P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
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	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.05		0.00000	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	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
Cashew nuts	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	L/C
Coconuts	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Hazelnuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.01		0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.05		0.00001	L/C	0.00002	0.00000	0.00000	0.00000	0.00001	0.00001	0.00001	0.00000

The review of the MRLs for apples and pears and CXLs for dithianon - proposed MRLs

Peanuts	0.01	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000
Apples	0.24	0.00064	0.00202	0.00357	0.00226	0.00181	0.00098	0.00086	0.00080	0.00053	0.00026
Pears	0.24	0.00034	0.00061	0.00157	0.00087	0.00053	0.00044	0.00035	0.00045	0.00055	0.00029
Apricots	0.43	0.00016	0.00058	0.00044	0.00027	0.00018	0.00016	0.00010	0.00033	0.00019	0.00016
Peaches	0.5	0.00068	0.00067	0.00157	0.00079	0.00059	0.00038	0.00022	0.00047	0.00047	0.00022
Plums	0.43	0.00039	0.00021	0.00093	0.00058	0.00034	0.00012	0.00011	0.00030	0.00028	0.00009
Cherries	0.43	0.00020	0.00061	0.00045	0.00065	0.00024	0.00031	0.00025	0.00022	0.00015	0.00003
Table grapes	1.01	0.00133	0.00167	0.00474	0.00218	0.00261	0.00112	0.00064	0.00206	0.00134	0.00047
Wine grapes	0.0021	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00002	0.00001	0.00000
Strawberries	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Blackberries	0.5	0.00006	L/C	0.00097	0.00003	0.00017	0.00013	0.00005	0.00016	0.00013	0.00002
Loganberries	0.5	0.00004	0.00030	0.00057	0.00008	0.00025	0.00013	0.00008	0.00011	0.00008	0.00005
Raspberries	0.01	0.00000	L/C	0.00002	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Gooseberries	3	0.00074	0.00155	0.00197	0.00073	0.00071	0.00071	0.00055	0.00217	0.00247	0.00071
Blackcurrants	3	0.00172	0.00355	0.00538	0.00539	0.00415	0.00308	0.00336	0.00107	0.00161	0.00084
Red currants	3	0.00022	L/C	0.00236	L/C	0.00017	0.00036	0.00013	0.00012	0.00101	L/C
White currants	3	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.01	0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000	0.00001	0.00001	L/C
Bananas	0.01	0.00002	0.00007	0.00007	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002
Dates	0.01	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00001	0.00000
Figs	0.01	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Kiwi fruit	0.01	0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000
Lychees	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Mangoes	0.01	0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004	0.00001	0.00000	L/C
Olives	0.01	0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C	0.00000	0.00000	L/C
Passion fruit	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C

The review of the MRLs for apples and pears and CXLs for dithianon – proposed MRLs

Pineapples	0.01		0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Pomegranates	0.01		0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000	0.00001	0.00001	0.00001
Beetroot	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Carrots	0.05		0.00004	0.00018	0.00012	0.00010	0.00006	0.00004	0.00005	0.00004	0.00005	0.00004
Celeriac	0.01		0.00000	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C
Horseradish	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Jerusalem artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Parsnips	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.01		0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	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		0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01		0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Spring onions	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Tomatoes	0.6		0.00083	0.00110	0.00158	0.00115	0.00110	0.00065	0.00080	0.00106	0.00087	0.00080
Peppers	0.6		0.00022	L/C	0.00048	0.00025	0.00041	0.00019	0.00017	0.00036	0.00034	0.00011
Aubergines	0.01		0.00000	L/C	0.00002	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000	L/C
Marrows	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001
Cucumbers	0.01		0.00000	0.00000	0.00002	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000
Gourd	0.01		0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.01		0.00000	0.00001	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Melons	0.01		0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00003	0.00003	0.00003	0.00001
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000

The review of the MRLs for apples and pears and CXLs for dithianon - proposed MRLs

Cauliflower	0.01	0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Brussels sprouts	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Head cabbage	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Chinese cabbage	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00000	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	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	0.01	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Spinach	0.6	0.00032	0.00060	0.00094	0.00052	0.00053	0.00038	0.00021	0.00041	0.00034	0.00021
Watercress	0.01	0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Chicory	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Parsley	0.01	0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Beans with pods	0.01	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000
Runner Beans	0.01	0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01	0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01	0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.6	0.00046	0.00144	0.00122	0.00084	0.00062	0.00044	0.00055	0.00052	0.00060	0.00044
Beansprouts	0.01	0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01	0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.01	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Fennel	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Globe artichokes	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Leeks	0.01	0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Rhubarb	0.01	0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.01	0.00002	0.00006	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001

The review of the MRLs for apples and pears and CXLs for dithianon – proposed MRLs

Lentils	0.01	0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.01	0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Oilseeds	0.02	0.00006	0.00013	0.00014	0.00014	0.00011	0.00008	0.00007	0.00009	0.00006	0.00008
Potatoes	0.1	0.00033	0.00111	0.00092	0.00083	0.00070	0.00053	0.00046	0.00035	0.00033	0.00032
Hops (dried 0.25% of beer)	64	0.00396	L/C	L/C	L/C	L/C	0.00040	0.00351	0.00336	0.00398	0.00301
Oats	0.01	0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01	0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
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
Maize	0.01	0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.05	0.00018	0.00014	0.00042	0.00044	0.00034	0.00025	0.00020	0.00021	0.00016	0.00017
Rice	0.05	0.00011	0.00014	0.00024	0.00019	0.00025	0.00020	0.00013	0.00010	0.00006	0.00002
Rye	0.01	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat fat	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
All types of kidney	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
All types of Liver	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
Other types of offal	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Eggs	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Milk	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Sugar beet	0.01	0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015

Table C.12 Scenario 3 - Chronic risk assessment undertaken using PRIMo revision 3.1 – Citrus and Raspberries input set to LOQ

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 to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food)	93.9%	NL toddler	9.39	25.9%	Apples	15.6%	Table grapes	10.4%	Pears	2.9%	
	73.0%	DE child	7.30	30.0%	Apples	13.8%	Table grapes	5.9%	Tomatoes	1.3%	
	53.7%	NL child	5.37	13.9%	Apples	10.4%	Table grapes	7.5%	Currants (red, black and white)	1.8%	
	51.9%	GEMS/Food G06	5.19	21.5%	Tomatoes	10.6%	Table grapes	3.6%	Wheat	1.4%	
	32.6%	GEMS/Food G15	3.26	7.2%	Tomatoes	3.6%	Potatoes	3.4%	Table grapes	1.0%	
	31.9%	RO general	3.19	11.6%	Tomatoes	3.7%	Potatoes	3.4%	Apples	0.7%	
	29.5%	GEMS/Food G10	2.95	8.2%	Tomatoes	3.0%	Table grapes	3.0%	Potatoes	1.1%	
	29.0%	GEMS/Food G08	2.90	6.8%	Tomatoes	3.9%	Potatoes	3.4%	Table grapes	1.1%	
	26.6%	UK toddler	2.66	4.1%	Apples	3.9%	Currants (red, black and white)	3.5%	Tomatoes	0.9%	
	26.3%	DE general	2.63	5.8%	Apples	4.2%	HOPS (dried)	3.9%	Tomatoes	1.0%	
	25.9%	GEMS/Food G11	2.59	5.5%	Tomatoes	4.2%	Table grapes	3.9%	Potatoes	1.1%	
	25.8%	FR child 3 15 yr	2.58	5.0%	Tomatoes	4.0%	Apples	3.6%	Table grapes	1.3%	
	25.2%	PT general	2.52	5.4%	Tomatoes	5.3%	Potatoes	2.8%	Table grapes	0.4%	

The review of the MRLs for apples and pears and CXLs for dithianon – proposed MRLs

25.2%	DE women 14-50 yr	2.52	6.2%	Apples	4.4%	Tomatoes	3.0%	Table grapes	1.1%
25.0%	GEMS/Food G07	2.50	6.5%	Tomatoes	3.8%	Potatoes	3.4%	Table grapes	1.0%
24.5%	UK infant	2.45	3.9%	Milk: Cattle	3.8%	Apples	3.4%	Peas (without pods)	0.8%
22.9%	DK child	2.29	5.6%	Apples	3.2%	Tomatoes	2.4%	Potatoes	1.0%
22.0%	FR toddler 2 3 yr	2.20	7.6%	Apples	2.9%	Milk: Cattle	2.9%	Tomatoes	1.0%
22.0%	SE general	2.20	4.6%	Tomatoes	4.2%	Potatoes	2.5%	Apples	0.8%
21.9%	IT toddler	2.19	8.6%	Tomatoes	3.3%	Wheat	2.1%	Apples	0.5%
21.6%	ES child	2.16	5.9%	Tomatoes	2.7%	Apples	2.2%	Wheat	0.7%
21.1%	PL general	2.11	5.3%	Tomatoes	4.9%	Apples	3.4%	Potatoes	0.2%
20.5%	IE adult	2.05	2.6%	Table grapes	2.4%	Tomatoes	2.3%	Potatoes	1.6%
20.0%	FI 3 yr	2.00	4.7%	Potatoes	3.4%	Tomatoes	2.3%	Table grapes	0.7%
18.6%	IT adult	1.86	7.0%	Tomatoes	2.1%	Wheat	1.9%	Apples	0.4%
18.2%	NL general	1.82	3.5%	Apples	2.5%	Table grapes	2.5%	Tomatoes	0.9%
15.3%	ES adult	1.53	4.7%	Tomatoes	1.8%	Apples	1.2%	Wheat	0.5%
15.0%	FI 6 yr	1.50	3.9%	Potatoes	2.6%	Tomatoes	1.8%	Table grapes	0.5%
14.7%	LT adult	1.47	4.5%	Apples	3.7%	Tomatoes	3.2%	Potatoes	0.3%
14.1%	UK vegetarian	1.41	3.7%	Tomatoes	1.9%	HOPS (dried)	1.4%	Apples	0.4%
13.8%	UK adult	1.38	4.2%	HOPS (dried)	2.6%	Tomatoes	1.4%	Potatoes	0.3%
13.1%	FR infant	1.31	4.0%	Apples	1.9%	Potatoes	1.7%	Milk: Cattle	0.5%
13.0%	DK adult	1.30	3.1%	Tomatoes	2.3%	Apples	1.7%	Table grapes	0.2%
11.5%	FR adult	1.15	2.8%	Tomatoes	1.8%	Apples	1.1%	Table grapes	0.5%
10.0%	FI adult	1.00	3.3%	Tomatoes	1.4%	Apples	1.2%	Potatoes	0.9%
4.9%	IE child	0.49	1.0%	Currants (red, black and white)	0.8%	Apples	0.6%	Potatoes	0.1%

Table C.13 Scenario 3 - Chronic risk assessment undertaken using UK model version 1.1 – Currants (black, red, and white) ‘fallback’ CXL (and citrus and raspberries input set to LOQ)

Active substance:

ADI: 0.01 mg/kg bw/day

Source: Dithianon

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	0.00616	0.00522	0.009952	0.006083	0.00574	0.00304	0.00522	0.00672	0.00724	0.00446
% of ADI	62%	52%	99.5%	61%	57%	30%	52%	67%	72%	45%

STMR		P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
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	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.05		0.00000	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	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
Cashew nuts	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	L/C
Coconuts	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Hazelnuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.01		0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.05		0.00001	L/C	0.00002	0.00000	0.00000	0.00000	0.00001	0.00001	0.00001	0.00000

The review of the MRLs for apples and pears and CXLs for dithianon – proposed MRLs

Peanuts	0.01	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000
Apples	0.24	0.00064	0.00202	0.00357	0.00226	0.00181	0.00098	0.00086	0.00080	0.00053	0.00026
Pears	0.24	0.00034	0.00061	0.00157	0.00087	0.00053	0.00044	0.00035	0.00045	0.00055	0.00029
Apricots	0.43	0.00016	0.00058	0.00044	0.00027	0.00018	0.00016	0.00010	0.00033	0.00019	0.00016
Peaches	0.5	0.00068	0.00067	0.00157	0.00079	0.00059	0.00038	0.00022	0.00047	0.00047	0.00022
Plums	0.43	0.00039	0.00021	0.00093	0.00058	0.00034	0.00012	0.00011	0.00030	0.00028	0.00009
Cherries	0.43	0.00020	0.00061	0.00045	0.00065	0.00024	0.00031	0.00025	0.00022	0.00015	0.00003
Table grapes	1.01	0.00133	0.00167	0.00474	0.00218	0.00261	0.00112	0.00064	0.00206	0.00134	0.00047
Wine grapes	0.0021	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00002	0.00001	0.00000
Strawberries	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Blackberries	0.5	0.00006	L/C	0.00097	0.00003	0.00017	0.00013	0.00005	0.00016	0.00013	0.00002
Loganberries	0.01	0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Raspberries	0.01	0.00000	L/C	0.00002	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Gooseberries	3	0.00074	0.00155	0.00197	0.00073	0.00071	0.00071	0.00055	0.00217	0.00247	0.00071
Blackcurrants	0.105	0.00006	0.00012	0.00019	0.00019	0.00015	0.00011	0.00012	0.00004	0.00006	0.00003
Red currants	0.105	0.00001	L/C	0.00008	L/C	0.00001	0.00001	0.00000	0.00000	0.00004	L/C
White currants	0.105	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.01	0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000	0.00001	0.00001	L/C
Bananas	0.01	0.00002	0.00007	0.00007	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002
Dates	0.01	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00001	0.00000
Figs	0.01	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Kiwi fruit	0.01	0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000
Lychees	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Mangoes	0.01	0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004	0.00001	0.00000	L/C
Olives	0.01	0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C	0.00000	0.00000	L/C
Passion fruit	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C

The review of the MRLs for apples and pears and CXLs for dithianon - proposed MRLs

Pineapples	0.01		0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Pomegranates	0.01		0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000	0.00001	0.00001	0.00001
Beetroot	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Carrots	0.05		0.00004	0.00018	0.00012	0.00010	0.00006	0.00004	0.00005	0.00004	0.00005	0.00004
Celeriac	0.01		0.00000	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C
Horseradish	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Jerusalem artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Parsnips	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.01		0.00000	L/C	0.00001	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	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		0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01		0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Spring onions	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Tomatoes	0.6		0.00083	0.00110	0.00158	0.00115	0.00110	0.00065	0.00080	0.00106	0.00087	0.00080
Peppers	0.6		0.00022	L/C	0.00048	0.00025	0.00041	0.00019	0.00017	0.00036	0.00034	0.00011
Aubergines	0.01		0.00000	L/C	0.00002	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000	L/C
Marrows	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001
Cucumbers	0.01		0.00000	0.00000	0.00002	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000
Gourd	0.01		0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.01		0.00000	0.00001	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Melons	0.01		0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00003	0.00003	0.00003	0.00001
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000

The review of the MRLs for apples and pears and CXLs for dithianon – proposed MRLs

Cauliflower	0.01	0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Brussels sprouts	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Head cabbage	0.01	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Chinese cabbage	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00000	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	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	0.01	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Spinach	0.6	0.00032	0.00060	0.00094	0.00052	0.00053	0.00038	0.00021	0.00041	0.00034	0.00021
Watercress	0.01	0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Chicory	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Parsley	0.01	0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Beans with pods	0.01	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000
Runner Beans	0.01	0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01	0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01	0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.6	0.00046	0.00144	0.00122	0.00084	0.00062	0.00044	0.00055	0.00052	0.00060	0.00044
Beansprouts	0.01	0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01	0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.01	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Fennel	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Globe artichokes	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Leeks	0.01	0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Rhubarb	0.01	0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.01	0.00002	0.00006	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001

The review of the MRLs for apples and pears and CXLs for dithianon - proposed MRLs

Lentils	0.01	0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.01	0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Oilseeds	0.02	0.00006	0.00013	0.00014	0.00014	0.00011	0.00008	0.00007	0.00009	0.00006	0.00008
Potatoes	0.1	0.00033	0.00111	0.00092	0.00083	0.00070	0.00053	0.00046	0.00035	0.00033	0.00032
Tea (dried leaves)	0.01	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Hops (dried 0.25% of beer)	64	0.00396	L/C	L/C	L/C	L/C	0.00040	0.00351	0.00336	0.00398	0.00301
Oats	0.01	0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01	0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
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
Maize	0.01	0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.05	0.00018	0.00014	0.00042	0.00044	0.00034	0.00025	0.00020	0.00021	0.00016	0.00017
Rice	0.05	0.00011	0.00014	0.00024	0.00019	0.00025	0.00020	0.00013	0.00010	0.00006	0.00002
Rye	0.01	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat fat	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
All types of kidney	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
All types of Liver	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
Other types of offal	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Eggs	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Milk	0	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Sugar beet	0.01	0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015

Table C.14 Scenario 3 - Chronic risk assessment undertaken using PRIMo revision 3.1 – Currants (black, red, and white) 'fallback' CXL (and citrus and raspberries input set to LOQ)

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)	84.3%	NL toddler	8.43	25.9%	Apples	15.6%	Table grapes	10.4%	Pears	2.9%	0.3%
	70.4%	DE child	7.04	30.0%	Apples	13.8%	Table grapes	5.9%	Tomatoes	1.3%	0.1%
	51.9%	GEMS/Food G06	5.19	21.5%	Tomatoes	10.6%	Table grapes	3.6%	Wheat	1.4%	0.0%
	46.5%	NL child	4.65	13.9%	Apples	10.4%	Table grapes	3.4%	Potatoes	1.8%	0.3%
	32.2%	GEMS/Food G15	3.22	7.2%	Tomatoes	3.6%	Potatoes	3.4%	Table grapes	1.0%	0.0%
	31.9%	RO general	3.19	11.6%	Tomatoes	3.7%	Potatoes	3.4%	Apples	0.7%	
	28.7%	GEMS/Food G10	2.87	8.2%	Tomatoes	3.0%	Table grapes	3.0%	Potatoes	1.1%	0.0%
	27.0%	GEMS/Food G08	2.70	6.8%	Tomatoes	3.9%	Potatoes	3.4%	Table grapes	1.1%	0.1%
	25.7%	FR child 3 15 yr	2.57	5.0%	Tomatoes	4.0%	Apples	3.6%	Table grapes	1.3%	0.0%
	25.7%	GEMS/Food G11	2.57	5.5%	Tomatoes	4.2%	Table grapes	3.9%	Potatoes	1.1%	0.0%
	25.2%	PT general	2.52	5.4%	Tomatoes	5.3%	Potatoes	2.8%	Table grapes	0.4%	
	25.1%	DE general	2.51	5.8%	Apples	4.2%	HOPS (dried)	3.9%	Tomatoes	1.0%	0.0%
	24.7%	GEMS/Food G07	2.47	6.5%	Tomatoes	3.8%	Potatoes	3.4%	Table grapes	1.0%	0.0%
	23.9%	DE women 14-50 yr	2.39	6.2%	Apples	4.4%	Tomatoes	3.0%	Table grapes	1.1%	0.0%
	22.8%	DK child	2.28	5.6%	Apples	3.2%	Tomatoes	2.4%	Potatoes	1.0%	0.0%
	22.8%	UK toddler	2.28	4.1%	Apples	3.5%	Tomatoes	3.5%	Potatoes	0.9%	0.1%

The review of the MRLs for apples and pears and CXLs for dithianon - proposed MRLs

	22.5%	UK infant	2.25	3.9%	Milk: Cattle	3.8%	Apples	3.4%	Peas (without pods)	0.8%	0.1%
	22.0%	FR toddler 2 3 yr	2.20	7.6%	Apples	2.9%	Milk: Cattle	2.9%	Tomatoes	1.0%	0.0%
	21.9%	IT toddler	2.19	8.6%	Tomatoes	3.3%	Wheat	2.1%	Apples	0.5%	
	21.6%	ES child	2.16	5.9%	Tomatoes	2.7%	Apples	2.2%	Wheat	0.7%	
	21.5%	SE general	2.15	4.6%	Tomatoes	4.2%	Potatoes	2.5%	Apples	0.8%	0.0%
	21.1%	PL general	2.11	5.3%	Tomatoes	4.9%	Apples	3.4%	Potatoes	0.2%	
	20.5%	IE adult	2.05	2.6%	Table grapes	2.4%	Tomatoes	2.3%	Potatoes	1.6%	
	18.6%	IT adult	1.86	7.0%	Tomatoes	2.1%	Wheat	1.9%	Apples	0.4%	
	18.0%	FI 3 yr	1.80	4.7%	Potatoes	3.4%	Tomatoes	2.3%	Table grapes	0.7%	0.1%
	17.2%	NL general	1.72	3.5%	Apples	2.5%	Table grapes	2.5%	Tomatoes	0.9%	0.0%
	15.3%	ES adult	1.53	4.7%	Tomatoes	1.8%	Apples	1.2%	Wheat	0.5%	
	14.0%	LT adult	1.40	4.5%	Apples	3.7%	Tomatoes	3.2%	Potatoes	0.3%	0.0%
	13.8%	FI 6 yr	1.38	3.9%	Potatoes	2.6%	Tomatoes	1.8%	Table grapes	0.5%	0.0%
	13.7%	UK vegetarian	1.37	3.7%	Tomatoes	1.9%	HOPS (dried)	1.4%	Apples	0.4%	0.0%
	13.3%	UK adult	1.33	4.2%	HOPS (dried)	2.6%	Tomatoes	1.4%	Potatoes	0.3%	0.0%
	13.0%	FR infant	1.30	4.0%	Apples	1.9%	Potatoes	1.7%	Milk: Cattle	0.5%	0.0%
	13.0%	DK adult	1.30	3.1%	Tomatoes	2.3%	Apples	1.7%	Table grapes	0.2%	0.0%
	11.5%	FR adult	1.15	2.8%	Tomatoes	1.8%	Apples	1.1%	Table grapes	0.5%	0.0%
	9.0%	FI adult	0.90	3.3%	Tomatoes	1.4%	Apples	1.2%	Potatoes	0.9%	0.0%
	4.0%	IE child	0.40	0.8%	Apples	0.6%	Potatoes	0.6%	Wheat	0.1%	0.0%

Table C.15 Scenario 3 - Acute risk assessment undertaken using UK model version 1.2 currants (black, red and white) ‘fallback’ CXL

Acute Intakes
(97.5th
percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Apples	0.65		0.00972	8.1	0.06368	53.1	0.04683	39.0	0.03624	30.2	0.02672	22.3
Pears	0.65		0.01148	9.6	0.04707	39.2	0.05517	46.0	0.03910	32.6	0.02597	21.6

			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
Apples	0.65		0.01677	14.0	0.01375	11.5	0.01151	9.6	0.00865	7.2	0.00860	7.2
Pears	0.65		0.01707	14.2	0.01307	10.9	0.01288	10.7	0.01200	10.0	0.01182	9.8

Table C.16 Scenario 3 - Acute risk assessment undertaken using PRIMo 3.1 for currants (black, red and white) 'fallback' CXL

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	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)
	5.85%	Currants (red, black and white)	0 / 0.89	7.02	4.90%	Currants (red, black and white)	0 / 0.89	5.87
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	2.5%	Currants (red, black and white) / juice	0 / 0.11	3.00	1.1%	Currants (red, black and white) / juice	0 / 0.11	1.34
#NUM!					#NUM!			

Appendix D - Detailed evaluation of the additional studies relied on

D.1 Methods of analysis

No additional studies submitted

D.2 Mammalian toxicology

No additional studies submitted

DRAFT

D.3 Residue data

D.3.1 Nature and magnitude of residues in primary crops

D.3.1.1 Nature of residues

No additional studies submitted

DRAFT

D.3.1.2 Magnitude of residues

D.3.1.2.1 Apples – Study 1

Reference: Study on the residue behaviour of BAS 216 F in pome fruits after application of BAS 216 F under field condition in Belgium, the Netherlands, United Kingdom, Southern France, Italy, Greece, Spain and Germany, 2011, [REDACTED] 2012, BASFDocID 2012/1150991

Guideline(s): Yes
EEC 91/414 Annex II (Part A Section 6)
EEC 91/414 Annex III (Part A Section 8)
EEC 1607/VI/97 rev. 2 10.06.1999
EEC 7029/VI/95 rev. 5
EEC 7525/VI/95 rev. 7

Deviations: Yes

L110276 – Test item was applied in the first application to plot 2 30.79% required amount and plot 3 32.14% over the required amount.
L110277 – Chemical use history is not available

No deviations had an impact on the study

GLP: Yes

Validity of the study: Acceptable

Materials and methods

Eight open field trials were conducted in Northern and Southern Europe on apples using a WG formulation containing 700 g/kg dithianon during the 2011 growing season. All trials were considered independent of one another. SEU trials are not relevant to the UK so have not been considered further.

Three plots were tested:

- Test plot 1: 6 x 350 g/ha, RTI – 5 days, PHI 42 days
- Test plot 2: initial three applications 3 x 530 g/ha initial applications, last three applications 3 x 350 g/ha; RTI – 5 days; PHI 42 days
- Test plot 3: 4 x 350 g/ha, RTI – 5 days, PHI 42 days.

Test plot 3 has not been considered further.

Test plot 1 is in line with the authorised cGAP (6 x 350 g/ha, RTI – 5 days, PHI 42 days); test plot 2 is overdosed compared to the authorised cGAP; however, the final three applications and the PHI are the same; therefore, the results of these trials have been reported, and have been compared to test plot 1.

For test plot 1, formulation BAS 216 03F was applied six times via foliar spray at a nominal rate of 350 g a.s./ha. Actual rates ranged from 322-380 g a.s./ha per application. The retreatment intervals were 5 ± 2 days. Spray volumes ranged from 774-856 L/ha.

For test plot 2, formulation BAS 216 03F was applied six times, three foliar applications at a rate of 525 g a.s./ha and and three at 350 g a.s./ha. Actual rates ranged from 506-694 g a.s./ha and 346-369 g a.s./ha per application. The retreatment intervals between applications were 7 ± 1 days (exception for the first four applications was 5 days). Spray volumes ranged from 771-1057 L/ha.

Weather data was reported for the trials and no exceptional weather events were noted.

Samples were collected at 0, 34-36, 42-43 and 48-50 after the last application (DALA). Samples weighing a minimum of 1 kg (minimum of 12 fruits per specimen) were frozen with 6 hours and transported at $\leq -18^{\circ}\text{C}$. Samples were frozen for a maximum of 292 days prior to analysis. Dithianon residues have been shown to be stable in high water commodities for up to 12 months.

Residues of dithianon were analysed by analytical method L0152/01 with a LOQ of 0.01 mg/kg. Full details and validation for this method can be found in COP 2012/01846 (HSE int. ref.: [REDACTED]).

Results and discussions

The analytical method (L0152/01) was satisfactorily validated in COP 2012/01846 (HSE int. ref.: [REDACTED]). The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for dithianon using an appropriate number of samples were presented. No residues were detected above LOQ in the control samples.

Residues of dithianon in apples (whole fruit) 42-43 DALA in test plot 1 were between 0.13-0.40 mg/kg.

Table D.3.1.2.1-1 Residue trials on apples

Reference: Study on the residue behaviour of BAS 216 F in pome fruits after application of BAS 216 F under field condition in Belgium, the Netherlands, United Kingdom, Southern France, Italy, Greece, Spain and Germany, 2011, [REDACTED] 2012, BASFDocID 2012/1150991

GLP: Yes Sample storage conditions: 292 days, ≤-18°C

Crop/crop group: Apples Analytical method: L0152/01, validated

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): 0.01

Formulation: WG Residues calculated as: Dithianon

Content of active substance: 700 g/kg

Trial No Location Year	Commodity Variety	Date of 1.Sowing or planting 2. Flowering 3.Harvest	Application rate per			Number of treatments and last date	Interval between applications (days)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			g a.s./ ha	Water (L/ha)	g a.s./ hL							
L110273 Germany 2011	Apple, Rubinette	1. 15/10/2006	363	829	-	6 24/ 08/11	6 ± 3 (4 day RTI for final application)	BBCH 79	Whole fruit	0.59	0	Method: L0152/01 LOQ: 0.01 mg/kg
		2. 26/04/2011	375	856						0.27	35	
		to 12/05/2011	365	833						0.40	42	
		3. 04/10/2011	365	833						0.13	48	
		to 11/10/2011	344	787								
			344	787								

			532 547 547 365 346 365	810 833 833 833 792 833	-	6 24/08/11	7 ± 2 (4 day RTI for final application)	BBCH 79	Whole fruit	0.54 0.30 0.35 0.13	0 35 42 48	
L110274 Belgium 2011	Apple, Dacosta	1. 10/03/2000 2. 26/04/2011 to 12/05/2011 3. 20/09/2011 to 30/09/2011	350 352 342 342 365 380	800 805 781 781 834 868	-	6 12/08/11	5 ± 1	BBCH 79	Whole fruit	0.56 0.12 <u>0.16</u> 0.10	0 35 42 49	Method: L0152/01 LOQ: 0.01 mg/kg
			541 535 506 346 346 369	824 815 771 790 790 844	-	6 12/08/11	6 ± 1	BBCH 79	Whole fruit	0.79 0.11 0.19 0.15	0 35 42 49	
L110275 The Netherlands 2011	Apple, Elstar	1. 10/02/1998 2. 25/04/2011 to 11/05/2011 3. 19/09/2011 to 28/09/2011	353 353 348 357 353 338	806 806 796 816 806 772	-	6 10/08/11	5 ± 1	BBCH 79	Whole fruit	1.02 <u>0.20</u> <u>0.16</u> 0.10	0 35 42 49	Method: L0152/01 LOQ: 0.01 mg/kg
			518 531 540 360 348 347	789 809 823 823 796 792	-	6 10/08/11	6 ± 1	BBCH 79	Whole fruit	1.51 0.48 0.31 0.20	0 35 42 49	

L110276 UK 2011	Apple, Cox	1. 1990 2. 18/04/2011 to 27/04/2011 3. 12/09/2011 to 16/09/2011	339	774	-	6	5 ± 2	BBCH 76- 78	Whole fruit	0.43 <u>0.18</u> <u>0.13</u> 0.10	0 34 42 49	Method: L0152/01 LOQ: 0.01 mg/kg
			348 350 345 355 362	796 800 788 812 828	-	6	7 ± 2 (4 day RTI for final application)	BBCH 76- 78	Whole fruit	0.81 0.25 0.22 0.13	0 34 42 49	

Solid underline – trials selected to support PHI of 35 days

Dotted underline – trials selected to support PHI of 42 days (in many cases, only solid underline is required)

D.3.1.2.2 Apples – Study 2

Reference: BAS 216 03 F: Determination of residues of Dithianon in apples (RAC fruit) following four to six treatments with BAS 216 03 F (700 g/kg Dithianon) under open field conditions in Northern and Southern Europe in 2010, [REDACTED] 2011 BASFDocID 2011/1150053

Guideline(s): Yes
EEC 91/414 Annex II (Part A Section 6)
EEC 91/414 Annex III (Part A Section 8)
EEC 1607/VI/97 rev. 2 10.06.1999
EEC 7029/VI/95 rev. 5
EEC 7525/VI/95 rev. 7

Deviations: Yes

L100462 – 1st application was conducted 69 days before harvest instead of 67 ± 1 .
L100464 – Last application was conducted 40 DBH, 7 days after previous application. Delay was due to unstable weather.
L100466 – At the second application, there was a deviation of +20.4% in actual volume applied. Temperature during second application was 33°C. On day of last application, sampling of the control plot was carried out before last application, not after.
L100468 – Relative humidity was not recorded during applications and samplings
Samples in multiple trials experienced temperature fluctuations during transport, all remained frozen

No deviations had an impact on the study

GLP: Yes

Validity of the study: Acceptable

Materials and methods

Eight open field trials were conducted in Northern and Southern Europe on apples using a WG formulation containing 700 g/kg dithianon during the 2010 growing season. All trials were considered independent of one another. SEU trials are not relevant to the UK so have not been considered further.

Two plots were tested:

- Test plot 1: 6 x 350 g/ha, RTI – 5 days, PHI 42 days
- Test plot 2: 4 x 350 g/ha, RTI – 5 days, PHI 42 days.

Test plot 2 has not been considered further.

Formulation BAS 216 03F was applied six times via foliar spray at a nominal rate of 350 g a.s./ha. Actual rates ranged from 315-421 g a.s./ha per application. The retreatment intervals were 5 ± 1 days. Spray volumes were 763-867 L/ha.

Weather data was reported for the trials, exceptional weather was reported (see deviations) but had no impact on the study.

Samples were collected at 0, 34-36, 41-42 and 49 after the last application (DALA). Samples weighing a minimum of 1 kg (minimum of 12 fruits per specimen) were frozen with 6 hours and transported at $\leq -18^{\circ}\text{C}$. Samples were frozen for a maximum of 179 days prior to analysis. Dithianon residues have been shown to be stable in high water commodities for up to 12 months.

Residues of dithianon were analysed by analytical method L0152/01 with a LOQ of 0.01 mg/kg. Full details and validation for this method can be found in COP 2012/01846 (HSE int. ref.: [REDACTED]).

Results and discussions

The analytical method (L0152/01) was satisfactorily validated in COP 2012/01846 (HSE int. ref.: [REDACTED]). The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for dithianon using an appropriate number of samples were presented. No residues were detected above LOQ in the control samples.

Residues of dithianon in apples (whole fruit) 41-42 DALA in test plot 1 were between 0.04-0.19 mg/kg.

Table D.3.1.2.2-1 Residue trials on apples

Reference: BAS 216 03 F: Determination of residues of Dithianon in apples (RAC fruit) following four to six treatments with BAS 216 03 F (700 g/kg Dithianon) under open field conditions in Northern and Southern Europe in 2010, [REDACTED] 2011 BASFDocID 2011/1150053

GLP: Yes Sample storage conditions: 292 days, ≤-18°C

Crop/crop group: Apples Analytical method: L0152/01, validated

Indoor/outdoor: Outdoor Limit of Quantification (mg/kg): 0.01

Formulation: WG Residues calculated as: Dithianon

Content of active substance: 700 g/kg

Trial No Location Year	Commodity Variety	Date of 1.Sowing or planting 2.Flowering 3.Harvest	Application rate per treatment			Number of treatments and last date	Interval between applications (days)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			g a.s./ ha	Water (L/ha)	g a.s. / hL							
L100461 Germany 2010	Apple, Pinova	1. 1996	341	780	-	6 10/08/10	5 ± 1	BBCH 79	Fruit	0.48	0	Method: L0152/0 1 LOQ: 0.01 mg/kg
		2. N/A	376	860						0.15	34	
		3. 28/09/10	340	776						0.09	41	
			350	800						0.09	48	
			364	832								
			368	840								

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L100462 The Netherlands 2010	Apple, Pinova	1. 1996 2. N/A 3. 28/09/10	362 373 365 368 334 365	827 852 833 840 763 833	-	6 11/08/10	5 ± 1	BBCH 78	Fruit	0.22 0.03 <u>0.04</u> 0.03	0 36 42 49	Method: L0152/0 1 LOQ: 0.01 mg/kg
L100463 Northern France 2010	Apple, Jonagold Dacosta	1. 1992 2. 24/04/10 to 07/05/10 3. 23/09/10	378 373 379 369 364 364	863 852 867 843 832 832	-	6 05/08/10	5 ± 1	BBCH 76	Fruit	0.64 <u>0.24</u> <u>0.19</u> 0.18	0 35 41 49	Method: L0152/0 1 LOQ: 0.01 mg/kg
L100464 UK 2010	Apple, Jonagold Dacosta	1. 1992 2. 24/04/10 to 07/05/10 3. 23/09/10	350 350 350 350 350 350	800 800 800 800 800 800	-	6 22/08/10	5 ± 1	BBCH 77	Fruit	0.72 <u>0.12</u> <u>0.10</u> 0.010	0 35 42 49	Method: L0152/0 1 LOQ: 0.01 mg/kg

Solid underline – trials selected to support PHI of 35 days

Dotted underline – trials selected to support PHI of 42 days (in many cases, only solid underline is required)

D.3.1.2.3 Apples – Study 3

Reference:	Study on the residue behaviour of BAS 216 F (Dithianon) and Phosphonic Acid in pome fruits after application of BAS 643 01 F under field condition in United Kingdom, The Netherlands, Southern France, Greece, Italy, Spain and Germany, 2012, [REDACTED] 2013, BASFDocID 2013/1003731
Guideline(s):	Yes Reg. (EC) No. 1107/2009 EEC 7029/VI/95 – rev. 5 EEC 7525/VI/95 – rev. 9
Deviations:	Yes L120344 – 1 st and 2 nd application overdosed by 11.2% and 26.4%, respectively. A buffer zone of 20 m was not established between study plots and other crops since the test item was not in use across the entire orchard. At sample timing 42 DALA there was not enough fruit left within the treated plot and so the shipped sample was made up to weight, with the retained sample less than required (the grower had already harvested the trial). Actual weights are as follows: L120344004 = 2 kg, L1203440004B = 0.65 kg. Over 2 kg was achieved for both samples from the treated plot. From the 29 th September until the 10 th October there were fluctuations in the freezer store temperature from -20 to -13.5°C. Samples remained frozen throughout. On the 14 th November there was a fluctuation in the freezer truck temperature range dropping to -17.5°C. Samples remained frozen throughout. No deviations had an impact on the study
GLP:	Yes
Validity of the study:	Acceptable

Materials and methods

Eight open field trials were conducted in Northern and Southern Europe on apples using a SC formulation containing 125 g/L dithianon and 375 g/L phosphonic acid during the 2012 growing season. All trials were considered independent of one another. SEU trials are not

relevant to the UK so have not been considered further. Phosphonic acid is not relevant to this review and has not been considered further.

Formulation BAS 643 01 F was applied six times via foliar spray at a nominal rate of 312.5 g a.s./ha. Actual rates ranged from 287-395 g a.s./ha per application. The retreatment intervals were 5 ± 1 days. Spray volumes were 198-825 L/ha.

Weather data was reported for the trials, exceptional weather was reported (see deviations) but had no impact on the study.

Samples were collected at 0, 27-29, 35-36 and 42 after the last application (DALA). Samples weighing a minimum of 1 kg (minimum of 12 fruits per specimen) were frozen with 5 hours and transported at $\leq -18^{\circ}\text{C}$. Samples were frozen for a maximum of 179 days prior to analysis. Dithianon residues have been shown to be stable in high water commodities for up to 12 months.

Residues of dithianon were analysed by analytical method L0152/01 with a LOQ of 0.01 mg/kg. Full details and validation for this method can be found in COP 2012/01846 (HSE int. ref.: [REDACTED]).

Results and discussions

The analytical method (L0152/01) was satisfactorily validated in COP 2012/01846 (HSE int. ref.: [REDACTED]). The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for dithianon using an appropriate number of samples were presented. No residues were detected above LOQ in the control samples.

Residues of dithianon in apples (whole fruit) 35-42 DALA were between 0.17-0.42 mg/kg.

Table D.3.1.2.3-1 Residue trials on apples

Reference:	Study on the residue behaviour of BAS 216 F (Dithianon) and Phosphonic Acid in pome fruits after application of BAS 643 01 F under field condition in United Kingdom, The Netherlands, Southern France, Greece, Italy, Spain and Germany, 2012, [REDACTED] 2013, BASFDocID 2013/1003731		
GLP:	Yes	Sample storage conditions:	200 days, ≤-18°C
Crop/crop group:	Apple	Analytical method:	L0152/01, validated
Indoor/outdoor:	Outdoor	Limit of Quantification (mg/kg):	0.01
Formulation:	SC	Residues calculated as:	Dithianon
Content of active substance:	125 g/L		

Trial No Location Year	Commodity Variety	Date of 1.Sowing or planting 2.Flowering 3.Harvest	Application rate per treatment			Dates of treatment or number and last date	Interval between applications (days)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			g a.s./ ha	Water L/ha	g a.s./ hL							
L120342 67433 Neustadt Germany	FP 226 Braeburn	1. N/A	311	498	-	6 17/08/12	5 ± 1	BBCH 78-81	Whole fruit	0.94	0	Method: L0152/0 1 LOQ: 0.01 mg/kg
		2. 26/04-	313	500						0.60	27	
		07/05/201	306	490						0.38	35	
		2	319	510						<u>0.52</u>	42	
		3. 15/07-	320	820								
		05/08/201	322	825								
		2										

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Trial No Location Year	Commodity Variety	Date of 1.Sowing or planting 2.Flowering 3.Harvest	Application	rate	per treatment	Dates of treatment or number and last date	Interval between applications (days)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
L120343 16356 Werneuchen Germany	FP 226 Jonagold	1. 1998 2. 01/05- 13/05/201 2 3. 11/10/201 2	287 295 325 316 308 319	460 472 520 506 788 816	-	6 30/08/12	5 ± 2	BBCH 81	Whole fruit	0.61 0.33 0.30 <u>0.31</u>	0 28 35 42	Method: L0152/0 1 LOQ: 0.01 mg/kg
L120344 Skenfrith NP25 5NR UK	FP 226 Hastings	1. 2009 2. 16/05- 26/05/201 2 3. 03/10/201 2	347 395 319 339 310 333	222 253 204 217 298 320	-	6 24/08/12	5 ± 1	BBCH 81-85	Whole fruit	1.33 0.49 <u>0.24</u> <u>0.21</u>	0 27 35 42	Method: L0152/0 1 LOQ: 0.01 mg/kg
L120345 6561 KR Groesbeek The Netherlands	FP 226 Jonagold	1. 10/02/199 8 2. 18/04- 10/05/201 2 3. 22/09- 28/09/201 2	316 310 322 316 314 314	202 198 206 202 302 302	-	6 17/08/12	5 ± 1	BBCH 81	Whole fruit	0.96 0.57 <u>0.43</u> <u>0.32</u>	0 27 36 42	Method: L0152/0 1 LOQ: 0.01 mg/kg

Solid underline – trials selected to support PHI of 35 days

Dotted underline – trials selected to support PHI of 42 days (in many cases, only solid underline is required)

D.3.1.2.4 Apples – Study 4

Reference: Study on the residue behavior of Dithianon (BAS 216 F) and Phosphorous Acid on apples after the application of BAS 643 01 F under field conditions in Belgium, France (North and South), Germany, Greece, Italy and Spain, 2013, Martin, T., 2014, BASFDocID 2014/1031598

Guideline(s): Yes
Reg. (EC) No. 1107/2009
EEC 7029/VI/95 – rev. 5
EEC 7525/VI/95 – rev. 9

Deviations: Yes

L130094 – Photographic records were not sent promptly after taken at 35 DALA
L130096 – 19th September the freezer for specimen storage was above -18°C for 1h 30 mins.
Samples remained frozen throughout.
No deviations had an impact on the study

GLP: Yes

Validity of the study: Acceptable

Materials and methods

Eight open field trials were conducted in Northern and Southern Europe on apples using a SC formulation containing 125 g/L dithianon and 375 g/L phosphonic acid during the 2013 growing season. All trials were considered independent of one another. SEU trials are not relevant to the UK so have not been considered further. Phosphonic acid is not relevant to this review and has not been considered further.

Formulation BAS 643 01 F was applied six times via foliar spray at a nominal rate of 312.5 g a.s./ha. Actual rates ranged from 290.5-338 g a.s./ha per application. The retreatment intervals were 5 ± 1 days. Spray volumes were 191.9-805 L/ha.

Weather data was reported for the trials, exceptional weather was reported (see deviations) but had no impact on the study.

Samples were collected at 0, 27-29, 34-35 and 42 after the last application (DALA). Samples weighing a minimum of 1 kg (minimum of 12 fruits per specimen) were frozen with 6 hours and transported at $\leq -18^{\circ}\text{C}$. Samples were frozen for a maximum of 179 days prior to analysis. Dithianon residues have been shown to be stable in high water commodities for up to 12 months.

Residues of dithianon were analysed by analytical method L0152/01 with a LOQ of 0.01 mg/kg. Full details and validation for this method can be found in COP 2012/01846 (HSE int. ref.: [REDACTED])

Results and discussions

The analytical method (L0152/01) was satisfactorily validated in COP 2012/01846 (HSE int. ref.: [REDACTED]). The LOQ of the method is 0.01 mg/kg. Acceptable procedural recovery data for dithianon using an appropriate number of samples were presented. No residues were detected above LOQ in the control samples.

Residues of dithianon in apples (whole fruit) 34-42 DALA were between 0.17-0.42 mg/kg.

Table D.3.1.2.4-1 Residue trials on apples

Reference:	Study on the residue behavior of Dithianon (BAS 216 F) and Phosphorous Acid on apples after the application of BAS 643 01 F under field conditions in Belgium, France (North and South), Germany, Greece, Italy and Spain, 2013, ██████████ 2014, BASFDocID 2014/1031598		
GLP:	Yes	Sample storage conditions:	143 days, ≤-18°C
Crop/crop group:	Apple	Analytical method:	L0152/01, validated
Indoor/outdoor:	Outdoor	Limit of Quantification (mg/kg):	0.01
Formulation:	SC	Residues calculated as:	Dithianon
Content of active substance:	125 g/L		

Trial No Location Year	Commodity Variety	Date of 1.Sowing or planting 2.Flowering 3.Harvest	Application rate p-er treatment			Dates of treatment or number and last date	Interval between applications (days)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			g a.s./ ha	Water (L/ha)	g a.s./ hL							
L13009 4 67433 Neustadt Germany	FP 226 Pinova	1. 2004	325	520.0	-	6 28/08/13	5 ± 2	BBCH 81	Whole fruit	0.46	0	Method: L0152/0 1 LOQ: 0.01 mg/kg
		2. 27/04-	338	540.0						0.26	29	
		08/05/2013	330	527.5						<u>0.25</u>	34	
		3.	320	512.5						<u>0.12</u>	42	
		05/09/2013	305	780.0								
			315	805.0								
L13009 5	FP 226 Rubinette	1. 2006	313.5	501.5	-	6 21/08/13	5 ± 1	BBCH 81	Whole fruit	1.80	0	Method: L0152/0 1 LOQ:
		2. 02/05-	313.5	501.5						0.94	28	
		16/05/2013	301.4	482.3						<u>0.42</u>	35	

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Trial No Location Year	Commodity Variety	Date of 1.Sowing or planting 2.Flowering 3.Harvest	Application	rate	p-er treatment	Dates of treatment or number and last date	Interval between applications (days)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
41472 Neuss German y		3. 25/09- 10/10/2013	320.7 308.9 301.4	513.1 790.9 771.6						0.42	42	0.01 mg/kg
L13009 67170 Rottelsh eim Norther n France	FP 226 Opal	1. 2009 2. 24/04- 06/05/2013 3. 20/09/- 27/09/2013	299.8 335.3 331.4 295.9 299.9 326.1	191.9 214.6 212.1 189.4 287.9 313.1	-	6 15/08/13	5 ± 1	BBCH 79-81	Whole fruit	0.71 0.35 <u>0.33</u> <u>0.16</u>	0 28 35 42	Method: L0152/0 1 LOQ: 0.01 mg/kg
L13009 6 3470 Kortena ken Belgium	FP 226 Dacosta	1. 2000 2. 10/05- 24/05/2013 3. 90/09- 08/10/2013	314.3 321.4 292.9 300.0 290.5 309.5	201.1 205.7 187.4 192.0 278.9 297.1	-	6 27/08/13	5 ± 1	BBCH 81	Whole fruit	0.66 0.46 <u>0.17</u> <u>0.16</u>	0 28 35 42	Method: L0152/0 1 LOQ: 0.01 mg/kg

Solid underline – trials selected to support PHI of 35 days

Dotted underline – trials selected to support PHI of 42 days (in many cases, only solid underline is required)

D.3.2 Nature and magnitude of residues in processed commodities

No additional studies submitted

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D.3.3 Nature and magnitude of residues in rotational crops

No additional studies submitted

DRAFT

D.3.4 Nature and magnitude of residues in livestock

No additional studies submitted

DRAFT

D.3.5 Residues in honey

No additional studies submitted

DRAFT

D.3.6 Storage stability

No additional studies submitted

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Appendix E – List of endpoints

The endpoints have not changed as a result of this assessment. The full list of endpoints is outlined in EFSA, 2010.

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Appendix F – Import Tolerances

Not applicable

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Appendix G – Compound codes

No new metabolism studies were evaluated during this assessment and hence this section has not been completed.

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Appendix H – 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 ₉₀	Period required for 90% dissipation (define method of estimation)
DT ₅₀	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 (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 ₅₀	Lethal concentration, median
LD ₅₀	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 NB the limit of quantification and limit of determination are the same. Assimilated Regulation 396/2005 refers to the limit of determination Assimilated Regulation 1107/2009 refers to the limit of quantification 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

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