REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for cycloxydim in various crops[1]

European Food Safety Authority[2]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, hereafter referred to as the evaluating Member State (EMS), received an application from company BASF SE to modify the existing MRLs for cycloxydim in a wide range of crops. Many of the MRL proposals have in the meanwhile been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues and implemented in the EU legislation. Only those crops for which an increase in the existing MRL for cycloxydim is still required according to the original application were considered by EFSA. According to EFSA, the data are sufficient to derive MRL proposals on beetroots, celeriacs, horseradishes, Jerusalem artichokes, parsnips, salsifies, swedes, aubergines, Brussels sprouts, head cabbages, Chinese cabbages, kales, escaroles, purslanes, beet leaves, rapeseeds, herbal infusions from roots and horseradish spices. Based on the risk assessment results, EFSA concludes that the intended EU uses of cycloxydim will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a public health concern.

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KEY WORDS

cycloxydim, various crops, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, cyclohexene oxime herbicide

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, hereafter referred to as the evaluating Member State (EMS), received an application from company BASF SE to modify the existing MRLs for the active substance cycloxydim in a wide range of crops in order to accommodate uses within the European Union (EU). The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA. These MRL proposals have in the meanwhile been evaluated by the JMPR and adopted as Codex limits (CXL) by the Codex Alimentarius Commission (CAC) in 2013. Since most of the CXLs have been transposed in the EU legislation by Regulation (EU) No 491/2014, EFSA has considered under the current assessment, only those crops for which the raising of the existing MRL for cycloxydim would still be required according to the original application.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) prepared under Directive 91/414/EEC, the Commission Review Report on cycloxydim, the conclusion on the peer review of the pesticide risk assessment of the active substance cycloxydim and the JMPR Evaluation report.

The toxicological profile of cycloxydim was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.07 mg/kg bw per day and an acute reference dose (ARfD) of 2 mg/kg bw.

The metabolism of cycloxydim in primary crops was investigated in the root (sugar beet), pulses/oilseeds (soybean) and cereals (maize) crop groups, using a single foliar application. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as "*cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl)glutaric acid S-dioxide (BH 517-TGSO2) and 3-hydroxy-3-(3-thianyl)glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim*". For the uses on the crops under consideration, EFSA concludes that the metabolism of cycloxydim is sufficiently addressed and the residue definitions agreed in the peer review are applicable. Sufficiently validated analytical methods are available to control residues of cycloxydim according to the enforcement residue definition at the LOQ of 0.05 mg/kg for each analyte.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals for beetroots, celeriacs, Jerusalem artichokes, parsnips, horseradishes, salsifies, swedes, aubergines, Brussels sprouts, head cabbages, Chinese cabbages, kales, escaroles, purslanes, beet leaves, rapeseeds, herbal infusions from roots and horseradish spices.

Studies investigating the nature of cycloxydim residues in processed commodities were assessed in the framework of the peer review. Under standard hydrolysis conditions, cycloxydim was almost totally degraded to metabolites covered by the common moiety analytical methods and therefore by the residue definitions proposed for primary crops. Processing studies on carrots were submitted and processing factors were proposed. However, lacking details of processing conditions, EFSA does not recommend the inclusion of the derived processing factors in Annex VI of Regulation (EC) No 396/2005. Processing studies will be reconsidered in the MRL review according to Article 12 of Regulation (EC) No 396/2005.

The occurrence of cycloxydim residues in rotational crops was investigated in the framework of the peer review. Based on the available information, it was concluded that significant residues of cycloxydim are unlikely to occur in rotational crops.

The calculated livestock dietary burdens indicate that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for all relevant livestock species. Considering that the dietary livestock burdens based on the uses authorised within EU are lower than the animal burdens estimated by the 2012 JMPR for the setting of CXLs in products of animal origin that have been recently transposed in the EU legislation, EFSA concludes that there is no need to change the existing MRL values set for animal products.

The consumer risk assessment was performed with a revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used STMR values as derived

from the submitted residue trials. Where a lower MRL or no MRL proposal was derived, the existing MRL was used as input value. For the remaining commodities of plant and animal origin, the existing MRLs as established in Regulation (EC) No 491/2014 were used as input values. Acute exposure assessment was undertaken only for the crops under consideration.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The Highest chronic intake accounted for 68 % of the ADI (FR, toddler). No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration. The highest acute exposure was calculated to be 8% the ARfD for celeriac (BE, Child).

EFSA concludes that the intended use of cycloxydim on beetroots, celeriacs, horseradishes, parsnips, salsifies, Jerusalem artichokes, swedes, aubergines, Brussels sprouts, head cabbages, Chinese cabbages, kales, escaroles, beet leaves, purslanes, rapeseeds, herbal infusions from roots and horseradish spices will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

SUMMARY TABLE

Code[(a)]	**Commodity**	**Existing EU MRL** (mg/kg)	**Proposed EU MRL** (mg/kg)	**Comment/Justification**
Enforcement residue definition: *cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl)glutaric acid S-dioxide (BH 517-TGSO2) and 3-hydroxy-3-(3-thianyl)glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim*				
0153030	Raspberries	0.05*	0.05*	No change. No residues expected since application after harvest of the fruits.
0154030	Currants	0.05*	0.05*	
0213010	Beetroots	0.2	0.9	NEU. Extrapolation from trials on carrots
0213030	Celeriacs	1	5	SEU. Extrapolation from trials on carrots
0213040	Horseradishes	0.2	0.9	NEU. Extrapolation from trials on carrots.
0213050	Jerusalem artichokes			
0213060	Parsnips			
0213090	Salsifies	0.2	1.5	NEU. Extrapolation from trials on carrots.
0213100	Swedes	0.2	0.9	NEU. Extrapolation from trials on carrots.
0231030	Aubergines	1.0	1.5	NEU and SEU. Extrapolation from tomatoes.
0242010	Brussels sprouts	3	6	NEU and SEU
0242020	Head cabbages	3	5	NEU and SEU
0243010	Chinese cabbages	2	3	NEU and SEU
0243020	Kale	3	3	NEU and SEU (no change)
0251030	Escaroles	0.5	1.0	NEU. Extrapolation from trials on lettuce.
0251040	Cress	0.5	0.5	No change. Extrapolation not supported (trials on open leaf varieties missing). Clarification of the GAPs requested.
0251050	Land cress			
0251060	Rockets, Rucola	0.5	0.5	
0251070	Red mustards	0.2	0.2	
0251080	Leaves/sprouts Brassica	0.2	0.2	
0252010	Spinaches	2	2	No change, since a lower MRL of 0.6 mg/kg is derived from the submitted trials.
0252020	Purslanes	0.5	0.6	NEU. Extrapolation from trials on spinaches
0252030	Beet leaves	0.2	0.6	

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
0300020	Lentils	5	5	No change, clarification of the GAPs requested
0401010	Linseed	7	7	
0401030	Poppy seed	0.2	0.2	
0401060	Rapeseeds	7	9	NEU and SEU
0633000	Herbal infusions from roots (dried)	0.05*	7	NEU. Extrapolation from trials on carrots, applying a default dehydration factor of 8.
0840040	Horseradish (spices)	0.05*	7	

(a): According to Annex I of Regulation (EC) No 396/2005.

(*): Indicates that the MRL is set at the limit of analytical quantification.

TABLE OF CONTENTS

Abstract 1
Summary 2
Table of contents 5
Background 6
Terms of reference 6
The active substance and its use pattern 7
Assessment 8
1. Method of analysis 8
1.1. Methods for enforcement of residues in food of plant origin 8
1.2. Methods for enforcement of residues in food of animal origin 8
2. Mammalian toxicology 8
3. Residues 9
3.1. Nature and magnitude of residues in plant 9
3.1.1. Primary crops 9
3.1.2. Rotational crops 16
3.2. Nature and magnitude of residues in livestock 17
3.2.1. Dietary burden of livestock 17
4. Consumer risk assessment 18
Conclusions and recommendations 20
References 22
Appendices 24
Appendix A. Good Agricultural Practice (GAPs) 24
Appendix B. Pesticide Residue Intake Model (PRIMo) 26
Appendix C. List of metabolites and related structural formula 28
Abbreviations 30

BACKGROUND

Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[4], repealed by Regulation (EC) No 1107/2009[5], shall submit to a Member State, when appropriate, an application to set or to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Germany, hereafter referred to as the EMS, received an application from the company BASF SE[6] to modify the existing MRLs for the active substance cycloxydim in a wide range of crops. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 04 December 2013.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013- 00984 and the following subject:

Cycloxydim - Modification of MRLs in a wide range of commodities

At the time of the assessment of the MRL application, the EMS Germany proposed to modify the existing MRLs of cycloxydim in a wide range of crops. However, many of the MRL proposals have in the meanwhile been evaluated by the JMPR, followed by the adoption of the respective CXLs by the Codex Alimentarius Commission in 2013. Since many of these CXLs have been taken over in the EU legislation by Regulation (EU) 491/2014[7], under the current assessment. **EFSA has considered only those crops for which an increase in the existing MRL for cycloxydim is still required according to the original application.** EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided. In this particular case the deadline for providing the reasoned opinion was 06 June 2014

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

[6] BASF SE, P.O., Box 120, Limburgerhof, 67114, Germany

[7] Commission Regulation (EU) No 491/2014 of 5 May 2014 amending Annexes II and III to regulation (EC) No 396/2005 of the European Parliament and of teh Council as regards maximum residue levels for ametoctradin, azoxystrobin, cycloxydim, cyfluthrin, dinotefuran, fenbuconazole, fenvalerate, fludioxonil, fluopyram, flutriafol, fluxapyroxad, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products. OJ L 146, 16.5.2014, p.1-91.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Cycloxydim is the ISO common name for (5*RS*)-2-[(*EZ*)-1-(ethoxyimino)butyl]-3-hydroxy-5-[(3*RS*)-thian-3-yl]cyclohex-2-en-1-one (IUPAC). Cycloxydim is racemic having a chiral centre in the heterocycle whereas the carbocycle is essentially symmetric because of the facile tautomery of the vinologous acid. The ratio of *E*:*Z* in technical material is 99.2: 0.8; the ratio *R*:*S* is 1:1 (racemic mixture) (EC, 2014). Both enantiomers have comparable herbicidal activity, complementary in some respects (Austria, 2009). The chemical structure of the compound is reported below.

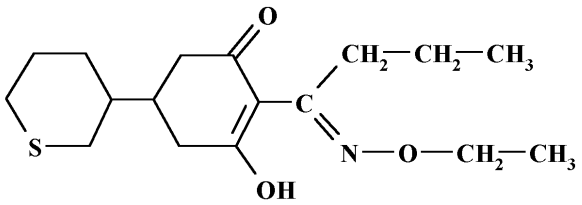

Figure 1: Structure of cycloxydim. Molecular mass: 325.5

Cycloxydim is a systemic foliar herbicide. The active substance is used to control annual and perennial grass weeds as well as volunteer cereals in broadleaf crops such as sugar beets, oilseed rape, potatoes, beans and cycloxydim tolerant maize. After uptake via the aerial parts of the plants it acts as an inhibitor of acetyl-CoA-carboxylase in susceptible species.

Cycloxydim was evaluated in the framework of Council Directive 91/414/EEC with Austria designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2011/4/EU[8] which entered into force on 01 June 2011 for use as herbicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[9] cycloxydim is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The submission by 31 May 2013 of further information concerning the analytical methods for cycloxydim residues in plant and animal products was confirmed by Directive 2011/4/EU. According to EU review report of March 2014, the enforcement methods for residues in plant and animal matrices have been submitted and are considered adequate; the Standing Committee on the Food Chain and Animal Health considers that the issues pertinent to the request for confirmatory data have been fully addressed (EC, 2014).

The representative uses evaluated in the peer review were outdoor foliar applications against perennial grasses in oilseed rape, sugar beet, potato, bean, and tolerant maize (by natural plant breeding). The Draft Assessment Report (DAR) of cycloxydim has been peer reviewed and an EFSA conclusion is available (EFSA, 2010).

The EU MRLs for cycloxydim are established in Annex III of Regulation (EC) No 396/2005. Most of the MRLs assessed by the EMS under the current application have been evaluated by the JMPR, followed by the adoption of the respective CXLs by the Codex Alimentarius Commission in 2013. Those CXLs for which no data gaps and consumer intake concerns have been identified have been taken over in the EU legislation by means of Commission Regulation (EU) 491/2014.

The details of the intended GAPs for cycloxydim are given in Appendix A. EFSA disregarded the GAPs for those crops for which no modification of the MRL was proposed by the EMS and for which higher MRLs have been established in Regulation (EC) No 491/2014.

[8] Commission Directive 2011/4/EU of 20 January 2011 amending Council Directive 91/4141/EEC to include cycloxydim as active substance and amending Decision 2008/934/EC. OJ L 18, 21.1.2011, p.30-33

[9] Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1-186.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Germany, 2013), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Austria, 2009), the Commission Review Report on cycloxydim (EC, 2010c, 2014), the conclusion on the peer review of the pesticide risk assessment of the active substance cycloxydim (EFSA, 2010) and the JMPR Evaluation report (FAO, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[10] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of cycloxydim residues in plant commodities were assessed in the DAR and during the peer review. It was concluded that fully validated methods of analysis for products of plant origin are not available and have to be submitted (EFSA, 2010). In 2013 the applicant submitted the required data which were assessed by the RMS (Austria, 2013). According to the EU review report, it was concluded that the submitted methods are adequate to determine residues of cycloxydim in plant matrices according to the proposed enforcement residue definition "*cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl)glutaric acid S-dioxide (BH 517-TGSO2) and/or 3-hydroxy-3-(3-(thianyl)glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim*" (EC, 2014).

The proposed enforcement method is a common moiety method referenced 407/1, which determines cycloxydim (including all non-hydroxylated metabolites that can be oxidised to BH 517-TGSO2) and its metabolite BH 517-5-OH-TSO2 that can be oxidised to BH 517-5-OH-TGSO2 (Austria, 2009). With respect to the confirmatory data the applicant submitted validation data to prove the applicability of the primary method for the determination of further non- hydroxylated metabolites of cycloxydim, such as BH 517-TSO, BH 517-T1SO and BH 517-T2SO, and a hydroxylated metabolite BH 517-5-OH-TSO (Austria, 2013). The principle of the method involves the extraction of metabolites using isopropanol/distilled water mixture, oxidation of parent compound and relevant metabolites with H_2O_2 under alkaline conditions to BH 517-TGSO2 and BH 517-5-OH-TGSO2. The final determination is performed using HPLC-MS/MS.

The validation data indicate that the method is sufficiently validated to control residues of cycloxydim according to the enforcement residue definition in high water-, high acid-, high oil content[11] and dry commodities at the LOQ of 0.05 mg/kg for each analyte.

1.2. Methods for enforcement of residues in food of animal origin

Analytical methods for the determination of residues in food of animal origin were not assessed in the current application, since no MRL proposals were derived for commodities of animal origin.

2. Mammalian toxicology

The toxicological profile of the active substance cycloxydim was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2010). The data were sufficient to derive toxicological reference values for cycloxydim which are compiled in Table 2-1.

[10] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

[11] The method has not been validated to determine additional cycloxydim metabolites (B517-TSO, BH 517-T1SO and BH 517- T2SO, BH 517-5-OH-TSO) in high oil content matrices according to the confirmatory data

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Cycloxydim					
ADI	EFSA	2010	0.07 mg/kg bw per day	Rat, 24 and 18 months	100
ARfD	EFSA	2010	2 mg/kg bw	Rabbit and rat, developmental NOAEL in the teratogenicity studies	100

Although the NOAEL on which the ARfD is derived, from adverse effects in foetuses resulting from exposure during pregnancy, the ARfD is applicable to the general population and not only to women of child-bearing age according to EU policy.

It is noted that JMPR established an ADI of 0.07 mg/kg bw per day for the compound and an ARfD of 2 mg/kg bw set for women of childbearing age; for the general population setting of an ARfD was considered not necessary for the active substance (FAO, 2009).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of cycloxydim was investigated in the framework of the peer review under Directive 91/414/EEC in the root (sugar beet), pulses/oilseeds (soybean) and cereal crop groups (maize), using a single foliar application and ^{14}C-labelling on the cyclohexanone moiety (Austria, 2009, EFSA, 2010). The overview of the metabolism study designs is presented in Table 3-1.

Table 3-1: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling[(a)] DAT (days)	Comments
Root	Sugar beet	Nutrient solution : 1× 200 g/ha	7, 22, 46, 77, 119	Root uptake
		Foliar treatment 1× 650 g/ha	1, 94	
Cereals	Maize*	Foliar treatment: a) 1× 400 g/ha (BBCH 22-23) b) 1× 800 g/ha (BBCH 61-67)	a) 72, 96 b) 54	* naturally tolerant maize
Pulses/ Oilseeds	Soybean	Foliar treatment: a) 1× 200 g/ha at fruit setting or at 3 leaf or 2 leaf stage b) 1× 1000 g/ha (at flowering)	a) 45 or 71 or 82 b) 69	

(a): DAT, Days after treatment.

The active substance is rapidly and intensively metabolised and the parent cycloxydim is never detected in plants except in trace amounts when samples are collected just after application. The metabolism proceeds first by oxidation to the sulphoxide and sulphone metabolites BH 517-TSO and BH 517-TSO2. Further loss of the alkyl side chain at the oxime group gives the imine metabolites BH 517-T1SO and BH 517-T1SO2, and the oxazole metabolites BH 517-T2SO and BH 517-T2SO2 are formed by Beckman rearrangement. All these metabolites are also found in their hydroxylated forms (BH 517-5-OH-TSO, BH 517-6-OH-T2SO…). In addition, cleavage of the cyclohexenone ring results in substituted glutaric acid derivative metabolites (BH 517-TGSO, BH 517-TGSO2).

A common moieties method was developed for plant matrices where residues are quantified after oxidation to BH 517-TGSO2 and BH 517-5-OH-TGSO2 or to their methyl esters. Considering the ability of these analytical methods to quantify a significant part of the residues in plants, the following definition was proposed by the peer review for monitoring and risk assessment; "*cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl)glutaric acid S-dioxide (BH 517-TGSO2) and 3-hydroxy-3-(3-thianyl)glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim*" (EFSA, 2010).

The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review. For the uses on the crops under consideration, EFSA concludes that the metabolism of cycloxydim is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

a. Raspberries and blackcurrants

NEU GAP: 1× 600 g/ha, soil application after harvest of the fruits

No residue trials have been submitted as the EMS expects "no-residue" situation in the crop from the intended use pattern. The EMS thus proposes to set the MRL at 0.09 mg/kg. Since the application of the active substance is proposed after the harvest, residues are not expected to be present in the fruits that will be present on the plant the following year, and therefore, EFSA would not recommend the change of the MRL value currently set at the LOQ of 0.05 mg/kg under Regulation (EC) No 396/2005.

b. Beetroots, parsnips, swedes, horseradishes, Jerusalem artichokes, herbal infusions from roots, horseradish spices

NEU GAP: outdoor 1× 500 g/ha, (from BBCH 11) PHI 35 days (all crops under point b.)

The EMS proposes to derive the MRLs from residue trials conducted on carrots in the Netherlands, France, Belgium and Germany in 1991 and 2009. Trials were designed as decline trials and provide information on the residue situation in the crop according to the intended GAP. The number of residue trials is sufficient to propose by extrapolation from carrots an MRL of 0.9 mg/kg on beetroots, parsnips, swedes, horseradish and Jerusalem artichokes covering the NEU uses.

Since the MRL applies to the dried commodity, an MRL of 7 mg/kg is derived for herbal infusions from roots and horseradish spices, by extrapolation from the trials on carrots and applying a default dehydration factor of 8 (based on a dry matter content of *ca* 12% in fresh roots and *ca* 90% in dried roots).

SEU GAP: outdoor 1× 400 g/ha, no PHI proposed (beetroots only)

The EMS proposes to derive an MRL proposal for beetroot from the trials conducted in SEU on carrot. However, either a growth stage at last application or a PHI have not been proposed and therefore, it is not known which residue data should be selected to derive an MRL proposal. Pending the clarification of the SEU GAP for beetroot, no MRL is proposed in support of the SEU uses.

c. Celeriacs

NEU GAP: outdoor 1× 500 g/ha (from BBCH 11); no PHI proposed

The applicant submitted four residue trials on celeriac which were performed in the Netherlands, United Kingdom, France and Germany in 2007 and 2009. However, since a growth stage at the last application or a PHI has not been proposed, it is not known which data should be selected. Therefore an MRL is not proposed for NEU. Clarification of the NEU GAP is requested.

SEU GAP: outdoor 1× 450 g/ha; PHI 28 days

The applicant submitted four SEU trials on celeriac, which were not performed according to the intended GAP and therefore not considered further. The EMS proposed to derive an MRL for celeriac in SEU by extrapolation from eleven residue trials on carrots performed in France, Greece, Italy and Spain in 2003, 2006 and 2009. Four trials were disregarded by EFSA since analyses were not made on roots but on the whole plants. Since celeriac is a minor crop, an MRL of 5 mg/kg is derived from the remaining seven trials and extrapolated to celeriac.

d. Salsifies

GAP NEU: 1× 600 g/ha, PHI 28 days.

Residue trials on salsify have not been submitted and the EMS proposes to derive an MRL proposal by extrapolation from eight residue trials on carrots performed in the Netherlands, France, Belgium and Germany in 1991 and 2009. However, four trials do not provide residue data at the intended PHI of 28 days and therefore, an MRL of 1.5 mg/kg is derived for salsify from the four remaining trials.

e. Aubergines

NEU GAP: outdoor 1× 500 g/ha, (from BBCH 13) PHI 35 days
SEU GAP: outdoor 1× 450 g/ha, PHI 28 days

Eight NEU and eight SEU trials conducted on tomato according to the respective GAPs have been submitted. An MRL proposal of 1.5 mg/kg is derived from the trials conducted according to NEU GAP and extrapolated to aubergines. This MRL cover the SEU uses of the active substance on aubergines.

f. Brussels sprouts

NEU GAP: outdoor 1× 450 g/ha, PHI 56 days
SEU GAP: outdoor 1× 600 g/ha, PHI 60 days

The applicant submitted eight NEU residue trials on Brussels sprouts performed in France, United Kingdom, the Netherlands, Sweden and Belgium in 2006 and 2007 and four SEU trials conducted in Spain, France, Italy and Greece in 2007. Since the NEU and SEU trials were conducted according to the same use pattern (1× 500 g/ha, PHI 48 to 51 days) and in compliance with the supported GAP considering a ±25 % tolerance rule, both datasets were merged together to derive a MRL proposal of 6 mg/kg for Brussels sprouts.

g. Head cabbages

NEU GAP: outdoor 1× 600 g/ha, PHI 28 days

A total nine residue trials on head cabbage, performed in Belgium, France, Sweden, United Kingdom and Germany in 2002 and 2007 were submitted. Data are sufficient to derive a MRL proposal of 5 mg/kg.

SEU GAP: outdoor 1× 450 g/ha, PHI 28 days

Five SEU overdosed trials were submitted (600 g/ha) but leading to a lower MRL proposal of 4 mg/kg than the NEU trials. Head cabbage is a minor crop in SEU, and therefore EFSA concludes than the use of cycloxydim in SEU is covered by the MRL derived in NEU.

h. Kales, Chinese cabbages

NEU and SEU GAP: outdoor 1× 500 g/ha, PHI 42 days

The applicant submitted four NEU residue trials on kale, performed in Germany, United Kingdom, the Netherlands and France in 2007 and 2009 and two SEU trials on Chinese cabbage and two trials on kale performed in Italy, Spain, Greece and France in 2007 and 2009. Considering that both crops belong to the leafy brassica crop group and since the NEU and SEU datasets are not significantly different (U-test, 5%), EFSA merged both datasets to derive an MRL proposal of 3 mg/kg for kale and Chinese cabbage. It is noted that the MRL proposal for kale is identical to the existing EU MRL.

i. Escaroles

NEU GAP: outdoor 1× 500 g/ha, PHI 21 days

Residue trials on escarole were not provided. The EMS proposes to derive the MRL from twelve GAP compliant trials conducted on head lettuce in Denmark, France, Germany and Sweden in 2002 and 2005. The number of submitted trials is sufficient to derive a MRL proposal of 1 mg/kg extrapolated to escarole.

j. Baby leaves, land cress, rocket species, red mustard, leaves and sprouts of Brassica spp.

NEU GAP: outdoor 1× 500 g/ha, no PHI

No residue trials were submitted on baby leaf lettuce. The EMS proposes to combine residue data on head lettuce (12 trials) and spinach (4 trials) and to extrapolate the derived MRL to cress, land cress, rocket species, red mustard and leaves and sprouts of *Brassica spp*. According to EU guidance document, such an extrapolation is not supported, since a minimum of 8 residue trials on open leaf varieties must be provided (EC, 2011). Moreover, since a growth stage at last application or a PHI has not been proposed, the setting of an MRL is not possible and a clarification of the GAP is required.

k. Spinaches (NEU and SEU)**, purslanes** (NEU) **and beet leaves** (NEU)

NEU GAP: outdoor 1× 500 g/ha, (from BBCH 11) PHI 21 day

The applicant submitted four GAP compliant residue trials on spinaches, which were performed in France and Germany in 2007. Residues ranged from <0.09 to 0.30 mg/kg, resulting in an MRL proposal of 0.6 mg/kg, extrapolated to purslane and beet leaves. It is noted that this MRL is lower than the existing EU MRL of 2 mg/kg set for spinach.

SEU GAP: outdoor 1× 600 g/ha, PHI 30 days

The applicant submitted four GAP compliant residue trials on spinaches, which were performed during the growing season 2007. Residues were in the ranged of <0.09 to 0.20 mg/kg in the trials conducted in Spain, Greece and Italy and 2.4 mg/kg in France. This high value was explained by the applicant as due to adverse climatic conditions (low temperatures in November). Based on this highest value, the EMS proposes an MRL of 3 mg/kg for spinaches (although a value of 6 mg/kg is suggested by the OECD calculator). EFSA is of the opinion that one “abnormal” value resulting from adverse climatic conditions should not be taken as a basis for the MRL setting and therefore proposes to remain with the current MRL value of 2 mg/kg on spinaches.

l. Lentils, lupins

SEU GAP: 1× 400 g/ha, no PHI, no growth stage at the last application

The EMS proposes to derive a MRL of 20 mg/kg for cycloxydim in lentils and lupins from the combined data set on dry peas and dry beans and reflecting the NEU GAP on these crops (1x 600 g/ha, PHI 60 days for peas and no PHI specified for beans). However, the notified GAP for lentils provides information neither on the PHI nor the growth stage at the last application and therefore it is not known which data should be selected for deriving an MRL proposal for lentils. Regarding lupins, the applicant has not notified a GAP. Pending clarification on the GAPs, no MRL proposals can be derived for lentils and lupins.

m. Linseeds

NEU GAP: 1× 600 g/ha, no PHI, no growth stage at the last application

Residue trials on linseeds have not been submitted. The EMS proposes to use the residue data on oilseed rape to extrapolate to linseed. However, since the notified GAP do not provide information neither on the PHI interval nor the growth stage at the last application, the GAPs on linseed and rapeseed cannot be compared. A MRL is therefore not proposed and the applicant is requested to clarify the GAPs.

n. Poppy seeds

NEU GAP: 1× 400 g/ha, no PHI, no growth stage at the last application

Residue trials on poppy seed have not been submitted and the EMS proposes to use the residue data on oilseed rape to extrapolate to poppy seed. However, since the notified GAP on poppy seed do not provide information neither on the PHI interval nor the growth stage at the last application, the GAPs on poppy seed and rapeseed cannot be compared. The applicant has to clarify the GAP for poppy seed. No MRL proposal is derived.

o. Rapeseeds

NEU GAP: 1× 500 g/ha, PHI 84 days

Twelve residue trials on oilseed rape were submitted but four were disregarded as either under- or over-dosed (230; 1300 g/ha). An MRL proposal of 9 mg/kg is derived from the eight remaining trials

conducted in Germany, the Netherlands, France, United Kingdom and Belgium in 1992 and 2009 in compliance with the supported GAP.

SEU GAP: 1× 600 g/ha, PHI 100 days

Only seven GAP compliant residue trials conducted in Italy, Spain and France in 2003 were submitted. However, since the submitted dataset results in a lower MRL proposal (8 mg/kg) an additional trial is not requested and it is concluded that the MRL derived from the northern dataset cover the use of cycloxydim in southern EU.

The results of the residue trials, the related risk assessment input values (HR, STMR) and the MRL proposals are summarised in Table 3-2.

The storage stability of cycloxydim in primary crops was investigated in the DAR under Directive 91/414/EEC (Austria, 2009). The storage stability studies were conducted using samples spiked with the parent cycloxydim or with BH 517-TSO and BH 517-T2SO2, or with BH 517-5-OH-TSO2, these compounds being regarded as representative of the hydroxylated and non-hydroxylated metabolites identified in plants. The metabolites BH 517-TSO, BH 517-T2SO2 and BH 517-5-OH-TSO2 were stable for up to 2 years in high water (pineapple sugar beet) and high oil (rapeseed) content matrices. Cycloxydim and BH 517-5-OH-TSO2 were stable for up to 2 years in high starch (maize), high oil (oilseed), high water (pea) and high acid (strawberry) content matrices, using a common moieties analytical method (EFSA, 2010). As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical methods used to analyse the supervised residue field trial samples have been sufficiently validated and were proven to be fit for the purpose (Germany, 2013). The samples of the submitted supervised residue field trials were analysed according to the proposed enforcement residue definition. The residue data were provided also for the metabolite BH 517-TSO.

EFSA concludes that the data are sufficient to propose the following MRLs:

- 0.9 mg/kg Beetroots, horseradishes, Jerusalem artichokes, parsnips, swedes, NEU (no proposal for SEU), extrapolation from trials on carrots
- 5 mg/kg Celeriacs, NEU (no proposal for SEU), extrapolation from trials on carrots
- 1.5 mg/kg Salsifies, NEU, extrapolation from trials on carrots
- 1.5 mg/kg Aubergines, NEU and SEU, extrapolation from trials on tomato
- 6 mg/kg Brussels sprouts, SEU and NEU
- 5 mg/kg Head cabbages, NEU and SEU
- 3 mg/kg Chinese cabbages, Kales, SEU and NEU
- 1 mg/kg Escarole, NEU (extroplation from trials on lettuce)
- 0.6 mg/kg Purslanes, beet leaves, NEU (extrapolation from trials on spinach)
- 9 mg/kg Rapeseeds, NEU and SEU
- 7 mg/kg Herbal infusions from roots and horseradish spice (dried), NEU (extrapolation from trials on carrot, applying a default dehydration factor of 8)

For baby leaves, cress, land cress, rockets, red mustards, leaves and sprouts of Brassica spp., lentils, linseeds and poppy seeds various data gaps were identified which precluded EFSA deriving MRL proposals.

Table 3-2: Overview of the available residues trials data

Crop (Trial GAPs)	**Region Indoor** (a)	**Individual trial results** (mg/kg) (b)	**Recommendations/comments** €	**MRL** proposal (mg/kg)	**HR** (mg/kg) (d)	**STMR** (mg/kg) €
Carrots (*ca* 1× 500 g/ha, PHI 35 d)	NEU	0.12; 0.14; 0.19; 0.25; 0.22; 0.35; 0.38; 0.53	MRL $_{OECD}$=0.83/0.9 **Extrapolation to beetroots, parsnips, swedes, horseradish and Jerusalem artichokes**	0.9	0.53	0.24
			Extrapolation to herbal infusions from roots, and horseradish spices applying a dehydration factor of 8	7	4.24	1.88
Carrots (1× 450 g/há, PHI 28 d)	SEU	0.18; 0.29; 0.33; 0.44; 0.47; 1.07; 2.99	MRL $_{OECD}$=4.8/5.0 **Extrapolation to celeriacs** (minor crop)	5.0	2.99	0.44
Carrots (*ca* 1× 500 g/ha, PHI 28 d)	NEU	0.32; 0.42; 0.44; 0.64	MRL$_{OECD}$: 1.4/1.5 **Extrapolation to salsifies** (minor crop)	1.5	0.64	0.43
Tomatoes (1× 500 g/ha, PHI 35 d)	NEU	0.21; 0.39; 0.39; 0.45; 0.52; 0.52; 0.59; 0.84	MRL derived from the trials conducted according to the NEU GAP. MRL$_{OECD}$: 1.5/1.5	1.5	0.84	0.48
Tomatoes (1× 450 g/ha, PHI 28 d)	SEU	0.12; 0.19; 0.26; 0.32; 0.36; 0.39; 0.43; 0.51	**Extrapolation to aubergines**	1	0.51	0.34
Head cabbages (1× 600 g/ha, PHI 28 d)	NEU	<0.09; 0.40; 0.50; 0.50; 0.63; 0.74; 1.04; 1.26; 3.03	MRL $_{OECD}$= 4.4/5.0	5.0	3.03	0.63
Head cabbages (1× 450 g/ha, PHI 28 d)	SEU	0.88; 1.05; 1.23; 1.40; 1.73	Southern trials slightly overdosed (600 g/ha) but resulting in a lower MRL proposal than northern trials. MRL $_{OECD}$= 3.8/4.0	4.0	1.73	1.23
Brussels sprouts (1× 500 g/ha, PHI 48 to 51 d)	NEU	0.69; 0.85; 1.03; 1.08; 1.29; 1.70; 2.61; 3.57	NEU and SEU datasets not significantly different (U-Test, 5%). MRL derived from the merged data. MRL $_{OECD}$:5.60/6.0	6.0	3.57	1.50
	SEU	0.32; 1.9; 1.92; 2.96				
Kales, Chinese cabbages (1× 500 g/ha, PHI 42 d)	NEU	Kale: <0.09; 0.61; 0.97; 1.80	NEU and SEU datasets not significantly different (U-test, 5%); MRL, derived from the merged data. MRL $_{OECD}$:3.0/3.0	3.0	1.80	0.75
	SEU	Kale: 0.89; 0.94 Chinese cabbage: <0.09; 0.23				
Head lettuces (1× 500 g/ha, PHI 21 d)	NEU	<0.09; 0.11; 0.12; 0.17; 0.21; 2 × 0.26; 2 × 0.34; 0.35; 0.46; 0.73	MRL $_{OECD}$:1.0/1.0 **Extrapolation to escaroles**	1.0	0.73	0.26

Crop (Trial GAPs)	**Region Indoor** (a)	**Individual trial results** (mg/kg) (b)	**Recommendations/comments** €	**MRL** proposal (mg/kg)	**HR** (mg/kg) (d)	**STMR** (mg/kg) €
Spinaches (1× 500 g/ha; PHI 21 d)	NEU	<0.09; 2× 0.12; 0.30	MRL $_{OECD}$:0.54/0.60 **Extrapolation to purslanes and beet leaves**	0.6	0.3	0.12
Spinaches (1× 600 g/ha; PHI 30 d)	SEU	<0.09; 0.19; 0.20	One value of 2.4 mg/kg observed in a trial conducted in France and resulting from adverse climatic conditions (low temperature) disregarded by EFSA.	-	-	-
Rapeseeds (1× 500 g/ha, PHI 84 d)	NEU	1.02; 1.49; 1.90; 1.91; 2.53; 3.39; 4.6; 5.28	MRL $_{OECD}$:8.9/9.0	9.0	5.28	2.22
Rapeseeds (1× 600 g/ha, PHI 100 d)	SEU	0.54; 0.77; 1.61; 2.77; 2.85; 3.10; 3.98	MRL $_{OECD}$:7.4/8.0	8.0	3.98	2.77

(a): **NEU:** Outdoor trials conducted in northern Europe, **SEU:** Outdoor trials conducted in southern Europe, **Indoor:** indoor EU trials or **Country code:** if non-EU trials (EC, 2011).
(b): Individual residue levels considered for MRL calculation are reported in ascending order as following: 3× <0.01, 0.01, 6× 0.02, 0.04, 0.08, 2× 0.10, 0.15, 0.17
Underlined value: residue value taken at a longer PHI
(c): Any information/comment supporting the decision and OECD MRL calculation (e.g. MRL$_{OECD}$: 0.82/0.9; unrounded/rounded values)
(d) **STMR:** Median value of the individual trial results according to residue definition for risk assessment.
(e): **HR**: Highest value of the individual trial results according to the residue definition for risk assessment.
*: Indicates that the MRL is proposed at the Limit of Quantification (LOQ).

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of cycloxydim was investigated under standard hydrolysis conditions. The studies were reported in the DAR and in the conclusion on the peer review (Austria, 2009; EFSA, 2010). Cycloxydim was almost totally degraded under the standard hydrolysis conditions, mainly to the oxazole metabolite BH 517-T2S (75 to 94 % TRR) and to a lesser extent to its sulfoxide BH 517-T2SO. All these metabolites are covered by the common moiety methods and therefore by the proposed plant residue definitions (EFSA, 2010).

In the framework of the peer review, processing studies were provided and processing factors (PF) were derived for various potato, pea and rapeseed fractions (EFSA, 2010). Two studies on rapeseeds were reported in the evaluation report submitted by the EMS (Germany, 2013), while additional information was available in the DAR and assessed in the framework of the peer review (EFSA, 2010). All available data and median PFs derived for rapeseeds were reported in Table 3-3.

Under the current application the processing studies with carrots were submitted as a part of residue trials. Information on the processing conditions was not provided. Samples were collected in four trials conducted with a single application at 1130 to 1240 g/ha (PHI of 28 days) and processed into cooked, canned carrot and carrot juice. Derived processing factors are summarized in the table below.

Table 3-3: Overview of the available processing studies

Raw commodities/ Processed commodity	Number of studies	individual PF values	Median PF	Comments
Enforcement residue definition: *cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl)glutaric acid S-dioxide (BH 517-TGSO2) and 3-hydroxy-3-(3-thianyl)glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim*				
Carrot/cooked	4	0.56, 0.57, 0.79, 0.83	0.68	Study details not provided.
Carrot/canned	4	0.25, 0.28, 0.32, 0.44	0.30	
Carrot/juice	4	0.33, 0.42, 0.47, 0.59	0.44	
Carrot/peeled	4	0.43, 0.77, 0.96, 1.00	0.87	
Rapeseed/refined oil	4	0.02, 0.03, 0.05, 0.09	0.04	Studies already assessed in the framework of the peer review (EFSA, 2010).
Rapeseed/crude oil	6	0.10, 0.10, 0.11, 0.14, 0.16, 0.26	0.12	
Rapeseed/press cake meal	6	1.04, 1.19, 1.59, 1.73, 1.95, 2.08	1.66	
Rapeseed/press cake	4	0.71, 1.14, 1.24, 1.50	1.18	

Lacking details of processing study conditions for carrots, EFSA does not recommend the inclusion of the derived processing factors in Annex VI of Regulation (EC) No 396/2005. All processing studies will be reconsidered in the MRL review according to Article 12 of Regulation (EC) No 396/2005

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Many crops under consideration can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed.

According to the degradation studies, cycloxydim exhibits a very low persistence in soil ($DT_{90\ lab}$=8.6 days). The major soil metabolite is the sulfoxide metabolite BH 517-TSO, which exhibits also a low persistence in soil (max $DT_{90\ field}$=46 days). Considering the xwfast degradation of cycloxydim and its metabolite in the soil, no further studies investigating the nature and magnitude of the compound uptake in rotational crops are required (EC, 1997c).

However, a metabolism of cycloxydim in rotational crops was provided in the framework of the peer review and it was concluded that the metabolic pathway in succeeding crops is similar to the primary crop metabolism and that the same residue definition applies. Moreover, the TRR observed in crop commodities in this rotational crop study were low, confirming that no residues of cycloxydim or its metabolites above the LOQ are expected in rotational crops (EFSA, 2010).

3.2. Nature and magnitude of residues in livestock

Since swedes, head cabbage, kale and rapeseed and their by-products can be fed to livestock, the nature and magnitude of cycloxydim residues in livestock has to be assessed in the framework of this application (EC, 1996).

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology (EC, 1996). The input values for the dietary burden calculation were selected according to the latest FAO recommendations (FAO, 2009 a, b) considering the livestock intake from rapeseed, head cabbage, kale, swedes and from all following feed products on which existing EU MRLs were set above the LOQ in the EU legislation: apples (0.1 mg/kg), potatoes (3 mg/kg), turnips (1 mg/kg), dry beans and peas (30 mg/kg), lupin (5 mg/kg), linseed (7 mg/kg), peanuts (0.2 mg/kg), sunflower seed (6 mg/kg), cotton seed (0.5 mg/kg), soya bean (80 mg/kg), maize (0.2 mg/kg) and sugar beet (0.5 mg/kg). In order to account for the transfer of residues in processed feed commodities, the following processing factors (PF) were applied:

- Default PF of 2.5 for apple pomace, 1.3 for cotton seed and soya bean meal and 2 for linseed, peanut and sunflower meal,
- PF of 1.62 for rapeseed meal (Table 3-3).

Input values and results of the dietary burden calculations are summarised in Table 3-4 and Table 3-5 respectively. In addition, the calculated animal burdens considered by the 2012 JMPR for the setting of CXL values in products of animal origin (FAO, 2013) that were transposed in the EU legislation by Regulation (EU) No 491/2015 are reported in Table 3-5.

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Risk assessment residue definition: *cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl)glutaric acid S-dioxide (BH 517-TGSO2) and 3-hydroxy-3-(3-thianyl)glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim*				
Swedes	0.24	STMR (Table 3-2)	0.53	HR (Table 3-2)
Head cabbage	1.23	STMR (Table 3-2)	3.03	HR (Table 3-2)
Kale	0.75	STMR (Table 3-2)	1.80	HR (Table 3-2)
Rapeseed meal	4.5	STMR (Table 3-2) × PF (1.66)	4.5	STMR (Table 3-2) × PF (1.66)
Turnips	1	MRL	1	MRL
Apple pomace	0.25	MRL*PF (2.5)	0.25	MRL*PF (2.5)
Maize	0.09	STMR (FAO, 2013)	0.09	STMR (FAO, 2013)
Dry beans	4.4	STMR (FAO, 2013)	4.4	STMR (FAO, 2013)
Dry peas	5.6	STMR (FAO, 2013)	5.6	STMR (FAO, 2013)
Lupin	5	MRL	5	MRL
Potatoes	0.74	STMR (FAO, 2013)	1.6	HR (FAO, 2013)

Commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Sugar beet	0.5	MRL	0.5	MRL
Cotton meal	0.65	MRL × PF (1.3)	0.65	MRL*PF (1.3)
Peanut meal	0.4	MRL × PF (2)	0.4	MRL*PF (2)
Soya meal	16.9	STMR (FAO, 2013) × PF (1.3)	16.9	STMR (FAO, 2013) * PF (1.3)
Sunflower meal	0.75	STMR (FAO, 2013) × PF (2)	0.75	STMR (FAO, 2013)*PF (2)
Linseed meal	3.8	STMR (FAO, 2013) × PF (2)	3.8	STMR (FAO, 2013) *PF (2)

Table 3-5: Results of the dietary burden calculation

Animals	Median burden (mg/kg bw/d)	Maximum burden (mg/kg bw/d)	Highest contributing commodity[(a)]	Maximum burden (mg/kg DM)	Trigger exceeded (Y/N)	Maximum JMPR 2012 (mg/kg DM)
Risk assessment residue definition: *cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl)glutaric acid S-dioxide (BH 517-TGSO2) and 3-hydroxy-3-(3-thianyl)glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim*						
Dairy cattle	0.375	0.382	Soya bean meal	10.5	Y	22.6[(b)]
Beef cattle	0.538	0.555	Turnips	12.9	Y	26.8[(c)]
Poultry	0.376	0.385	Turnips	6.1	Y	10.9[(b)]
Pigs	0.449	0.465	Turnips	11.6	Y	[(d)]

(a): Calculated for the maximum dietary burden
(b): Based on the EU livestock dietary intakes.
(c): Based on the Australian livestock dietary intakes.
(d): Cattle dietary burden taken into account for the setting of MRL for "mammals other than marine mammals".

The calculated livestock dietary burdens indicate that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for all relevant livestock species and are mainly driven by the uses on soya and turnips.

Considering that the dietary livestock burdens based on the uses authorised within EU are lower than the animal burdens estimated by the 2012 JMPR for the setting of CXLs in products of animal origin that have been transposed in the EU legislation by Regulation (EU) 491/2014, EFSA concludes that there is no need to change the MRL values set for animal products at EU level.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population [12] (EFSA, 2007).

For the calculation of the chronic exposure, EFSA used median residue values (STMR) derived from the residue trials on the crops under consideration (see Table 3-2). Where lower MRL or no MRL values were derived from the submitted trials, the existing MRL was used as input value. For the remaining commodities of plant and animal origin, the existing MRLs as established by Regulation (EU) No 491/2014 were taken as input values. For several crops, the STMR values corresponding to the CXL available from the JMPR evaluation (FAO, 2013) were considered.

[12] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Risk assessment residue definition: *cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl)glutaric acid S-dioxide (BH 517-TGSO2) and 3-hydroxy-3-(3-thianyl)glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim*				
Beetroot, parsnips, swedes, horseradishes, J. artichokes	0.24	STMR (Table 3-2)	0.53	HR (Table 3-2)
Celeriac	0.44	STMR (Table 3-2)	2.99	HR (Table 3-2)
Salsify	0.43	STMR (Table 3-2)	0.64	HR (Table 3-2)
Aubergines	0.48	STMR (Table 3-2)	0.84	HR (Table 3-2)
Brussels sprouts	1.50	STMR (Table 3-2)	3.57	HR (Table 3-2)
Head cabbage	1.23	STMR (Table 3-2)	3.03	HR (Table 3-2)
Kale, Chinese cabbage	0.75	STMR (Table 3-2)	1.80	HR (Table 3-2)
Scarole	0.26	STMR (Table 3-2)	0.73	HR (Table 3-2)
Purslane, beet leaves,	0.12	STMR (Table 3-2)	0.30	HR (Table 3-2)
Rapeseed	2.77	STMR (Table 3-2)	2.77	STMR (Table 3-2)
Herbal infusions from roots, Horseradish spices	1.88	STMR (Table 3-2)	4.24	HR (Table 3-2)
Soya bean	13	STMR (FAO, 2013)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Beans (with pods)	0.35	STMR (FAO, 2013)		
Beans (dry)	4.4	STMR (FAO, 2013)		
Peas (dry)	5.6	STMR (FAO, 2013)		
Other plant and animal commodities	MRL	MRLs listed in Regulation (EU) 491/2014		

The estimated exposure was then compared with the toxicological reference values derived for cycloxydim (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term or acute consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo model. The highest chronic intake was estimated to be 68 % of the ADI (FR, toddler) and the highest acute intake 8% of the ARfD for celeriac (BE, child).

EFSA concludes that the intended use of cycloxydim on beetroots, celeriac, parsnips, horseradishes, Jerusalem artichokes, swedes, aubergines, Brussels sprouts, head cabbages, kale, Chinese cabbages, scarole, spinaches, beet leaves, purslanes, oilseed rape and roots of herbal infusions will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

The toxicological profile of cycloxydim was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.07 mg/kg bw per day and an acute reference dose (ARfD) of 2 mg/kg bw.

The metabolism of cycloxydim in primary crops was investigated in the root (sugar beet), pulses/oilseeds (soybean) and cereals (maize) crop groups, using a single foliar application. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as "*cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl)glutaric acid S-dioxide (BH 517-TGSO2) and 3-hydroxy-3-(3-thianyl)glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim*". For the uses on the crops under consideration, EFSA concludes that the metabolism of cycloxydim is sufficiently addressed and the residue definitions agreed in the peer review are applicable. Sufficiently validated analytical methods are available to control residues of cycloxydim according to the enforcement residue definition at the LOQ of 0.05 mg/kg for each analyte.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals for beetroots, celeriacs, Jerusalem artichokes, parsnips, horseradishes, salsifies, swedes, aubergines, Brussels sprouts, head cabbages, Chinese cabbages, kales, escaroles, purslanes, beet leaves, rapeseeds, herbal infusions from roots and horseradish spices.

Studies investigating the nature of cycloxydim residues in processed commodities were assessed in the framework of the peer review. Under standard hydrolysis conditions, cycloxydim was almost totally degraded to metabolites covered by the common moiety analytical methods and therefore by the residue definitions proposed for primary crops. Processing studies on carrots were submitted and processing factors were proposed. However, lacking details of processing conditions, EFSA does not recommend the inclusion of the derived processing factors in Annex VI of Regulation (EC) No 396/2005. Processing studies will be reconsidered in the MRL review according to Article 12 of Regulation (EC) No 396/2005.

The occurrence of cycloxydim residues in rotational crops was investigated in the framework of the peer review. Based on the available information, it was concluded that significant residues of cycloxydim are unlikely to occur in rotational crops.

The calculated livestock dietary burdens indicate that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for all relevant livestock species. Considering that the dietary livestock burdens based on the uses authorised within EU are lower than the animal burdens estimated by the 2012 JMPR for the setting of CXLs in products of animal origin that have been recently transposed in the EU legislation, EFSA concludes that there is no need to change the existing MRL values set for animal products.

The consumer risk assessment was performed with a revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used STMR values as derived from the submitted residue trials. Where a lower MRL or no MRL proposal was derived, the existing MRL was used as input value. For the remaining commodities of plant and animal origin, the existing MRLs as established in Regulation (EC) No 491/2014 were used as input values. Acute exposure assessment was undertaken only for the crops under consideration.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The Highest chronic intake accounted for 68 % of the ADI (FR, toddler). No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration. The highest acute exposure was calculated to be 8% the ARfD for celeriac (BE, Child).

EFSA concludes that the intended use of cycloxydim on beetroots, celeriacs, horseradishes, parsnips, salsifies, Jerusalem artichokes, swedes, aubergines, Brussels sprouts, head cabbages, Chinese cabbages, kales, escaroles, beet leaves, purslanes, rapeseeds, herbal infusions from roots and horseradish spices will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

SUMMARY TABLE

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: *cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl)glutaric acid S-dioxide (BH 517-TGSO2) and 3-hydroxy-3-(3-thianyl)glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim*				
0153030	Raspberries	0.05*	0.05*	No change. No residues expected since application after harvest of the fruits.
0154030	Currants	0.05*	0.05*	
0213010	Beetroots	0.2	0.9	NEU. Extrapolation from trials on carrots
0213030	Celeriacs	1	5	SEU. Extrapolation from trials on carrots
0213040	Horseradishes	0.2	0.9	NEU. Extrapolation from trials on carrots.
0213050	Jerusalem artichokes			
0213060	Parsnips			
0213090	Salsifies	0.2	1.5	NEU. Extrapolation from trials on carrots.
0213100	Swedes	0.2	0.9	NEU. Extrapolation from trials on carrots.
0231030	Aubergines	1.0	1.5	NEU and SEU. Extrapolation from tomatoes.
0242010	Brussels sprouts	3	6	NEU and SEU
0242020	Head cabbages	3	5	NEU and SEU
0243010	Chinese cabbages	2	3	NEU and SEU
0243020	Kale	3	3	NEU and SEU (no change)
0251030	Escaroles	0.5	1.0	NEU. Extrapolation from trials on lettuce.
0251040	Cress	0.5	0.5	No change. Extrapolation not supported (trials on open leaf varieties missing). Clarification of the GAPs requested.
0251050	Land cress			
0251060	Rockets, Rucola	0.5	0.5	
0251070	Red mustards	0.2	0.2	
0251080	Leaves/sprouts Brassica	0.2	0.2	
0252010	Spinaches	2	2	No change, since a lower MRL of 0.6 mg/kg is derived from the submitted trials.
0252020	Purslanes	0.5	0.6	NEU. Extrapolation from trials on spinaches
0252030	Beet leaves	0.2	0.6	
0300020	Lentils	5	5	No change, clarification of the GAPs requested
0401010	Linseed	7	7	
0401030	Poppy seed	0.2	0.2	
0401060	Rapeseeds	7	9	NEU and SEU
0633000	Herbal infusions from roots (dried)	0.05*	7	NEU. Extrapolation from trials on carrots, applying a default dehydration factor of 8.
0840040	Horseradish (spices)	0.05*	7	

(a): According to Annex I of Regulation (EC) No 396/2005.

(*): Indicates that the MRL is set at the limit of analytical quantification.

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APPENDICES

Appendix A. GOOD AGRICULTURAL PRACTICE (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. a.s. (i)	Method kind (f-h)	Growth stage & season (j)	number min-max (k)	g a.s./hL min-max	Water L/ha min-max	g a.s./ha min-max		
Raspberries, Blackcurrants	SW (NEU)	F	perennial grasses	EC	100 g/L	spray	15-20 cm (weed)	1	200-600	100-200	400-600	n.a.	Application after harvest of the fruits
Beetroot	DE (NEU)	F	*Agropyron repens*	EC	100 g/L	spray	from BBCH 11	1	75-100	150-600	500	35	
	ES (SEU)	F	*Agropyron repens*	EC	100 g/L	spray	15-40 cm (weeds)	1	n.a.	n.a.	300-400	F	
Celeriac	DE (NEU)	F	*Agropyron repens*	EC	100 g/L	spray	from BBCH 11	1	75-100	150-600	500	F	
	CY (SEU)	F	*Agropyron repens*	EC	100 g/L	spray	until weed flowering	1	200-400	200-400	350-450	28	
Horseradish, Parsnips Jerusalem artichokes	DE (NEU)	F	*Agropyron repens*	EC	100 g/L	spray	from BBCH 11	1	75-100	150-600	500	35	
Salsify	LU (NEU)	F	*Agropyron repens*	EC	100 g/L	spray	before tillering	1	130-400	150-200	400-600	28	
Swedes	UK (NEU)	F	creeping bent, common couch	EC	100 g/L	spray	from BBCH 11	1	75-100	150-600	500	35	
Egg plants	DE (NEU)	F	*Agropyron repens*	EC	100 g/L	spray	from BBCH 13	1	330-125	150-400	500	35	
	CY (SEU)	F	*Cynodon dactylon*	EC	100 g/L	spray	until weed flowering	1	875-2250	200-400	350-450	28	
Brussels sprouts	UK (NEU)	F	Creeping bent	EC	100 g/L	spray	15 -20 cm	1	136-225	200-330	450	56	
	IT (SEU)	F	*Cynodon dactylon*	EC	100 g/L	spray		1	125-300	200-400	500-600	60	GAP for “cabbage”
Head cabbage	LU (NEU)	F	*Agropyron repens*	EC	100 g/L	spray	before tillering	1	133-400	150-300	400-600	28	
	CY (SEU)	F	*Cynodon dactylon*	EC	100 g/L	spray		1	875-2250	200-400	350-450	28	
Curly kale, Chinese cabbage	SEU & NEU	F		EC	100 g/L	spray	15-20 cm	1	875-2250	150-600	500	42	

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. a.s. (i)	Method kind (f-h)	Growth stage & season (j)	number min-max (k)	g a.s./hL min-max	Water L/ha min-max	g a.s./ha min-max		
Scarole	DE (NEU)	F	*Agropyron repens*	EC	100 g/L	spray		1	83-330	150-600	500	21	
Baby leaves	DE (NEU)	F	*Agropyron repens*	EC	100 g/L	spray		1	83-330	200-400	500	F	Except lamb`s lettuce
Spinach	DE (NEU)	F	*Agropyron repens*	EC	100 g/L	spray	from BBCH 11	1	83-330	150-600	500	21	
	IT (SEU)	F		EC	100 g/L	spray		1	125-300	200-400	500-600	30	
Beet leaves (chard) Purslane	DE (NEU)	F	*Agropyron repens*	EC	100 g/L	spray	from BBCH 11	1	83-330	150-600	500	21	
Lentils	ES (SEU)	F		EC	100 g/L	spray		1			300-400	F	
Linseed	LU (NEU)	F		EC	100 g/L	spray		1	133-400	150-300	400-600	F	
Poppy seed	SK (NEU)	F		EC	100 g/L	spray		1	133-400	150-300	400	F	
Oilseed rape	AT (NEU)	F	*Agropyron repens*	EC	100 g/L	spray	15-20 cm	1	167-250	200-300	500	84	
	IT (SEU)	F	*Agropyron repens*	EC	100 g/L	spray	15-20 cm	1	125-300	200-400	500-600	100	
Herbal infusions (roots)	DE (NEU)	F	*Agropyron repens*	EC	100 g/L	spray	from BBCH 11	1	75-100	150-600	500	35	

Remarks:

(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
(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 plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/restrictions (i.e. feeding, grazing)

Appendix B. Pesticide Residue Intake Model (PRIMO)

Cycloxydim

Status of the active substance:	**included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,07**	ARfD (mg/kg bw):	**2**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
11	68
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRLs at LOQ (in % of ADI)
68	FR toddler	22	Potatoes	17	Carrots	7	Peas (without pods)	
61	WHO Cluster diet B	11	Potatoes	11	Soya bean	7	Tomatoes	
57	NL child	25	Potatoes	9	Peas (without pods)	4	Carrots	
55	UK Infant	14	Potatoes	12	Peas (without pods)	9	Carrots	
54	FR infant	19	Carrots	18	Potatoes	6	Peas (without pods)	
54	UK Toddler	16	Sugar beet (root)	15	Potatoes	6	Peas (without pods)	
52	WHO cluster diet E	16	Potatoes	11	Soya bean	3	Peas (without pods)	
51	PT General population	23	Potatoes	6	Soya bean	5	Carrots	
42	WHO Cluster diet F	15	Potatoes	12	Soya bean	3	Carrots	
42	WHO regional European diet	17	Potatoes	4	Peas (without pods)	3	Carrots	
42	WHO cluster diet D	17	Potatoes	7	Soya bean	4	Sunflower seed	
41	IE adult	10	Potatoes	5	Peas (without pods)	2	Carrots	
40	DE child	11	Potatoes	7	Carrots	4	Peppers	
38	SE general population 90th percentile	18	Potatoes	6	Carrots	2	Peppers	
30	DK child	10	Potatoes	10	Carrots	3	Peppers	
28	NL general	12	Potatoes	4	Peas (without pods)	2	Cauliflower	
24	ES child	8	Potatoes	2	Tomatoes	2	Lentils	
24	PL general population	15	Potatoes	2	Carrots	2	Tomatoes	
23	UK vegetarian	6	Potatoes	3	Peas (without pods)	3	Sugar beet (root)	
20	UK Adult	6	Potatoes	3	Sugar beet (root)	3	Peas (without pods)	
19	LT adult	14	Potatoes	1	Tomatoes	1	Carrots	
19	FR all population	5	Potatoes	3	Wine grapes	3	Sunflower seed	
18	ES adult	4	Potatoes	2	Peppers	2	Tomatoes	
17	DK adult	6	Potatoes	3	Carrots	2	Peas (without pods)	
16	IT kids/toddler	4	Potatoes	3	Tomatoes	2	Peas (without pods)	
13	IT adult	3	Potatoes	2	Tomatoes	2	Peas (without pods)	
11	FI adult	5	Potatoes	1	Carrots	1	Tomatoes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Cycloxydim is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations

Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

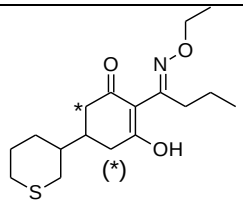
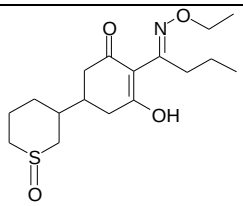
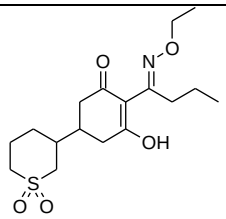
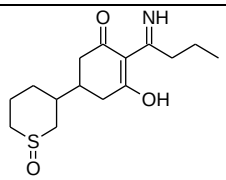
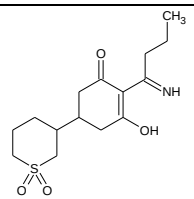
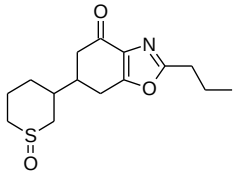
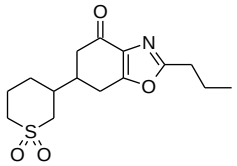
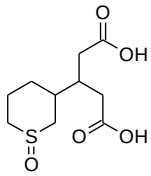
Unprocessed commodities

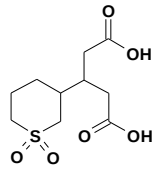
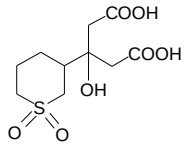
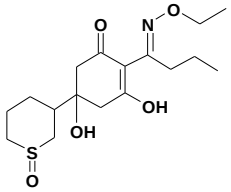
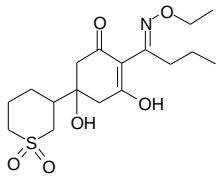
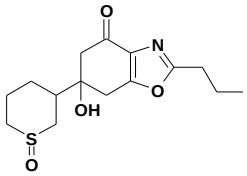
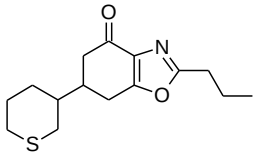
No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
8	Celeriac	2.99 / -	8	Celeriac	2.99 / -	5	Head cabbage	3.03 / -	3	Chinese cabbage	1.8 / -
8	Head cabbage	3.03 / -	5	Head cabbage	3.03 / -	3	Chinese cabbage	1.8 / -	3	Head cabbage	3.03 / -
6	Kale	1.8 / -	4	Kale	1.8 / -	3	Celeriac	2.99 / -	3	Celeriac	2.99 / -
3	Chinese cabbage	1.8 / -	3	Chinese cabbage	1.8 / -	2	Kale	1.8 / -	1	Kale	1.8 / -
3	Scarole (broad-leaf	0.73 / -	3	Scarole (broad-leaf	0.73 / -	1	Aubergines (egg	0.84 / -	1	Aubergines (egg plants)	0.84 / -
2	Brussels sprouts	3.57 / -	2	Brussels sprouts	3.57 / -	1	Brussels sprouts	3.57 / -	1	Brussels sprouts	3.57 / -
1	Swedes	0.53 / -	1	Swedes	0.53 / -	1	Swedes	0.53 / -	1	Swedes	0.53 / -
1	Salsify	0.64 / -	1	Aubergines (egg plants)	0.84 / -	0	Parsnips	0.53 / -	0	Scarole (broad-leaf endive)	0.73 / -
1	Aubergines (egg plants)	0.84 / -	1	Salsify	0.64 / -	0	Salsify	0.64 / -	0	Parsnips	0.53 / -
1	Parsnips	0.53 / -	1	Parsnips	0.53 / -	0	Scarole (broad-leaf endive)	0.73 / -	0	Salsify	0.64 / -
0	Beet leaves (chard)	0.3 / -	0	Beet leaves (chard)	0.3 / -	0	Purslane	0.3 / -	0	Purslane	0.3 / -
0	Purslane	0.3 / -	0	Purslane	0.3 / -	0	Jerusalem artichokes	0.53 / -	0	Jerusalem artichokes	0.53 / -
0	Rape seed	2.77 / -	0	Rape seed	2.77 / -	0	Beet leaves (chard)	0.3 / -	0	Beet leaves (chard)	0.3 / -
0	Horseradish	0.53 / -	0	Horseradish	0.53 / -	0	Horseradish	0.53 / -	0	Horseradish	0.53 / -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			

Appendix C. List of metabolites and related structural formula

Code/Trivial name	Chemical name	Structural formula
Cycloxydim BH 517 H E/Z isomer	2-[1-(ethylimino)butyl]-3-hydroxy-5-(tetrahydro-2H-thiopyran-3-yl)-2-cyclohexen-1-one MW=325.5	
BH 517-TSO E/Z isomer MW=341.5	2-[1-(ethylimino)butyl]-3-hydroxy-5-(tetrahydro-2H-thiopyran-3-yl)-2-cyclohexen-1-one S-oxide MW=341.5	
BH 517-TSO2 E/Z isomer	2-[1-(ethylimino)butyl]-3-hydroxy-5-(tetrahydro-2H-thiopyran-3-yl)-2-cyclohexen-1-one S-dioxide	
BH 517-T1SO	2-butanimidoyl-3-hydroxy-5-(1-oxidotetrahydro-2*H*-thiopyran-3-yl)cyclohex-2-en-1-one	
BH 517-T1SO2	2-butanimidoyl-5-(1,1-dioxidotetrahydro-2H-thiopyran-3-yl)-3-hydroxycyclohex-2-en-1-one	
BH-517-T2SO	2-propyl-6-(3-thianyl)-4,5,6,7-tetrahydrobenzoxazol-4-one S-oxide	
BH 517-T2SO2	2-propyl-6-(3-thianyl)-4,5,6,7-tetrahydrobenzoxazol-4-one S-dioxide	
BH 517-TGSO	3-(1-oxidotetrahydro-2*H*-thiopyran-3-yl) pentanedioic acid	

Code/Trivial name	Chemical name	Structural formula
BH 517-TGSO2 (also oxidation product of cycloxydim)	3-(3-thianyl)glutaric acid S- dioxide MW=264.3	
BH 517-5-OH-TGSO2 or BH 517-OH-TGSO2 (also oxidation product of BH 517-5-OH-TSO2)	3-hydroxy-3-(3-thianyl)glutaric acid S-dioxide MW=280.3	
BH 517-5-OH-TSO	2-[1-(ethoxyimino)butyl]-3,5-dihydroxy-5-(3-thianyl)-2-cycloexene-1-one S-oxide	
BH 517-5-OH-TSO2	2-[1-(ethoxyimino)butyl]-3,5-dihydroxy-5-(3-thianyl)-2-cycloexene-1-one S-dioxide	
BH 517-6-OH-T2SO		
BH 517-T2S	2-propyl-6-(3-thianyl)-4,5,6,7-tetrahydro benzoxazol-4-one	

ABBREVIATIONS

ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
BE	Belgium
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report
DT_{90}	period required for 90 % dissipation (define method of estimation)
EC	European Community
EC	emulsifiable concentrate
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FR	France
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
HPLC	high performance liquid chromatography
HR	highest residue
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RMS	rapporteur Member State
SEU	Southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake