Review of the existing maximum residue levels for clethodim according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance clethodim. To assess the occurrence of clethodim residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL could not be proposed because an overall consumer risk assessment could not be finalised. Risk managers should be made aware that the genotoxic potential of the clethodim metabolite 3-chloroallyl alcohol, the aglycon of 3-chloroallyl alcohol glucoside (M14A/M15A) could not be concluded and no toxicological reference values could be derived for this metabolite. Until a conclusion on the toxicological properties of the metabolite is reached, a decision on the residue definition for risk assessment cannot be made which is a prerequisite to perform a reliable dietary risk assessment.

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Keywords: clethodim, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, cyclohexene oxime, herbicide, 3-chloroallyl alcohol glucoside

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Summary

Clethodim was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/21/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.

The restriction to sugar beets of the use of plant protection products consisting of or containing clethodim was lifted with the Commission Implementing Regulation (EU) No 87/2012. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked the Netherlands, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 10 August 2017 and finalised on 10 October 2017. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 15 January 2018.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS and Member States, EFSA prepared in November 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 29 November 2018 were discussed in a meeting of experts, which took place on 24 January 2019, and the outcome of that meeting was considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of clethodim was investigated after foliar treatment in root and tuber crops, pulses and oilseeds, and leafy vegetables. A general metabolic pathway in all three crop groups can be elucidated. The parent clethodim is extensively metabolised in mature crops and mostly not detected in all groups. One major pathway is sulfoxidation to clethodim sulfoxide followed by further oxidation to clethodim sulfone which was mainly observed in root and tuber vegetables. Another pathway is the elimination of the chloroallyl moiety, leading to the formation of clethodim imine and 3-chloroallyl metabolites, including 3-chloroallyl alcohol glucosides (M14A/M15A) which was the main pathway in the spinach study and maybe considered as such for leafy crops. It has however to be noted that although the same metabolites were potentially identified in all metabolism studies in carrot, cotton and spinach, there were clear quantitative differences, especially with regard to the amount of M14A (3-chloroallyl alcohol glucoside) and M3/4A in spinach (leafy crops).

The metabolism of clethodim in three rotational crop studies covering cereals, root and tuber vegetables, and leafy crops was similar as the pathway in primary crops in that clethodim is extensively degraded and was not detected in any of the analysed extracts. Individual soil metabolites identified in the rotational crop study are not expected to exceed the limit of quantification (LOQ) of 0.01 mg/kg, provided that clethodim is used according the good agricultural practices (GAPs) assess in this review.

Based on the results of the hydrolysis studies, it can be concluded that clethodim is hydrolysed to clethodim oxazole and clethodim trione. Information on the fate of the allyl moiety of clethodim is not provided. Therefore, additional studies to provide information on the fate of the allyl-moiety are still needed. In addition, notably since clethodim is not expected in raw plant commodities, additional hydrolysis studies where all metabolites relevant for the risk assessment are analysed are still needed.

Toxicity of the metabolites M14R/M15R, M16R/M17R and M18R (M19R in spinach) is known to be covered by the parent clethodim. Information on structure and toxicity of M3/4A is not available and it is not possible to conclude on the toxicological relevance of this metabolite in the framework of this review.

Metabolites M14A/M15A represents the 3-chloroallyl alcohol glucoside and, due to the possible release of unconjugated products, conjugates should be considered. The metabolite 3-chloroallyl alcohol (the aglycon of M14A/15A), is a common metabolite with the active substance 1,3-dichloropropene. For this metabolite, genotoxicity could not be concluded in the framework of the renewal of the approval of 1,3-dichloropropene where additional toxicological studies were recently assessed.
In an expert meeting, it was agreed to have two separate residue definitions for risk assessment. The following common residue definitions are proposed for plant commodities:

Monitoring: sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim.

Risk assessment residue definition 1: sum of clethodim, clethodim sulfoxide, clethodim sulfone and metabolites M14R/15R, M16R/M17R and M18R/M19R, expressed as clethodim.

Risk assessment residue definition 2: M14A/M15A.

The same residue definitions apply to rotational crops. For processed commodities, residue definitions are not proposed because information is inconclusive.

Based on the metabolism study in spinach, mathematically a conservative indicative conversion factor between monitoring to risk assessment of 19 as tentatively applied to crops other than root and tuber vegetables, pulses and oilseeds where the conversion factor of 2.5 derived during the peer review was applied.

It can be concluded that clethodim, clethodim sulfoxide and clethodim sulfone can be enforced in high water, high acid, high oil content and dry commodities with a combined LOQ of enforcement of 0.014 mg/kg, expressed as clethodim (rounded to 0.02 mg/kg).

With regard to the magnitude of residues in raw plant commodities, the available data are sufficient to calculate MRLs for all commodities under evaluation, except for cane fruits (blackberries, raspberries, blueberries), other small fruits and berries (cranberries, currants, gooseberries, rose hips, elderberries), broccoli, cauliflower, Brussels sprouts, spinach, witloofs, asparagus, rice grain and straw, and pea vines were data were insufficient.

None of the residue trials analysed for the proposed metabolites for inclusion in residue definition (RD) 1, conversion factors were derived from the metabolism studies which allowed to derive at least tentative risk assessment values for RD1. RD2 includes metabolite M14A/M15A for which genotoxicity could not be concluded. Therefore, risk assessment values according to RD2 could not be derived. Since RD2 is tentatively proposed, all MRLs should be considered only tentative until the missing information on the respective metabolites is provided and an overall consumer risk assessment can be finalised.

Clethodim is authorised for use on crops that might be fed to livestock. For animal commodities, based on the two metabolism studies conducted with the parent, the following residue definition for monitoring and risk assessment is tentatively proposed: sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim. A sufficiently validated method is available for enforcement of the proposed residue definition at the combined LOQ of 0.03 mg/kg.

Significant levels of clethodim equivalents are expected in all animal commodities except milks where the MRL is proposed at the LOQ. Considering the uncertainty linked to the residue definitions in plant commodities, these MRLs are considered as tentative and indicative only. Furthermore, since in the feeding study clethodim equivalents were derived by a common moiety method the results are not compatible with the tentatively proposed residue definition.

Considering the above outlined uncertainties, an overall risk assessment could not be performed and only an indicative chronic consumer exposure according to the proposed tentative RD1 resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to calculate MRLs, EFSA considered the existing EU MRL multiplied by a tentative conversion factor proposed based on RD1 for an indicative calculation. The highest tentatively estimated chronic exposure represented 12.7% of the acceptable daily intake (ADI) (FR, toddler). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended codex maximum residue limits (CXLs) have also been established for clethodim. According to RD1, indicative estimations of the consumer exposure, considering these CXLs, were therefore tentatively carried out and the highest chronic exposure represented 27.6% of the ADI (WHO, cluster diet B).

EFSA emphasises that the available studies do not investigate the possible impact of plant and animal metabolism on the isomer ratio of clethodim and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.
Table of contents

Abstract................................................................................................................................................... 1
Summary................................................................................................................................................. 3
Background ............................................................................................................................................. 6
Terms of Reference .................................................................................................................................. 7
The active substance and its use pattern ................................................................................................... 7
Assessment.............................................................................................................................................. 8
1. Residues in plants ................................................................................................................................ 8
1.1. Nature of residues and methods of analysis in plants ....................................................................... 8
1.1.1. Nature of residues in primary crops ................................................................................................. 8
1.1.2. Nature of residues in rotational crops ............................................................................................... 9
1.1.3. Nature of residues in processed commodities ................................................................................... 10
1.1.4. Methods of analysis in plants ........................................................................................................... 10
1.1.5. Stability of residues in plants ........................................................................................................... 10
1.1.6. Proposed residue definitions........................................................................................................... 11
1.2. Magnitude of residues in plants ......................................................................................................... 12
1.2.1. Magnitude of residues in primary crops ......................................................................................... 12
1.2.2. Magnitude of residues in rotational crops ....................................................................................... 14
1.2.3. Magnitude of residues in processed commodities ....................................................................... 14
1.2.4. Proposed MRLs .............................................................................................................................. 15
2. Residues in livestock ....................................................................................................................... 15
2.1. Nature of residues and methods of analysis in livestock .................................................................... 16
2.2. Magnitude of residues in livestock ................................................................................................... 17
3. Consumer risk assessment .............................................................................................................. 17
3.1. Indicative consumer risk assessment without consideration of the existing CXLs............................... 17
3.2. Indicative consumer risk assessment with consideration of the existing CXLs .................................. 18
Conclusions.............................................................................................................................................. 18
Recommendations.................................................................................................................................... 20
References............................................................................................................................................... 24
Abbreviations ........................................................................................................................................... 25
Appendix A – Summary of authorised uses considered for the review of MRLs........................................ 27
Appendix B – List of end points ............................................................................................................. 48
Appendix C – Pesticide Residue Intake Model (PRIMo) ........................................................................ 70
Appendix D – Input values for the exposure calculations ....................................................................... 74
Appendix E – Decision tree for deriving MRL recommendations............................................................ 81
Appendix F – Used compound codes..................................................................................................... 83
Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC\(^2\) a reasoned opinion on the review of the existing MRLs for that active substance. As clethodim was included in Annex I to Council Directive 91/414/EEC on 1 June 2011 by means of Commission Directive 2011/21/EU\(^3\), and has been deemed to be approved under Regulation (EC) No 1107/2009\(^4\), in accordance with Commission Implementing Regulation (EU) No 540/2011\(^5\), as amended by Commission Implementing Regulation (EU) No 541/2011\(^6\), EFSA initiated the review of all existing MRLs for that active substance. The restriction to sugar beets of the use of plant protection products consisting of or containing clethodim was lifted with the Commission Implementing Regulation (EU) No 87/2012\(^7\).

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that, in the framework of Directive 91/414/EEC, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

The Netherlands, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for clethodim and to prepare a supporting evaluation report (Netherlands, 2012, 2016). The supporting evaluation report was submitted initially to EFSA on 5 January 2012 and an updated evaluation report submitted on January 2016 (updated on April 2016). The PROFile was submitted on 26 January 2017. The PROFile and the evaluation report made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 10 August 2017 and finalised on 10 October 2017. Additional evaluation reports were submitted by Belgium, the Czech Republic, Denmark, France, Germany, Greece, Italy, the Netherlands, Portugal, Spain, the United Kingdom, and the European Union Reference Laboratories for Pesticide Residues (Belgium, 2017; Czech Republic, 2017; Denmark, 2017; EURL, 2017; France, 2017; Germany, 2017; Greece, 2017; Italy, 2017; Netherlands, 2017, 2018; Portugal, 2017, Spain, 2017; United Kingdom, 2017) and, after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was

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\(^1\) Regulation (EC) No 396/2005 of the European 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, 16.3.2005, p. 1-16.

\(^2\) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32. Repealed by Regulation (EC) No 1107/2009.

\(^3\) Commission Directive 2011/21/EU of 2 March 2011 amending Council Directive 91/414/EEC to include clethodim as active substance and amending Decision 2008/934/EC. OJ No L 58, 3.3.2011, p. 49-52.

\(^4\) 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.

\(^5\) Commission Implementing Regulation (EU) No 540/2011 of 25 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, 11.6.2011, p. 1-186.

\(^6\) Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 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, 11.6.2011, p. 187-188.

\(^7\) Commission Implementing Regulation (EU) No 87/2012 of 1 February 2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clethodim. OJ No L 30, 2.2.2012, p. 8-10.
made available to all Member States on 15 January 2018. Further clarifications were sought from Member States via a written procedure in January-February 2018.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission (codex maximum residue limit (CXLs)) and the additional information provided by the Member States, EFSA prepared in November 2018 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 29 November 2018 were evaluated by EFSA. As further discussion on some unresolved issues was required, a meeting with Member State experts took place on 24 January 2019. The conclusions of this meeting were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Netherlands, 2012, 2016) and the evaluation reports submitted by Member States Belgium, the Czech Republic, Denmark, France, Germany, Greece, Italy, the Netherlands, Portugal, Spain, the United Kingdom, and the European Union Reference Laboratories for Pesticide Residues (Belgium, 2017; Czech Republic, 2017; Denmark, 2017, 2018; EURL, 2017; France, 2017; Germany, 2017; Greece, 2017; Italy, 2017; Netherlands, 2017, 2018; Portugal, 2017; Spain, 2017; United Kingdom, 2017) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2018a) and the Member States consultation report (EFSA, 2019). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file PRIMo(EU) and PRIMo(CXL)) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, screenshots of the Report sheets of the PRIMo(EU) and PRIMo(CXL) are presented in Appendix C.

**Terms of Reference**

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

**The active substance and its use pattern**

Clethodim is the ISO common name for (5RS)-2-\{(1EZ)-1-\{(2E)-3-chloroallyloximino\}propyl\}-5-\{(2RS)-2-(ethylthio)propyl\}-3-hydroxycyclohex-2-en-1-one (IUPAC). It should be noted that amendments have been made to the ISO definition of the active substance to match the chemical definition of the technical material manufactured, which has E geometry on the allyl group but is a mixture of E and Z isomers at the oxime ether, and the carbon at position 5 appears to exhibit potential chirality, but is not considered as a chiral centre because of the rapid keto-enol tautomerism.

Clethodim belongs to the group of cyclohexanediones which are used as herbicides. Clethodim binds to acetyl CoA carboxylases which inhibits fatty acid synthesis. Clethodim is a systemic herbicide and is rapidly absorbed and readily translocated from treated foliage to the root system and growing parts of the plant.

The chemical structure of the active substance and its main metabolites are reported in Appendix F. Clethodim was evaluated in the framework of Directive 91/414/EEC with the Netherlands designated as RMS. The representative uses supported for the peer review process comprised spraying applications to control grass weeds in sugar beet. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2011/21/EU, which entered into force on 1 June 2011. Only use as a herbicide on sugar beet were authorised with the first approval. The restriction to sugar beets of the use of plant protection products consisting of or containing clethodim was lifted with the Commission Implementing Regulation (EU) No 87/2012. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, clethodim is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to use as a herbicide only (European Commission, 2014). An EFSA Conclusion on this active substance is available (EFSA, 2011).
The EU MRLs for clethodim are established in Annexes IIIA of Regulation (EC) No 396/2005 and CXLs for active substance were also established by the Codex Alimentarius Commission (CAC). There are no MRL changes occurred since the entry unto force of the Regulation mentioned above.

For the purpose of this MRL review, the critical uses of clethodim currently authorised within the EU, have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAP(s) for clethodim are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Netherlands, 2012, 2016, 2018), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Netherlands, 2005, 2009, 2011), the conclusion on the peer review of the pesticide risk assessment of the active substance clethodim (EFSA, 2011), the Joint Meeting on Pesticide residues (JMPR) Evaluation reports (FAO, 1994, 1997, 1999, 2002), as well as the evaluation reports submitted during the completeness check (Belgium, 2017; Czech Republic, 2017; Denmark, 2017; EURL, 2017; France, 2017; Germany, 2017; Greece, 2017; Italy, 2017; Netherlands, 2017, 2018; Portugal, 2017; Spain, 2017; United Kingdom, 2017) and the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance (EZ)-1,3-dichloropropene where 3-chloroallyl alcohol, which represents the aglycon of a clethodim metabolite was assessed (EFSA, 2018b). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a,b,c,d,e,f,g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of clethodim was investigated after foliar treatment in root crops, pulses and oilseeds and leafy crops (Netherlands, 2005, 2009, 2016). In the framework of the peer review two metabolism studies, one on oilseeds/pulses (cotton and soybean) and root crops (carrots) and a third study on root crops (carrots only) were assessed. A new recent study on leafy crops (spinach) was provided and assessed during this review.

In the first two studies on soybean, carrot and cotton after two applications of [4,6-14C-ring]-labelled or [2-14C-ally]-labelled clethodim at 280 g a.s./ha (carrot 1.2N), clethodim was not detected in any part of the plants except in carrot roots (0.8% or 1.1% total radioactive residue (TRR); 0.003 or 0.007 mg eq/kg, respectively) indicating extensive metabolism. Major metabolites were clethodim sulfoxide (in carrot leaves, carrot roots and soya beans), clethodim imine sulfoxide (in soybean leaves, in carrot leaves and in cotton leaves), clethodim 5-hydroxy sulfone (in soybean beans and carrot roots) and conjugates of clethodim sulfoxide (in soybean leaves, soya beans and in cotton leaves) (Netherlands, 2005).

In a third study on carrots, [4,6-14C-ring]-labelled or [2-14C-ally]-labelled clethodim was applied once at 624 or 638 g a.s./ha (1.8–1.7N of the critical GAP (cGAP) rate on root crops of the present review). In carrot foliage, clethodim was detected at very small concentrations in immature foliage (0.004–0.005 mg eq/kg) however not detected in mature foliage. Clethodim sulfoxide and clethodim sulfone were found in all foliage samples. M15R, M19R and M22R were significant metabolites in ring-labelled samples of immature foliage whereby M19R and clethodim sulfoxide glycoside (M26) were significant in mature foliage. In carrot roots at maturity, metabolites M3A, M15R, M17R, M18R and clethodim sulfoxide were significant (12–15% TRR and ca. 0.02 mg eq/kg) (Netherlands, 2005).

8 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, 11.6.2011, p. 127–175.
The third study provided a coherent outcome with the prior two studies however with additional identification of significant metabolites M3A, M15R, M17R, M18R, M19R and M22R (EFSA, 2011). An amended study report of the second carrot study was provided during this review, where it was shown that the metabolite M15R is a post-extraction artefact and that the structure assigned as M14R applies instead (Netherlands, 2016). Notably, metabolite codes representing similar structures are displayed in Appendix F namely: M14R/M15R, M16R/M17R, M18R/M19R and M14A/M15A.

A recent study on leafy crops (spinaches) was provided by the RMS and is considered during this review (Netherlands, 2016). Spinach plants were treated once with 500 g a.s./ha with ring- and allyl-labelled clethodim (1.7 N of the cGAP on leafy crops of the present review). In this study, clethodim, clethodim sulfoxide and clethodim sulfone accounted only for a minor part of the TRR (the sum ranged between 3.1% and 5.7% TRR) while significant metabolites in mature spinach were M3/4A (21% TRR; 0.726 mg eq/kg), M14R (14.2% TRR; 0.476 mg eq/kg), M14A/M15A (22.7% TRR; 0.785 mg eq/kg), M16R/M17R (34.45% TRR; 1.158 mg eq/kg) and M19R (12.5% TRR; 0.418 mg eq/kg) (Netherlands, 2016).

A general metabolic pathway in all three crop groups can be elucidated. The parent clethodim is extensively metabolised in mature crops and mostly not detected in all groups. One major pathway is sulfoxidation to clethodim sulfoxide followed by further oxidation to clethodim sulfone which was mainly observed in root and tuber vegetables. Another pathway is the elimination of the chloroallyl moiety, leading to the formation of clethodim imine and 3-chloroallyl metabolites, including 3-chloroallyl alcohol glucosides (M14A/M15A) which was the main pathway in the spinach study.

It has to be noted that although the same metabolites were potentially identified in all metabolism studies in carrot, cotton and spinach, there were clear quantitative differences, especially with regard to the amount of M14A (3-chloroallyl alcohol glucoside) and M3/4A in spinach (leafy crops) (Netherlands, 2016).

Results from the most recent studies in carrot and spinach, which were performed outdoor, indicated that the clethodim ring can be opened by photolysis reaction (based on formed imine metabolites) to form pentanedioic acids, including the following metabolites M14R (M15R in carrot), M16R/M17R noting that in metabolites M19R (M18R in carrot) the phenyl-ring was intact. These metabolites were not identified in the older metabolism studies on carrot, cotton and soybean which were performed indoor. On the other hand, the presence of clethodim imine metabolites were reported in the older studies and therefore cleavage of the chloroallyl group seems to have occurred and potentially ally-metabolites such as M3/4A and M14A/M15A could also have been formed in addition to metabolites M14R, M16R/M17R and M18R/M19R.

During the expert meeting, it was agreed that, based on the available metabolism studies, it is not possible to conclude on whether allyl metabolites (such as M14A/M15A) containing the chloroallyl group will be formed from cleavage of the side chain at significant levels also in/on other crop groups which were studied in 1988 indoor, when grown outdoor due to photolytic reactions. Those indoor studies may not be fully representative for outdoor conditions (EFSA, 2019). Therefore, a representative study in a fourth crop group (preferably fruit crops performed outdoor) is required.

### 1.1.2. Nature of residues in rotational crops

Clethodim is authorised for use on crops which can be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, periods required for 90% dissipation (DT$_{90}$ values) of clethodim, clethodim sulfoxide and clethodim sulfone in field studies were up to 8.5, 73.55 and 73.5 days, respectively, which is lower than the trigger value of 100 days. However, the DT$_{90}$ value of clethodim oxazole sulfone was up to 227 days in clay (EFSA, 2011). Therefore, further investigation of residues in rotational crops was performed and evaluated.

During the peer review, a confined rotational crop study was provided in which the metabolism in rotated lettuce, carrots and wheat grown after soil application of ring-4,6-$^{14}$C-labelled clethodim at 1.1 kg a.s./ha (corresponding to 2.9 N maximum rate) was investigated. The TRR was below 0.05 mg eq/kg in carrot root and crown, lettuce leaf (120 and 366 days after treatment (DAT)) and wheat grain.

In carrot leaf, lettuce leaf (30 days) and wheat straw and hull, the radioactive residue ranged from 0.053 mg eq/kg (mature carrot leaf) to 0.65 mg eq/kg (mature straw). Clethodim was not detected in any of the analysed extracts. Small amounts of clethodim imine sulfoxide (significant in lettuce leaf after 30 days [19% TRR, 0.016 mg eq/kg] and in carrot leaves after 366 days [11% TRR, 0.006 mg eq/kg]). Oxazole sulfoxide and oxazole sulfone were highest and significant in soil extracts collected in plots where carrot where sown after of 30 days (30 DAT with 12% TRR, 0.015–0.016 mg eq/kg) however
were found at lower levels in carrot leaves after 30 days (3.2% TRR; 0.011 mg eq/kg and 1.8% TRR; 0.006 mg eq/kg, respectively). Other metabolites were all below 10% TRR and 0.01 mg eq/kg.

The metabolism of clethodim in three rotational crop studies covering cereals, root and tuber vegetables and leafy crops was similar to the pathway in primary crops in that clethodim is extensively degraded and was not detected in any of the analysed extracts. Individual soil metabolites identified in the study are not expected to exceed the trigger value of 0.01 mg/kg.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were provided during this review (France, 2017). Studies were conducted with radiolabelled clethodim on the cyclohexyl ring simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6).

During pasteurisation, the degradation product clethodim oxazole was formed with an amount of 13.5% and during conditions simulating baking, brewing, boiling and sterilisation, clethodim oxazole, was formed with amounts of 80.4% and 96.3%, respectively, and an additional degradation product, clethodim trione with amounts of 5.4% and 3.8% was observed. There was no significant change in total radioactivity following processing (France, 2017).

Based on the results of the study, it can be concluded that clethodim is hydrolysed to clethodim oxazole and clethodim trione. Information on the fate of the allyl moiety of clethodim is not provided. Therefore, additional studies to provide information on the fate of the allyl-moiety are still needed (data gap). In addition, notably since clethodim is not expected in raw plant commodities, additional hydrolysis studies where all metabolites relevant for the risk assessment are analysed are still needed (data gap).

1.1.4. Methods of analysis in plants

In the framework of the peer-review, analytical methods based on liquid chromatography (LC) coupled to tandem mass spectrometry (MS/MS) detection for high water, high oil and dry commodities (validated in sugar beet, peas, soya beans) with a limit of quantification (LOQ) of 0.005 mg/kg for clethodim, clethodim sulfoxide and clethodim sulfone, respectively supported by independent laboratory validation (ILV) for high water and oil matrices were evaluated (Netherlands, 2009; EFSA, 2011).

During this review, a ILV of a LC-MS/MS method for dry and high acid matrices validated in wheat grain and grape bunches with a LOQ of 0.005 mg/kg for clethodim, clethodim sulfoxide and clethodim sulfone, respectively, and a confirmatory method for high oil and high water matrices for clethodim sulfone validated in oil seed rape and sugar beet leaves with a LOQ of 0.005 mg/kg was provided (France, 2017). In addition, a LC-MS/MS method with a LOQ of 0.005 mg/kg for clethodim, clethodim sulfone and clethodim sulfoxide, respectively, validated in grapes and supported by ILV was made available (Netherlands, 2016).

The EURLs provided a LC-MS/MS method for clethodim in high water (tomato, cucumber), high acid (orange, lemon) content commodities with a LOQ of 0.005 for cucumber and lemon and with a LOQ of 0.01 mg/kg for orange and tomato, for high oil (almond) content and dry commodities (wheat) with a LOQ of 0.01 mg/kg; for clethodim sulfoxide in high water (zucchini), high acid (orange juice) with a LOQ of 0.005 mg/kg and for high oil (cashew nuts) and dry (wheat flour) commodities with a LOQ of 0.05 mg/kg. In the same four matrices (zucchini, orange juice, wheat flour and cashew nuts), for clethodim sulfoxide a LOQ of 0.005 mg/kg was obtained (EURLs, 2017). During the Member State consultation the EURL informed on further successful validation of the method for clethodim in wheat, rye, oat and rice at 0.005 mg/kg and highlighted that during routine analyses a combined LOQ of 0.03 mg/kg would be achievable (EFSA, 2019). For the metabolites M17R and M18R, a validated LC-MS/MS method in all four matrices of plant origin with a individual LOQ of 0.01 mg/kg was evaluated and considered acceptable (Netherlands, 2018).

It can be concluded that clethodim, clethodim sulfoxide and clethodim sulfone can be enforced in high water, high acid, high oil content and dry commodities with a combined LOQ of enforcement of 0.014 mg/kg, expressed as clethodim (rounded to 0.02 mg/kg).

1.1.5. Stability of residues in plants

The storage stability of clethodim was investigated in high water, high acid, high oil content and dry matrices (EFSA, 2011; Netherlands, 2016). The available studies demonstrated storage stability for clethodim in dry and high oil commodities for up to nine months when stored at –18°C whereby it was
unstable in high water and high acid commodities. Clethodim sulfoxide, clethodim sulfone, M17R and M18R were stable in all four main matrices for a period of nine months when stored at –18°C.

1.1.6. Proposed residue definitions

The metabolism studies on soya beans, carrot and cotton assessed during the peer review provided a coherent metabolic pathway noting that in the study on carrots additional significant metabolites, namely M3A, M15R, M17R and M18R were identified. The peer review proposed to include metabolites M15R, M17R and M18R in the residue definition for risk assessment for root crops, pulses and to extrapolate it to oilseeds. The metabolite M3A was not included in the residue definition, given the clarification provided on its possible structure (allyl fragment) and the low concentrations this metabolite was expected to be present in plants (EFSA, 2011).

During the peer review, a conversion factor for risk assessment of 2.5 was also derived from the respective proportion, at which the different compounds were detected in mature roots in the metabolism study conducted on carrots with the 14C label on the cyclohexene ring. Since the metabolic profile between the respective two metabolism studies was considered similar, this conversion factor was extended to the oilseed and pulses group (EFSA, 2011).

Nevertheless, in the new metabolism study on spinach assessed in this review, the following significant metabolites (in particular allyl- and ring-derived metabolites) were identified, namely: M3/4A (17.5–21% TRR); M14A/M15A (21.10–22.7% TRR); M16R/M17R (33.3–34.45% TRR) and M19R (12.5% TRR) that should be further considered for inclusion at least in the residue definition for risk assessment.

For what concerns metabolite M3A/4A (M3/4A), it was noted during the expert meeting that it is not possible to conclude on its structure. Even though M3A/4A was found at significant levels in the spinach metabolism study further identification of its individual components was not performed. It was confirmed that metabolite M3A/4A observed in spinach is the same as M3A in carrots. It was agreed to consider M3A/4A as unidentified compounds and, for the time being, not to include this metabolite in the residue definition for risk assessment (EFSA, 2019).

Metabolites M14R/M15R, M16R/M17R and M18R (M19R in spinach) were considered less toxic than the parent clethodim (EFSA, 2011).

Metabolite M14A/M15A, a 3-chloroallyl alcohol glucoside is to be considered due to the possible release of unconjugated products. It is known that the metabolite 3-chloroallyl alcohol (the aglycon of 3-chloroallyl alcohol glucoside (M14A/M15A)), is a common metabolite with the active substance 1,3-dichloropropene for which in the framework of the renewal of the approval of 1,3-dichloropropene, additional toxicological studies were recently assessed (EFSA, 2018b). According to these studies, there are indications that 3-chloroallyl alcohol is more toxic than clethodim (the metabolite was demonstrated to be of higher toxicity than clethodim after repeated administration, with a no observed adverse effect level (NOAEL) of 3 mg/kg body weight (bw) per day for the metabolite vs 25 mg/kg bw per day in the 90-day study for parent, both having liver as target organ). Moreover, although 3-chloroallyl alcohol was negative in Ames test, this metabolite was positive in a mouse lymphoma assay and the in vivo micronucleus assay was considered as not reliable in the absence of evidence of bone marrow exposure. Consequently, the genotoxic potential of 3-chloroallyl alcohol could not be concluded and no toxicological reference values could be derived (EFSA, 2018b).

Based on the abovementioned considerations, the following residue definitions are proposed for plant commodities:

- Monitoring residue definition: sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim.
- Risk assessment residue definition 1: sum of clethodim, clethodim sulfoxide, clethodim sulfone and metabolites M14R/M15R, M16R/M17R and M18R/M19R, expressed as clethodim.
- Risk assessment residue definition 2: M14A/M15A.

It was further agreed during the expert meeting that, due to considerations on metabolite M14A/M15A, it will not be possible to perform a risk assessment according to the residue definition 2.

For residue definition 1, the following conversion factors from enforcement to risk assessment were agreed: 2.5 for root crops and pulses and oilseeds and 19 for leafy crops and for all crops not covered by a metabolism study (cereals, fruit crops) (EFSA, 2019).

During the expert meeting, it was discussed (EFSA, 2019) whether the proposed two residue definitions, particularly metabolite M14A/M15A however also M14R/15R and M16R/M17R should be
considered relevant for pulses, oilseeds and root crops considering the possible influence of light on metabolism (indoor vs outdoor studies) with a view to propose both residue definitions for all plant commodities. There were indications of molecule cleavage in metabolism studies in crops performed indoor. Furthermore, there were indications of cleavage of the chloroallyl group in all studies (such as the formation of imine metabolites e.g. imine sulfoxide and sulfone, M18R/M19R). Therefore, it was agreed to provisionally extend the proposed residue definitions to all plant commodities, pending the submission of an additional metabolism study (preferably on fruit crops performed outdoor).

The same residue definitions apply to rotational crops. For processed commodities, residue definitions are not proposed because information is inconclusive.

EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of clethodim and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of clethodim residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Netherlands, 2012, 2016), including residue trials evaluated in the framework of the peer review (EFSA, 2011) and additional data submitted during the completeness check (Belgium, 2017; Czech Republic, 2017; Denmark, 2017; France, 2017; Germany, 2017; Greece, 2017; Italy, 2017; Netherlands, 2018; Portugal, 2017; Spain, 2017; the United Kingdom, 2017).

Residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions with exception of samples for strawberries and carrots (southern European Union (SEU)) where storage information was not provided and linseeds (northern European Union (NEU)) (stored for less than 10.5 months) and chives NEU/SEU trials where samples analysed with a common moiety method were stored for 13.5 months. Considering that storage stability in all main matrices was demonstrated for nine months at −18°C, complete information on the storage conditions is considered desirable.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2016).

Residue trials are not available to support the authorisations on cane fruits (blackberries, raspberries, blueberries), other small fruits and berries (cranberries, currants, gooseberries, rose hips, elderberries), broccoli, cauliflowers, Brussels sprouts, spinaches, witloofs, asparagus, rice grain and straw and pea vines. Therefore, MRL or risk assessment values for these crops could not be calculated by EFSA and the following data gaps were identified:

- Cane fruits: Residue trials are not available and therefore eight trials on blackberries, raspberries and blueberries compliant with the northern outdoor GAP are still required.
- Other small fruits and berries: Residue trials are not available and therefore eight trials on cranberries, currants, gooseberries and rose hips compliant with the northern outdoor GAP are still required.
- Broccoli and cauliflowers: Residue trials are not available and therefore eight trials on cauliflowers and four trials on broccoli compliant with the northern outdoor GAP are still required.
- Brussels sprout: Residue trials are not available and therefore four trials on Brussels sprout compliant with the northern outdoor GAP are still required.
- Spinach: Residue trials are not available and therefore four trials on spinach compliant with the northern outdoor GAP and four compliant with the EU indoor GAP are still required.
- Witloofs: Residue trials are not available and therefore four trials on witloof compliant with the northern outdoor GAP are still required.
- Asparagus: Residue trials are not available to support the northern outdoor GAP on asparagus and therefore four trials on asparagus compliant with the northern outdoor GAP are still required.
Rice grain and straw: Two overdosed trials on rice grain and straw are available to support the southern outdoor GAP. Therefore, eight trials on rice grain and straw compliant with the southern outdoor GAP are still required.

Pea vines: Residue trials are not available to support the northern outdoor GAP on pea vines and therefore four trials on pea vines compliant with the northern outdoor GAP are still required.

Notably, all above required trials should be performed analysing simultaneously for enforcement and risk assessment residue definitions.

For all other crops, data were sufficient to calculate at least (tentative) MRLs and risk assessment values according to the tentative risk assessment residue definition one based on the available residue trials analysed according to the proposed residue definition for monitoring. Nevertheless, as none of the available residue trials were analysed for all relevant metabolites included in the proposed tentative residue definitions for risk assessment, the following data gaps were identified:

Wine and table grapes: Although a MRL can be derived from southern data, eight additional trials analysing simultaneously for the residue definitions for enforcement and risk assessment as tentatively proposed are still required.

Strawberries: Only four trials on strawberries are available to support the northern outdoor GAP. Although a tentative MRL can be derived from northern data, eight additional trials analysing simultaneously for the residue definitions for enforcement and risk assessment as tentatively proposed are still required.

Onions: Only five trials on onions are available to support the southern outdoor GAP and therefore a full data set on onions compliant with the southern outdoor GAP analysed according to the residue definitions for enforcement and risk assessment as tentatively proposed are still required.

Herbs and edible flowers (chives, chervil, celery leaves, parsley, sage, rosemary, thyme, basil, laurel/bay leaf, tarragon): While a tentative MRL is derived, a full data set of eight trials supporting each, the northern and southern European GAP and simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

Beans (with pods): Only overdosed trials are available to support the northern and southern authorisations and no residue trials are available to support the indoor use. Therefore, eight residue trials compliant with the northern outdoor GAP, eight residue trials compliant with southern outdoor GAP and indoor GAP simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

Beans and peas (without pods): Only overdosed trials are available to support the northern and southern authorisations. Therefore, eight residue trials compliant with the northern outdoor GAP and eight residue trials compliant with southern outdoor GAP simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

Peas (with pods): Only overdosed trials are available to support the northern and southern authorisations. Therefore, eight residue trials on peas (with pods) compliant with the northern outdoor GAP and eight residue trials on peas (with pods) compliant with southern outdoor GAP simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

Fresh lentils: While a tentative MRL can be derived from overdosed residue trials on beans (with pods), four residue trials on lentils (fresh) compliant with the northern outdoor GAP and four residue trials on lentils (fresh) compliant with southern outdoor GAP are still required noting that all required trials shall be simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed.

Beans (dry): While a tentative MRL can be derived from a combined data set on dry peas (six trials) and dry beans (two trials) compliant with the northern GAP, eight residue trials on beans (dry) compliant with the southern outdoor GAP simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

Peas (dry): Only three overdosed trials on dry peas are available which are analysed with a common moiety method and not according to the proposed residue definition for monitoring to support the northern outdoor GAP. While a tentative MRL can be derived, eight residue trials on peas (dry) compliant with the northern outdoor GAP and eight residue trials on peas (dry)
compliant with southern outdoor GAP simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

- **Lupini beans (dry):** Only three overdosed trials on dry peas are available which are analysed with a common moiety method and not according to the proposed residue definition for monitoring to support the northern outdoor GAP. While a tentative MRL can be derived, four residue trials on peas (dry) compliant with the northern outdoor GAP and four residue trials on peas (dry) compliant with southern outdoor GAP simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

- **Sesame, pumpkin, safflower, borage, hemp seeds and castor beans:** Eight GAP-compliant trials on rape seeds are available to support the northern GAP (no authorisations for sesame, pumpkin and safflower seeds); however, the southern GAP is only supported by three overdosed trials on rape and nine overdosed trials on sunflower seeds. Nevertheless, full data sets compliant with each, the northern outdoor GAP and the southern outdoor GAP simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

- **Sunflower and cotton seeds:** Fourteen overdosed trials on sunflower seeds are available to support the northern outdoor GAP and nine overdosed trials on sunflower seeds to support the southern outdoor GAP. Therefore, eight trials on sunflower seeds compliant with the northern and southern outdoor GAP simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

- **Mustard and Gold of Pleasure seeds:** Sixteen overdosed trials on rape seeds are available to support the northern outdoor GAP. While tentative MRL values were derived, eight trials on rape seeds compliant with the northern and eight trials compliant with the southern outdoor GAP simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

- **Sugar beet tops, fodder beet tops and turnip tops:** Six overdosed trials on alfalfa forage are available to support the northern outdoor GAP. While a MRL can be derived from a more critical fully supported southern outdoor GAP, four trials on alfalfa forage compliant with the northern outdoor GAP simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

- For poppy seeds, rape seeds/canola seeds and sugar beetroots: Overdosed residue trials on winter rape-seeds analysed for the residue definition for enforcement were providing residues below the LOQ which is indicating that a no residue situation is expected despite that the trials were not in compliance with the data requirements. However, considering information on metabolites of potential concern in the tentatively proposed residue definitions for risk assessment, full data sets simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

### 1.2.2. Magnitude of residues in rotational crops

Most of the 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. Field studies were not provided and a confined rotational crop study was considered as a surrogate (Section 1.1.2).

On the basis of the results, it is concluded that radioactivity does not tend to accumulate significantly in plants grown in soil treated with labelled clethodim. TRR (mg equivalent/kg) in mature rotational crops following application to bare soil at 1,100 g a.s./ha (2.9N of the cGAP for beans; 3.1N of cGAP for beetroots of this review) to bare soil were up to 0.05 mg eq/kg for the plant-back intervals of 30, 120 and 366 days for carrot leaf and roots, lettuce, wheat straw and grain where by individual compounds are not expected to be present in significant levels (above 0.01 mg/kg) when clethodim is applied according to the above conditions (EFSA, 2011).

Significant residues are not expected in succeeding crops under the cGAP conditions of this review, and therefore, the conclusion of the peer review is still considered valid.

### 1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on sugar beets (Netherlands, 2005). An overview of all available processing studies is
available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could not be derived while limited processing factors (not fully supported by data) were derived for processed commodities of sugar beets (molasses).

During the peer review, a field trial on sugar beets was carried out with foliar application of labelled clethodim twice with 1,401 g a.s./ha with a 16 days interval (totalling to 2,801 g a.s./ha (9.3N). Harvest of sugar beets took place 99 DAT. Treated and untreated beets were processed to fresh to dehydrated pulp, molasses, refined sugar and sliced roots. In the study, a common moiety method was used which analyses clethodim and its metabolites containing the 5-(ethylthiopropyl)cyclohexene-3-one moiety as dimethyl ester sulfone (DME) and its metabolites containing the 5-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moiety as dimethyl ester hydroxyl sulfone (DME-OH). The results are expressed as clethodim equivalents. In fresh sugar beets, residues were between 0.24 and 0.57 mg eq/kg in tops and < 0.1 mg eq/kg in roots and sliced roots, dehydrated pulp and refined sugar. In molasses combined clethodim, equivalent residues of 0.24–0.45 mg eq/kg were reported. The mean residue in molasses determined as DME was 0.28 mg eq/kg; however, considering the exaggerated application rate, residues above the LOQ of 0.05 or 0.1 mg/kg are not expected. A tentative processing factor of 2.8 was derived for molasses.

During this review, a processing study on the residue behaviour of clethodim in processed commodities of potatoes was provided and evaluated (France, 2017). Potato plants were treated with 334 g a.s./ha which represents 0.93N of the cGAP rate of potatoes (NEU). Three different processing procedures were carried out (starch processing, French fries or boiled potato processing). Residues of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as total clethodim equivalents, in treated potato specimens and processed fraction were reported. Residues of clethodim, clethodim sulfoxide and clethodim sulfone in raw potato tuber were at 0.066 mg/kg. In starch, this residue was reduced by a factor of 0.08 to below 0.005 mg/kg, in French fries by a factor of 0.15–0.01 mg/kg and in boiled potatoes by a factor of 0.11–0.0075 mg/kg.

Processing studies covering fruit, cereal, oilseeds and leafy crops are not available and since authorised uses on these crop groups are considered in this review, additional processing studies may be considered necessary. In addition, notably all studies have been performed analysing the residues according to the residue definition for enforcement in the raw commodities and none of the metabolites identified in Sections 1.1.1 and 1.1.2 on the nature in raw commodities and processed commodities were analysed for. Therefore, additional studies are required on the occurrence and magnitude of all significant metabolites, if applicable. It has further to be noted that if robust processing factors for root and tuber vegetables were to be required by risk managers, particularly for enforcement purposes, additional processing studies would be needed for processed commodities where a tentative processing factor is derived.

### 1.2.4. Proposed MRLs

The available data are sufficient to calculate MRLs for all commodities under evaluation, except for cane fruits (blackberries, raspberries, blueberries), other small fruits and berries (cranberries, currants, gooseberries, rose hips, elderberries), broccoli, cauliflowers, Brussels sprouts, spinach, walnuts, asparagus, rice grain and straw and pea vines were data were insufficient. None of the residue trials analysed for the proposed metabolites for inclusion in residue definition (RD) 1, conversion factors were derived from the metabolism studies which allowed to derive at least tentative risk assessment values for RD1. RD2 includes metabolite M14A/M15A for which genotoxicity could not be concluded. Therefore, risk assessment values according to RD2 could not be derived.

Since RD2 is tentatively proposed, all MRLs should be considered only tentative until the missing information on the respective metabolites is provided and an overall consumer risk assessment can be finalised.

Tentative MRLs were also calculated for alfalfa, clover, trefoil, vetch forage and sugar beet, fodder beet and turnip tops in view of a potential future need to set MRLs in feed items. In addition, it is be noted that EFSA is of the opinion that for all plant commodities full data sets simultaneously analysed according to residue definitions for enforcement and risk assessment as tentatively proposed are still required.

### 2. Residues in livestock

Clethodim is authorised for use on crops that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock according to OECD guidance (OECD, 2013),
which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in all commodities of animal origin.

It is noted that for several feed items, no residue data were available (e.g. rice grain and straw and pea vines). The animal intake of clethodim residues via these commodities has therefore not been assessed and may have been underestimated. However, this is not expected to have a major impact on the outcome of the dietary burden considering the high/overwhelming contribution of head cabbages. Furthermore, a contribution of metabolite M14A/M15A is not considered and therefore the dietary burden may be underestimated.

2.1. Nature of residues and methods of analysis in livestock

Two metabolism studies of clethodim, one in lactating goats and a second in laying hen were submitted during the peer review and were considered acceptable.

One lactating goat received propyl-labelled clethodim on three consecutive days and one dose on the fourth day at an actual dose of 24 mg/kg diet (1.2 mg/kg bw per day). Radioactive residues were highest in liver (0.41 mg eq/kg) and kidney (0.38 mg eq/kg). Residue levels in muscle and fat ranged between 0.033 and 0.079 mg eq/kg and in milk < 0.049 mg eq/kg. Clethodim was detected in liver at high levels (0.11 mg eq/kg; 28% TRR) and below 10% TRR in kidney and fat and in milk. Major metabolites were clethodim sulfoxide (liver: 33% TRR, 0.14 mg eq/kg; kidney: 37% TRR, 0.14 mg eq/kg; heart: 43% TRR, 0.025 mg eq/kg) and S-methyl sulfoxide (liver: 6.2% TRR, 0.025 mg eq/kg; kidney: 31% TRR, 0.12 mg eq/kg; except in milk on days one and three). Other observed metabolites were below 10% TRR.

It was concluded that residues in milk and ruminant tissues are sufficiently characterised. Notably, S-methyl metabolites can only be formed directly from the parent clethodim which is not expected to be present in plant commodities fed to livestock. Consequently, these metabolites are not expected in animal commodities.

In the second study, laying hens were dosed for five consecutive days with ring-4,6-labelled clethodim at a rate of 27 mg/kg diet (2.1 mg/kg bw per day) or 707 mg/kg diet (51.0 mg/kg bw per day). In total, 1.9% of the total administered dose was recovered in tissues. The residue levels were highest in kidney (1.2 mg eq/kg) and liver (0.7 mg e.g./kg) in muscle and fat 0.3 mg eq/kg were reported. No plateau was reached in eggs after 4 days with a maximum level of 0.22 mg eq/kg egg white. In kidney, liver and muscle tissue and eggs, major metabolites above 10% TRR were clethodim sulfoxide and clethodim sulfone. Clethodim was found at 7.5% TRR in liver, 34% TRR in egg yolk and 65% TRR in fat.

Clethodim, S-methyl clethodim sulfoxide and 5-OH clethodim sulfone residues in bovine milk, fat, kidney, liver and muscle were stable for 5 months during storage at −20°C. In egg, these compounds were stable for 2 months at −18°C.

During the peer review, no residue definition for animal commodities was proposed because the animal dietary burden was below the trigger value. In the present review, based on the two metabolism studies the following residue definition for monitoring and risk assessment is tentatively proposed: sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim. Since additional metabolites in plant commodities were considered relevant additional studies are needed (see Section 1.1.6). It is noted that in the available metabolism study livestock was fed with the parent compound only, which according to the residue trials, is not expected to be present in crops fed to livestock. Furthermore, no studies investigating the livestock metabolism of metabolites proposed for inclusion in the residue definitions for risk assessment are available. Therefore, the proposed residue definition for livestock should be considered tentative only, and additional livestock metabolism studies investigating the relevant metabolites found in plant, are still required.

A high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) for muscle, fat, liver, kidney, milk, eggs, with a combined LOQ of 0.05 mg/kg, for clethodim, clethodim sulfoxide, clethodim sulfone as sum was submitted during the peer review; however, an ILV was missing (Netherlands, 2005). During this review, a sufficiently validated HPLC-MS/MS method in milk, meat, liver, fat and eggs with an LOQ of 0.01 mg/kg for each metabolite, clethodim, clethodim sulfoxide and for clethodim sulfone and a combined LOQ of 0.03 mg/kg was provided (France, 2017).

It is concluded that sufficiently validated methods are available for enforcement of the proposed residue definition in all animal commodities at the combined LOQ of 0.03 mg/kg.
2.2. Magnitude of residues in livestock

In the framework of the peer review, feeding studies were performed with dairy cows and laying hen (Netherlands, 2005).

The study performed on cattle was used to derive MRL and risk assessment values in milk and tissues of ruminants/poultry. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. In the study, capsules with clethodim (5%) and clethodim sulfone (95%) were administered using different dosing levels ranging from 0.034/0.65; 0.1/1.9 and 0.29/5.6 clethodim/clethodim sulfoxide mg/kg bw per day. Samples of tissues and milk were analysed by a common moiety method. Clethodim and clethodim-like metabolites containing the 5-(2-ethylthiopropyl)cyclohexane-3-one moiety were converted to DME whereby 5-OH clethodim and 5-OH clethodim like metabolites containing the 5-(2-ethylthiopropyl)-5-hydroxycyclohexane-3-one moiety are converted to DME-OH and S-methyl-clethodim and S-methyl like metabolites are converted to S-methyl-DME. The residues are expressed as clethodim equivalents noting that this is not according to the proposed residue definitions for monitoring or risk assessment. The storage period of the samples was covered by the conditions for which storage stability was demonstrated thus decline of residues during storage of the trial samples is not expected.

The study performed on laying hen was used to derive MRL and risk assessment values in eggs and tissues of poultry. In the study, capsules with clethodim (5%) and clethodim sulfone (95%) were administered using different dosing levels ranging from 0.066/1.0; 0.16/3.0 and 0.48/9.4 clethodim/clethodim sulfoxide mg/kg bw per day. Samples of tissues and eggs were analysed with a common moiety method as outlined for ruminants and resulting in residues expressed as clethodim equivalents which is not according to the proposed residue definitions for monitoring or risk assessment. The storage period of the samples was covered by the conditions for which storage stability was demonstrated thus decline of residues during storage of the trial samples is not expected.

Based on these studies, MRL and risk assessment values were derived for all animal commodities, in compliance with the latest recommendations on this matter (FAO, 2009). It is noted that significant levels of clethodim equivalents are expected in all animal commodities except in milks where the MRL is tentatively proposed at the LOQ. Considering the uncertainty linked to the residue definitions in plant commodities, these MRLs are considered as tentative and indicative only. Furthermore, as results in the feeding study clethodim equivalents were derived by a common moiety method which is not compatible with the proposed residue definition.

3. Consumer risk assessment

In the framework of this review, only the uses of clethodim reported by the RMS in Appendix A were considered; however, the use of clethodim was previously also assessed by the JMPR (FAO, 1994, 1997, 1999, 2002). The CXLs, resulting from these assessment(s) by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

It is to be noted that since the genotoxic potential of the significant metabolite 3-chloroallyl alcohol, the aglycon of the clethodim metabolite 3-chloroallyl alcohol glucoside (M14A/M15A) could not be concluded and no toxicological reference values could be derived, an overall consumer risk assessment cannot be carried out. Nevertheless, with the available information, an indicative consumer risk was estimated considering RD1 as agreed during the expert meeting (EFSA, 2019).

3.1. Indicative consumer risk assessment without consideration of the existing CXLs

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be calculated by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009).

In the Expert Meeting, it was agreed that, since the risk assessment can only be performed according to risk assessment RD1 and not for risk assessment RD2, it will not be possible to perform an overall dietary consumer risk assessment and to derive MRL proposals in the recommendations (EFSA, 2019).
Nevertheless, for an indicative estimation, for those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL multiplied by tentative conversion factors (CFs) for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

The exposures calculated were compared with the toxicological reference value for clethodim, derived by EFSA (2011) under Directive 91/414/EEC. The highest chronic exposure based on the tentative residue definition for risk assessment one was calculated for FR (toddler), representing 12.7% of the acceptable daily intake (ADI), noting that an ARfD for clethodim was not considered necessary.

It has however to be noted that for the tentatively proposed residue definition two (Section 1.1.6) in the absence of required toxicological information, an overall consumer risk assessment cannot be finalised.

3.2. Indicative consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the estimations of the consumer exposure considering the tentatively proposed RD1, CXLs were compared with the calculated EU MRLs in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is also provided in Appendix D.

In the 1999 JMPR report, it is recommended that the definition of the residue for compliance with MRLs and for the estimation of dietary intake should be the sum of clethodim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfides and sulfoxides, expressed as clethodim. Both the residue definition for enforcement and for risk assessment are not compatible with those derived in Europe.

As the residue definition for enforcement of the CXLs is not compatible with the residue definition for enforcement proposed by EFSA, for information purposes, EFSA has performed an indicative risk assessment considering the relevant data from the JMPR evaluations (FAO, 1999).

For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR (except for rapeseeds, soya beans and cotton seeds where the CXL value was considered), multiplied by the tentative conversion factors of 2.5 (root and tuber vegetables, pulses and oilseeds) and 19 (all other crop groups) for risk assessment.

An overview of the input values used for this exposure calculation is also provided in Appendix D.3. Chronic and acute exposure calculations were performed using revision 2 of the EFSA PRIMo and the exposures calculated were compared with the toxicological reference values derived for clethodim. The highest chronic exposure was calculated for WHO Cluster diet B, representing 27.6% of the ADI. This assessment only aims to carry out an indicative assessment of CXLs for consumers, considering the tentatively proposed RD1.

These calculations indicate no potential risk to consumers for the existing CXLs on plant and animal commodities. However, considering that CXLs are currently expressed according to residue definitions which are not compatible with those proposed in Europe, they are not recommended for inclusion in the EU legislation.

Conclusions

The metabolism of clethodim was investigated after foliar treatment in root and tuber crops, pulses and oilseeds and leafy vegetables. A general metabolic pathway in all three crop groups can be elucidated. The parent clethodim is extensively metabolised in mature crops and mostly not detected in all groups. One major pathway is sulfoxidation to clethodim sulfoxide followed by further oxidation to clethodim sulfone which was mainly observed in root and tuber vegetables. Another pathway is the elimination of the chloroallyl moiety, leading to the formation of clethodim imine and 3-chloroallyl metabolites, including 3-chloroallyl alcohol glucosides (M14A/M15A) which was the main pathway in the spinach study and maybe considered as such for leafy crops. It has however to be noted that although the same metabolites were potentially identified in all metabolism studies in carrot, cotton and spinach, there were clear quantitative differences, especially with regard to the amount of M14A (3-chloroallyl alcohol glucoside) and M3/4A in spinach (leafy crops).
The metabolism of clethodim in three rotational crop studies covering cereals, root and tuber vegetables and leafy crops was similar as the pathway in primary crops in that clethodim is extensively degraded and was not detected in any of the analysed extracts. Individual soil metabolites identified in the rotational crop study are not expected to exceed the LOQ of 0.01 mg/kg, provided that clethodim is used according the GAPs assess in this review.

Based on the results of the hydrolysis studies, it can be concluded that clethodim is hydrolysed to clethodim oxazole and clethodim trione. Information on the fate of the allyl moiety of clethodim is not provided. Therefore, additional studies to provide information on the fate of the allyl-moiety are still needed. In addition, notably since clethodim is not expected in raw plant commodities, additional hydrolysis studies where all metabolites relevant for the risk assessment are analysed are still needed.

Toxicity of the metabolites M14R/M15R, M16R/M17R and M18R (M19R in spinach) is known to be covered by the parent clethodim. Information on structure and toxicity of M3/4A is not available and it is not possible to conclude on the toxicological relevance of this metabolite in the framework of this review.

Metabolites M14A/M15A represents the 3-chloroallyl alcohol glucoside and, due to the possible release of unconjugated products, conjugates should be considered. The metabolite 3-chlorolallyl alcohol (the aglycon of M14A/15A), is a common metabolite with the active substance 1,3-dichloropropene. For this metabolite genotoxicity could not be concluded in the framework of the renewal of the approval of 1,3-dichloropropene where additional toxicological studies were recently assessed.

In an expert meeting, it was agreed to have two separate residue definitions for risk assessment. The following common residue definitions are proposed for plant commodities:

- Monitoring: sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim;
- Risk assessment residue definition 1: sum of clethodim, clethodim sulfoxide, clethodim sulfone and metabolites M14R/15R, M16R/M17R and M18R/M19R, expressed as clethodim.
- Risk assessment residue definition 2: M14A/M15A.

The same residue definitions apply to rotational crops. For processed commodities, residue definitions are not proposed because information is inconclusive.

Based on the metabolism study in spinach, mathematically a conservative indicative conversion factor between monitoring to risk assessment of 19 as tentatively applied to crops other than root and tuber vegetables, pulses and oilseeds where the conversion factor of 2.5 derived during the peer review was applied.

It can be concluded that clethodim, clethodim sulfoxide and clethodim sulfone can be enforced in high water, high acid, high oil content and dry commodities with a combined LOQ of enforcement of 0.014 mg/kg, expressed as clethodim (rounded to 0.02 mg/kg).

With regard to the magnitude of residues in raw plant commodities, the available data are sufficient to calculate MRLs for all commodities under evaluation, except for cane fruits (blackberries, raspberries, blueberries), other small fruits and berries (cranberries, currants, gooseberries, rose hips, elderberries), broccoli, cauliflowers, Brussels sprouts, spinach, witloofs, asparagus, rice grain and straw and pea vines were data were insufficient.

None of the residue trials analysed for the proposed metabolites for inclusion in RD1, conversion factors were derived from the metabolism studies which allowed to derive at least tentative risk assessment values for RD1. RD2 includes metabolite M14A/M15A for which genotoxicity could not be concluded. Therefore, risk assessment values according to RD2 could not be derived. Since RD2 is tentatively proposed, all MRLs should be considered only tentative until the missing information on the respective metabolites is provided and an overall consumer risk assessment can be finalised.

Clethodim is authorised for use on crops that might be fed to livestock. For animal commodities, based on the two metabolism studies conducted with the parent, the following residue definition for monitoring and risk assessment is tentatively proposed: sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim. A sufficiently validated method is available for enforcement of the proposed residue definition at the combined LOQ of 0.03 mg/kg.

Significant levels of clethodim equivalents are expected in all animal commodities except milks where the MRL is proposed at the LOQ. Considering the uncertainty linked to the residue definitions in plant commodities, these MRLs are considered as tentative and indicative only. Furthermore, since in the feeding study clethodim equivalents were derived by a common moiety method the results are not compatible with the tentatively proposed residue definition.

Considering the above outlined uncertainties, an overall risk assessment could not be performed and only an indicative chronic consumer exposure according to the proposed tentative RD1 resulting
from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to calculate MRLs, EFSA considered the existing EU MRL multiplied by a tentative conversion factor proposed based on RD1 for an indicative calculation. The highest tentatively estimated chronic exposure represented 12.7% of the ADI (FR, toddler). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for clethodim. According to RD1, indicative estimations of the consumer exposure, considering these CXLs, were therefore tentatively carried out and the highest chronic exposure represented 27.6% of the ADI (WHO, cluster diet B).

EFSA emphasises that the available studies do not investigate the possible impact of plant and animal metabolism on the isomer ratio of clethodim and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion. No MRL values are listed in the table since none could be recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data. In particular, the genotoxic potential of the metabolite 3-chloroallyl alcohol, the aglycon of 3-chlorolallyl alcohol glucoside (M14A/M15A) a clethodim metabolite, could not be concluded and no toxicological reference values could be derived (see Table 1 footnotes for details).

It is noted that the current residue definition for enforcement still includes sethoxydim. Notably, sethoxydim is currently not approved. Therefore, the current list of MRLs for the active substances ‘clethodim’ and ‘sethoxydim’ should be considered to be split and MRLs for ‘clethodim’ and ‘sethoxydim’ listed separately.

In particular, the following data gaps were identified:

- additional residue trials for wine and table grapes, strawberries, cane fruits, other small fruits and berries, potatoes, carrots (celeriacs, horseradishes), Jerusalem artichokes, parsnips, parsley roots and salsifies, swedes and turnips, onions, garlic and shallots, spring onions/green onions and Welsh onions, tomatoes, broccoli, cauliflower, Brussels sprouts, head cabbages, spinaches, witloofs, herbs and edible flowers (chives, chervil, celery leaves, parsley, sage, rosemary, thyme, basil, edible flowers, laurel/bay leaf, tarragon), beans and peas with and without pods and fresh lentils, asparagus, globe artichokes, dry pulses (beans, peas and lupine beans), oil seeds (linseeds, poppy seeds, sesame, pumpkin, safflower seeds, borage seeds, hemp seeds, castor beans, sunflower and cotton seeds, rape/canola seeds, soya beans mustard seeds and Gold of Pleasure seeds), rice grain and straw, beet roots, fodder beet roots, sugar beet roots and chicory roots, sugar beet, fodder beet and turnip tops, alfalfa, clover, trefoil and vetch forage and pea vines analysed simultaneously according to the proposed residue definitions for enforcement and tentative residue definitions for risk assessment one and two;
- a representative metabolism study in a fourth crop group (preferably fruit crops performed outdoor);
- representative hydrolysis studies;
- representative processing studies analysing for all (ring- and allyl-) metabolites;
- information on the toxicological profile of the metabolite 3-chloroallyl alcohol and related allyl-metabolites;
- representative animal metabolism studies with relevant allyl- and phenyl-labelled clethodim metabolites;
- a representative animal feeding study where residues are analysed according to the proposed residue definitions for enforcement and risk assessment.

Member States are recommended to withdraw or modify the relevant authorisations at national level based on the identified data gaps.

It is noted that the current residue definition for enforcement still includes sethoxydim. Notably, sethoxydim is currently not approved. Therefore, the current list of MRLs for the active substances ‘clethodim’ and ‘sethoxydim’ should be considered to be split and MRLs for ‘clethodim’ and ‘sethoxydim’ listed separately.
Table 1: Summary table

| Code number | Commodity                           | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-------------------------------------|-------------------------|---------------------|----------------------|---------|
| 0151010     | Table grapes                        | 1                       | –                   | Further consideration needed(a) |         |
| 0151020     | Wine grapes                         | 0.5                     | –                   | Further consideration needed(a) |         |
| 0152000     | Strawberries                        | 0.5                     | –                   | Further consideration needed(a) |         |
| 0153010     | Blackberries                        | 0.1                     | –                   | Further consideration needed(a) |         |
| 0153030     | Raspberries (red and yellow)        | 0.1                     | –                   | Further consideration needed(b) |         |
| 0154010     | Blueberries                         | 0.1                     | –                   | Further consideration needed(b) |         |
| 0154020     | Cranberries                         | 0.5                     | –                   | Further consideration needed(b) |         |
| 0154030     | Currants (black, red and white)     | 0.1                     | –                   | Further consideration needed(b) |         |
| 0154040     | Gooseberries (green, red and yellow) | 0.1                   | –                   | Further consideration needed(b) |         |
| 0154050     | Rose hips                           | 0.1                     | –                   | Further consideration needed(b) |         |
| 0154080     | Elderberries                        | 0.1                     | –                   | Further consideration needed(b) |         |
| 0211000     | Potatoes                            | 0.5                     | 0.5                 | Further consideration needed(c) |         |
| 0213010     | Beetroots                           | 0.5                     | –                   | Further consideration needed(a) |         |
| 0213020     | Carrots                             | 0.5                     | –                   | Further consideration needed(a) |         |
| 0213030     | Celeriacs/turnip rooted celeries    | 0.5                     | –                   | Further consideration needed(a) |         |
| 0213040     | Horseradishes                       | 0.5                     | –                   | Further consideration needed(a) |         |
| 0213050     | Jerusalem artichokes                | 0.5                     | –                   | Further consideration needed(a) |         |
| 0213060     | Parsnips                            | 0.5                     | –                   | Further consideration needed(a) |         |
| 0213070     | Parsley roots/Hamburg roots parsley | 0.5                   | –                   | Further consideration needed(a) |         |
| 0213090     | Salsifies                           | 0.5                     | –                   | Further consideration needed(a) |         |
| 0213100     | Swedes/rutabagas                    | 0.5                     | –                   | Further consideration needed(a) |         |
| 0213110     | Turnips                             | 0.5                     | –                   | Further consideration needed(a) |         |
| 0220010     | Garlic                              | 0.5                     | 0.5                 | Further consideration needed(c) |         |
| 0220020     | Onions                              | 0.5                     | 0.5                 | Further consideration needed(c) |         |
| 0220030     | Shallots                            | 0.5                     | –                   | Further consideration needed(a) |         |
| 0220040     | Spring onions/green onions and Welsh onions | 0.5 | – | Further consideration needed(a) |         |
| 0231010     | Tomatoes                            | 1                       | 1                   | Further consideration needed(c) |         |
| 0241010     | Broccoli                            | 0.5                     | –                   | Further consideration needed(b) |         |
| 0241020     | Cauliflowers                        | 0.5                     | –                   | Further consideration needed(b) |         |
| 0242010     | Brussels sprouts                    | 0.5                     | –                   | Further consideration needed(b) |         |
| 0242020     | Head cabbages                       | 0.5                     | –                   | Further consideration needed(b) |         |
| 0252010     | Spinaches                           | 0.5                     | –                   | Further consideration needed(b) |         |
| 0255000     | Witloofs/Belgian endives            | 0.5                     | –                   | Further consideration needed(b) |         |
| 0256010     | Chervil                             | 0.5                     | –                   | Further consideration needed(b) |         |
| 0256020     | Chives                              | 0.5                     | –                   | Further consideration needed(b) |         |
| 0256030     | Celery leaves                       | 0.5                     | –                   | Further consideration needed(b) |         |
| 0256040     | Parsley                             | 0.5                     | –                   | Further consideration needed(b) |         |
| 0256050     | Sage                                | 0.5                     | –                   | Further consideration needed(b) |         |

**Enforcement residue definition (existing):** Clethodim (sum of sethoxydim and clethodim including degradation products calculated as sethoxydim)

**Enforcement residue definition (proposed):** Sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim
| Code number | Commodity                    | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|------------------------------|-------------------------|----------------------|-----------------------|---------|
| 0256060     | Rosemary                     | 0.5                     | –                    | Further consideration needed(a) |         |
| 0256070     | Thyme                        | 0.5                     | –                    | Further consideration needed(a) |         |
| 0256080     | Basil and edible flowers     | 0.5                     | –                    | Further consideration needed(a) |         |
| 0256090     | Laurel/bay leave             | 0.5                     | –                    | Further consideration needed(a) |         |
| 0256100     | Tarragon                     | 0.5                     | 0.5*                 | Further consideration needed(c) |         |
| 0260010     | Beans (with pods)            | 0.5                     | –                    | Further consideration needed(a) |         |
| 0260020     | Beans (without pods)         | 0.5                     | –                    | Further consideration needed(a) |         |
| 0260030     | Peas (with pods)             | 0.5                     | –                    | Further consideration needed(a) |         |
| 0260040     | Peas (without pods)          | 0.5                     | –                    | Further consideration needed(a) |         |
| 0260050     | Lentils                      | 0.5                     | –                    | Further consideration needed(a) |         |
| 0270010     | Asparagus                    | 0.5                     | –                    | Further consideration needed(a) |         |
| 0270050     | Globe artichokes             | 0.5                     | –                    | Further consideration needed(a) |         |
| 0300010     | Beans (dry)                  | 2                       | 2                    | Further consideration needed(c) |         |
| 0300030     | Peas (dry)                   | 2                       | 2                    | Further consideration needed(c) |         |
| 0300040     | Lupins/lupini beans (dry)    | 0.5                     | –                    | Further consideration needed(a) |         |
| 0401010     | Linseeds                     | 0.1                     | –                    | Further consideration needed(a) |         |
| 0401020     | Peanuts                      | 5                       | 5                    | Further consideration needed(c) |         |
| 0401030     | Poppy seeds                  | 0.1                     | –                    | Further consideration needed(a) |         |
| 0401040     | Sesame seeds                 | 0.1                     | –                    | Further consideration needed(a) |         |
| 0401050     | Sunflower seeds              | 0.5                     | 0.5                 | Further consideration needed(c) |         |
| 0401060     | Rapeseeds/canola seeds       | 1                       | 0.5                 | Further consideration needed(c) |         |
| 0401070     | Soya beans                   | 10                      | 10                   | Further consideration needed(c) |         |
| 0401080     | Mustard seeds                | 0.1                     | –                    | Further consideration needed(a) |         |
| 0401090     | Cotton seeds                 | 0.5                     | 0.5                 | Further consideration needed(c) |         |
| 0401100     | Pumpkin seeds                | 0.1                     | –                    | Further consideration needed(a) |         |
| 0401110     | Safflower seeds              | 0.1                     | –                    | Further consideration needed(a) |         |
| 0401120     | Borage seeds                 | 0.1                     | –                    | Further consideration needed(a) |         |
| 0401130     | Gold of pleasure seeds       | 0.1                     | –                    | Further consideration needed(a) |         |
| 0401140     | Hemp seeds                   | 0.1                     | –                    | Further consideration needed(a) |         |
| 0401150     | Castor beans                 | 0.1                     | –                    | Further consideration needed(a) |         |
| 0500060     | Rice                         | 0.1                     | –                    | Further consideration needed(a) |         |
| 0900010     | Sugar beet roots             | 0.5                     | 0.1                 | Further consideration needed(c) |         |
| 0900030     | Chicory roots                | 0.1                     | –                    | Further consideration needed(a) |         |

Review of the existing MRLs for clethodim

www.efsa.europa.eu/efsajournal 22 EFSA Journal 2019;17(5):5706
| Code number | Commodity             | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review                      | Comment                  |
|-------------|-----------------------|-------------------------|----------------------|-------------------------------------------|--------------------------|
| 1014020     | Goat fat tissue       | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1014030     | Goat liver            | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1014040     | Goat kidney           | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1015010     | Equine muscle         | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1015020     | Equine fat tissue     | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1015030     | Equine liver          | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1015040     | Equine kidney         | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1016010     | Poultry muscle        | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1016020     | Poultry fat tissue    | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1016030     | Poultry liver         | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1016040     | Poultry kidney        | 0.2                     | 0.2*                 | --                                        | Further consideration needed(c) |
| 1020010     | Cattle milk           | 0.05*                   | 0.05*                | --                                        | Further consideration needed(c) |
| 1020020     | Sheep milk            | 0.05*                   | 0.05*                | --                                        | Further consideration needed(c) |
| 1020030     | Goat milk             | 0.05*                   | 0.05*                | --                                        | Further consideration needed(c) |
| 1020040     | Horse milk            | 0.05*                   | 0.05*                | --                                        | Further consideration needed(c) |
| 1030000     | Bird eggs             | 0.05*                   | 0.05*                | --                                        | Further consideration needed(c) |
|             | Other commodities of  | Regulation (EC) No      |                      |                                           |                          |
|             | plant and animal origin| 839/2008                |                      |                                           | Further consideration needed(e) |

MRL: maximum residue level; CXL: codex maximum residue limit.

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

(a): GAP evaluated at EU level is not fully supported by data and an overall risk assessment could not be performed; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-I in Appendix E).

(b): GAP evaluated at EU level is not supported by data and an overall risk assessment could not be performed; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-I in Appendix E).

(c): GAP evaluated at EU level is not fully supported by data and an overall risk assessment could not be performed; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-II in Appendix E).

(d): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix E).

(e): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
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**Abbreviations**

- **a.i.** active ingredient
- **a.s.** active substance
- **ADI** acceptable daily intake
- **ARFD** acute reference dose
- **BBCH** growth stages of mono- and dicotyledonous plants
| Abbreviation | Description |
|--------------|-------------|
| bw           | body weight |
| CAC          | Codex Alimentarius Commission |
| CF           | conversion factor for enforcement residue definition to risk assessment residue definition |
| cGAP         | critical GAP |
| CXL          | codex maximum residue limit |
| DAR          | draft assessment report |
| DAT          | days after treatment |
| DB           | dietary burden |
| DM           | dry matter |
| DME          | dimethyl ester sulfone (analysed by using the common moiety method) |
| DME-OH       | dimethyl ester hydroxyl sulfone |
| DT90         | period required for 90% dissipation (define method of estimation) |
| EC           | emulsifiable concentrate |
| EMS          | evaluating Member State |
| eq           | residue expressed as a.s. equivalent |
| EURs         | European Union Reference Laboratories for Pesticide Residues (former CRLs) |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | good agricultural practice |
| HPLC-MS/MS   | high-performance liquid chromatography with tandem mass spectrometry |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| IESTI        | international estimated short-term intake |
| ILV          | independent laboratory validation |
| InChIKey     | International Chemical Identifier Key |
| ISO          | International Organisation for Standardization |
| IUPAC        | International Union of Pure and Applied Chemistry |
| JMPR         | Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| KL           | Combi-pack liquid/liquid |
| LC-MS/MS     | liquid chromatography with tandem mass spectrometry |
| LOQ          | limit of quantification |
| Mo           | monitoring |
| MRL          | maximum residue level |
| MS           | Member States |
| MW           | molecular weight |
| NEU          | northern European Union |
| NOAEL        | no observed adverse effect level |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant-back interval |
| PF           | processing factor |
| PHI          | pre-harvest interval |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| PROFile      | (EFSA) Pesticide Residues Overview File |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SC           | suspension concentrate |
| SEU          | southern European Union |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TRR          | total radioactive residue |
| WHO          | World Health Organization |
### Appendix A – Summary of authorised uses considered for the review of MRLs

| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|--------------------------------|------------|---------|
|                       |               |                                   | Type(b)     | Conc. a.s. | Method kind                     |            |         |
|                       |               |                                   | Range of growth stages & season(c) | Number min–max | Interval between applications (min) | g a.s./ha min–max | Water L/ha min–max | g a.s./ha min–max |         |
| **Strawberries**      | NL, CZ        | F Annual Monocotyledoneae ssp. (weeds which are difficult to control) | Foliar treatment – spraying | 0–16 | 1 | – | – | – | 0.24 kg a.i./ha | 30 | 200–400 L/ha. Equal/Less critical GAPs reported by DE, AT, SE, FI. NL and CZ GAP: PHI = 30 days supported by eight trials. DK reported a different GAP (BBCH 15–59 or after harvest, 1–2 × 0.12 kg a.s./ha; PHI = 40 days) |
| **Blackberries**      | DE            | F Annual bluegrass BBCH 12–29 | KL 240 g/L | Foliar treatment – spraying | 59 | 1 | – | – | – | 0.18 kg a.i./ha | n.a. | A different GAP was also reported by DE (BBCH 91 (after harvest), 1 × 0.18 kg a.s./ha, PHI: n.a.). Waiver for residue trials proposed |
| **Raspberries**       | DE            | F Annual bluegrass BBCH 12–29 | KL 240 g/L | Foliar treatment – spraying | 59 | 1 | – | – | – | 0.18 kg a.i./ha | n.a. | See comment above |
| **Blueberries**       | DE            | F Annual bluegrass BBCH 12–29 | KL 240 g/L | Foliar treatment – spraying | 59 | 1 | – | – | – | 0.18 kg a.i./ha | n.a. | See comment above |
| Crop and/or situation | MS or country | FG or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|--------------|---------|-----------------------------------|------------|------------|------------------------------|---------|
| **Cranberries**        | DE           | F       | Annual bluegrass BBCH 12-29       | KL         | 240 g/L    | Foliar treatment – spraying | 59 1    |
|                       |              |         |                                   |            |            |                              | 0.18 kg a.i./ha | n.a.      | See comment above |
| **Currants**           | DE           | F       | Annual bluegrass BBCH 12-29       | KL         | 240 g/L    | Foliar treatment – spraying | 59 1    |
|                       |              |         |                                   |            |            |                              | 0.18 kg a.i./ha | n.a.      | See comment above |
| **Gooseberries**       | DE           | F       | Annual bluegrass BBCH 12-29       | KL         | 240 g/L    | Foliar treatment – spraying | 59 1    |
|                       |              |         |                                   |            |            |                              | 0.18 kg a.i./ha | n.a.      | See comment above |
| **Rose hips**          | DE           | F       | Annual bluegrass BBCH 12-29       | KL         | 240 g/L    | Foliar treatment – spraying | 59 1    |
|                       |              |         |                                   |            |            |                              | 0.18 kg a.i./ha | n.a.      | See comment above |
| **Elderberries**       | DE           | F       | Annual bluegrass BBCH 12-29       | KL         | 240 g/L    | Foliar treatment – spraying | 59 1    |
|                       |              |         |                                   |            |            |                              | 0.18 kg a.i./ha | n.a.      | See comment above |
| **Potatoes**           | NL           | F       | Weeds                             | EC         | 120 g/L    | Foliar treatment – general | 12-33  |
|                       |              |         |                                   |            |            |                              | 0.3 kg a.i./ha  | 56        | Overall spray. Less critical GAPs reported by AT, BE, DE, FR, HU, SE |
| **Beetroots**          | DE           | F       | Weeds                             | KL         | 240 g/L    | Foliar treatment – general  | 12-33  |
|                       |              |         |                                   |            |            |                              | 0.36 kg a.i./ha | 100       | Overall spray. Different GAPs by FR (BBCH 12-33; 1 × 300 g a.s./ha; PHI = 60 days) and DK (BBCH 12-45; 2 × 168 g a.s./ha; PHI = 60 days) |
## Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|------------------------------------|-------------|-------------|---------------------------------|------------|---------|
|                       |               |                                    |             |             | g a.s./ha | g a.s./ha | g a.s./L | Water L/ha | Remarks |
|                        |               |                                    | Type(b)     | Conc. a.s.  | Method kind          | Range of growth stages & season(c) | Number min–max | Interval between applications (min) | PHI (days) |            |
| **Carrots FR, CZ**    | F             | Monocotyl weeds                    | EC          | 120 g/L     | Foliar treatment – spraying | 12–45 | 1 | – | – | 0.24 kg a.i./ha | 40 | 200–300 L/ha. HU GAP 288 g a.s./ha; no BBCH/PHI. Less critical GAPs reported by FIN, SE, BE (1 x 120 g a.s./ha; PHI = 40 days), NL and UK (1 x 240 g a.s./ha; PHI = 48 days); DK: 2 x 84 g a.s./ha, PHI = 60 days |
| **Celeriacs FR**      | F             | Perennial grasses                   | EC          | 240 g/L     | Foliar treatment – spraying | 12–45 | 1 | – | – | 0.24 kg a.i./ha | 40 | BE less critical GAP (1 x 120 g a.s./ha; PHI = 40 days). DK different GAP (BBCH 12–45; 2 x 168 g a.s./ha; PHI = 60 days) no data |
| **Horseradishes FR**  | F             | Perennial grasses                   | EC          | 240 g/L     | Foliar treatment – spraying | 12–45 | 1 | – | – | 0.24 kg a.i./ha | 40 |
| **Jerusalem artichokes FR** | F         | Perennial grasses                   | EC          | 240 g/L     | Foliar treatment – spraying | 12–45 | 1 | – | – | 0.24 kg a.i./ha | 40 |
| **Parsnips FR**       | F             | Perennial grasses                   | EC          | 240 g/L     | Foliar treatment – spraying | 12–45 | 1 | – | – | 0.24 kg a.i./ha | 40 | See celeriac NEU |
## Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | F G or I<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-------------------------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| **Parsley roots**     | FR F          | F                       | Perennial grasses                 | EC          | 120 g/L    | Foliar treatment – spraying   | 12–45      | 1       | 0.24 kg a.i./ha | 40        | For BE and DK GAPs see celeriac NEU. NL less critical GAP (PHI = 48 days; GAP including lovage, Aglika and Burnet saxfort roots) |
| **Salsifies**         | FR F          | F                       | Grass weeds                       | EC          | 240 g/L    | Foliar treatment – spraying   | 12–45      | 1       | 0.24 kg a.i./ha | 40        |                                |
| **Swedes**            | DE F          | F                       | *Agropyron repens* L.             | KL          | 241.9 g/L  | Foliar treatment – spraying   | 10         | 1       | 0.242 kg a.i./ha | After emergence of the crop and at 15–20 cm height of the weed |
| **Turnips**           | DE F          | F                       | *Agropyron repens* L.             | KL          | 241.9 g/L  | Foliar treatment – spraying   | 10         | 1       | 0.242 kg a.i./ha | After emergence of the crop and at 15–20 cm height of the weed |

<sup>(a)</sup> Crop and/or situation: FR = France; DE = Germany; NL = Netherlands; UK = United Kingdom.

<sup>(b)</sup> Type: EC = Emulsifiable concentrate; SL = Suspension liquid; WP = Water soluble powder.

<sup>(c)</sup> Range of growth stages & season: 12-45 = 12–45 days post-emergence.

<sup>(d)</sup> PHI (days): PHI = Pre-Harvest Interval.
### Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | Pests or Group of pests controlled | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min–max | Interval between applications (min) | g a.s./ha min–max | PHI (days) | Remarks |
|-----------------------|--------------|-----------------------------------|---------|-----------|-------------|-----------------------------------|----------------|-----------------------------------|-----------------|------------|---------|
| Garlic                | NL, UK       | F                                 | EC      | 120 g/L   | Foliar treatment – general       | 39                  | 1                                 | –               | –          | 0.24 kg a.i./ha | 56         | Less critical GAP in FR, BBCH 12-45, 1 × 0.12 kg a.s./ha; PHI = 56 days; overall spray; NL with BBCH 12-45, 1 × 0.24 kg a.s./ha, PHI = 56 days; DK reported different GAP (BBCH 12-45; 2 × 168 g a.s./ha; PHI = 40 days) not supported by data |
| Onions                | CZ, NL, UK   | F                                 | EC      | 120 g/L   | Foliar treatment – spraying      | 12-45               | 1                                 | –               | –          | 0.24 kg a.i./ha | 56         | 200–300 L/ha. Less critical GAPs in FR, BE, SE, DE and FIN. DK has different GAP (BBCH 12-45; 2 × 168 g a.s./ha; PHI = 40 days) |
| Shallots              | NL, UK       | F                                 | EC      | 120 g/L   | Foliar treatment – general       | 12-45               | 1                                 | –               | –          | 0.24 kg a.i./ha | 56         | Less critical GAP in FR, BBCH 12-45, 1 × 0.12 kg a.s./ha; PHI = 56 days; overall spray. DK: different GAP not supported by data |
Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | FG or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|---------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
|                       |              |         |                                   | Type(b)     | Conc. a.s. | Method kind                    | Range of growth stages & season(c) | Number min-max | Interval between applications (min) | g a.s./hl min-max | Water L/ha min-max | g a.s./ha min-max |          |         |
| Spring onions         | DE           | F       | Annual Monocotyledoneae ssp. Poa anua | KL          | 241.9 g/L | Foliar treatment – spraying    | 1          | –                | –               | –          | 0.181 kg a.i./ha | 35       |          |         |
| Broccoli              | NL           | F       | Annual Monocotyledoneae ssp. Poa anua | EC          | 120 g/L  | Foliar treatment – spraying    | 1          | –                | –               | –          | 0.24 kg a.i./ha | 28       |          |         |
| Cauliflowers          | NL           | F       | Annual Monocotyledoneae ssp. Poa anua | EC          | 120 g/L  | Foliar treatment – spraying    | 1          | –                | –               | –          | 0.24 kg a.i./ha | 28       |          |         |
| Brussels sprouts      | NL, UK       | F       | Annual Monocotyledoneae ssp. (except Agropyron repens L.) | EC          | 120 g/L  | Foliar treatment – spraying    | 12-41      | 1                | –               | –          | 0.24 kg a.i./ha | 28       |          |         |
| Head cabbages         | NL, CZ       | F       | Annual Monocotyledoneae ssp. (except Agropyron repens L.) | KL          | 241.9 g/L | Foliar treatment – spraying    | 12-41      | 1                | –               | –          | 0.24 kg a.i./ha | 28       |          |         |

Review of the existing MRLs for clethodim

www.efsa.europa.eu/efsajournal 32 EFSA Journal 2019;17(5):5706
## Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | F or G or I<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------|-----------------------------------|-------------|-----------------------------|-----------------|---------|
|                       |               |                             |                                   | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between applications (min) | g a.s./hL min-max | Water L/ha min-max | g a.s./ha min-max | |
| Spinaches             | BE            | F                            | Couch-grass                       | EC          | 240 g/L | Foliar treatment – spraying | 12–14 | 1 | – | – | 0.12 kg a.i./ha | | BE GAP not supported by trials (4 trials conducted with 1 × 375 g a.s./ha at BBCH 12–14 with no residues above LOQ (neither analytical method nor storage stability available) |
| Witloofs              | NL            | F                            | *Agropyron repens*                | EC          | 120 g/L | Foliar treatment – spraying | 1 | – | – | – | 0.3 kg a.i./ha | 56 | Witloofs for root production. Post-emergence |
| Chervil               | FR            | F                            | Weeds                             | EC          | 240 g/L | Foliar treatment – spraying | 16 | 1 | – | – | 0.12 kg a.i./ha | 60 | |
| Chives                | FR            | F                            | Weeds                             | EC          | 240 g/L | Foliar treatment – spraying | 16 | 1 | – | – | 0.12 kg a.i./ha | 60 | |
| Celery leaves         | FR            | F                            | Weeds                             | EC          | 240 g/L | Foliar treatment – spraying | 16 | 1 | – | – | 0.12 kg a.i./ha | 60 | |
| Parsley               | FR            | F                            | Weeds                             | EC          | 240 g/L | Foliar treatment – spraying | 16 | 1 | – | – | 0.12 kg a.i./ha | 60 | Proposed extrapolation from chives to herbs and edible flowers |
| Sage                  | FR            | F                            | Weeds                             | EC          | 240 g/L | Foliar treatment – spraying | 16 | 1 | – | – | 0.12 kg a.i./ha | 60 | |
### Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | F or G or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-------------|------------------------------------|-------------|-------------|--------------------------------|------------|---------|
| Rosemary | FR | F | Weeds | EC 240 g/L | Foliar treatment – spraying | 16 | 1 | – | 0.12 kg a.i./ha | 60 |
| Thyme | FR | F | Weeds | EC 240 g/L | Foliar treatment – spraying | 16 | 1 | – | 0.12 kg a.i./ha | 60 |
| Basil | FR | F | Weeds | EC 240 g/L | Foliar treatment – spraying | 16 | 1 | – | 0.12 kg a.i./ha | 60 |
| Laurel | FR | F | Weeds | EC 240 g/L | Foliar treatment – spraying | 16 | 1 | – | 0.12 kg a.i./ha | 60 |
| Tarragon | FR | F | Weeds | EC 240 g/L | Foliar treatment – spraying | 16 | 1 | – | 0.12 kg a.i./ha | 60 |
| Beans (with pods) | BE | F | Couch-grass | EC 240 g/L | Foliar treatment – spraying | 1 | – | – | 0.375 kg a.i./ha | 60 |

Twice 0.1875 kg a.i./ha Less critical GAPs reported by HU, FR, NL and UK different GAP (BBCH 12–39; 1 × 120 g a.s./ha; PHI = 30 days) supported by trials
### Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | F or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------|-----------------------------------|-------------|------------|--------------------------------|------------|---------|
| Beans (without pods)  | BE            | F         | Couch-grass                       | EC          | 240 g/L   | Foliar treatment – spraying   | 12–39 1    | 0.12 kg a.i./ha | 30 | Different GAP reported by UK: 1 × 0.12 kg a.s./ha; PHI = 30 days. Adequate extrapolation proposed by BE and UK |
| Peas (with pods)      | SE, FR        | F         | Volunteer cereals and annual grasses | EC          | 240 g/L   | Foliar treatment – general    | 32 1 – – – – | 0.12 kg a.i./ha | 30 | Overall spray. Adequate extrapolation proposed by FR. Less critical GAPs reported by HU |
| Peas (without pods)   | UK            | F         | Weeds                             | Foliar treatment – general | 12–39 1 | 0.12 kg a.i./ha | 30 | Overall spray. Equal/less critical GAPs reported by BE, SE and HU. UK and BE mentioned data available |
| Lentils (fresh)       | FR            | F         | Weeds                             | Foliar treatment – spraying | 12–39 1 | 0.12 kg a.i./ha | 30 | Proposed extrapolation from beans with pods by FR |
| Asparagus             | DE            | F         | Annual Monocotyledonae ssp. Poa annua | KL          | 240 g/L   | Foliar treatment – spraying | 12–29 1 | 0.181 kg a.i./ha | 30 |

(a) In Coutry groups, F = France, G = Germany, I = Italy

(b) Foliar treatment = spraying

(c) Range of growth stages & season

(d) PHI = Preceding Half-Life
## Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | F or G or I \(^{(a)}\) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|--------------------------|-----------------------------------|-------------|-------------|--------------------------------|----------|---------|
|                       |               |                          |                                   | Type \(^{(b)}\) Conc. a.s. Method kind | Range of growth stages & season \(^{(c)}\) | Number min–max | Interval between applications (min) | g a.s./L | g a.s./L | Water L/ha | Remarks |
| Beans (dry)           | BE            | F                        | Couch-grass                       | EC 240 g/L | Foliar treatment – spraying | 12–39 | 1 | – | – | 0.375 kg a.i./ha | 60 | Twice 0.1875 kg a.i./ha Less critical GAPs reported by FR (BBCH 14–39; 1 × 120 g a.s./ha; PHI = 60 days) with residue trials and by DE (BBCH 14–39; 1 × 120 g a.s./ha) |
| Peas (dry)            | DE, FR        | F                        | Weeds                             | Foliar treatment – general | 12–39 | 1 | – | – | 0.12 kg a.i./ha | 60 | Overall spray. Equal critical GAPs reported by DE. Additional residue trials reported by DE, FR |
| Lupins (dry)          | DE            | F                        | Weeds                             | KL 240 g/L | Foliar treatment – general | 12–39 | 1 | – | – | 0.12 kg a.i./ha | 60 | Overall spray. Equal/less critical GAPs reported by SE and HU. DE proposed extrapolation from overdosed trials on peas |
### Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|----------------------------|-------------|-------------|--------------------------------|------------|---------|
| Linseeds              | FR            | F                          | Weeds       | Foliar treatment – general | 0.12 kg a.i./ha | 70 | Overall spray. FR reported residue trials. NL less critical GAP (pre- and post-emergence; 1 x 120 g a.s./ha) |
| Poppy seeds           | CZ            | F                          | Weeds       | Foliar treatment – general | 0.24 kg a.i./ha | 90 | Overall spray. CZ provided residue trials. FR less critical GAP (BBCH 19–29; 1 x 120 g a.s./ha; PHI = 90 days) |
| Sunflower seeds       | FR            | F                          | Weeds       | Foliar treatment – general | 0.3 kg a.i./ha | 100 | Overall spray. Less critical GAPs reported by HU, NL (pre- and post-emergence; 1 x 240 g a.s./ha; PHI = 100 days) |
| Rapeseeds             | PO            | F                          | Weeds       | Foliar treatment – spraying | 0.24 kg a.i./ha | 70 | Overall spray. 200–300 L/ha. Additional residue trials reported by FR and UK. Less critical GAPs reported by AT, CZ, DE, NL, SE and FR |
## Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | FG or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|---------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
|                       |               |         |                                   | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between applications (min) | g a.s./hL min-max | Water L/ha min-max | g a.s./ha min-max |          | |
| Mustard seeds         | FR            | F       | Monocotyl weeds                   | EC        | 240 g/L    | Foliar treatment – spraying | 12-32      | 1 – – – – | 0.12 kg a.i./ha | 120         | Overall spray. UK different GAP (BBCH 21; 1 × 120 g a.s./ha; PHI = 120 days) |
| Borage seeds          | FR            | F       | Weeds                             | EC        | 240 g/L    | Foliar treatment – spraying | 19-29      | 1 – – – – | 0.12 kg a.i./ha | 90          | Overall spray |
| Gold of pleasure seeds| FR            | F       | Weeds                             | EC        | 240 g/L    | Foliar treatment – spraying | 12-32      | 1 – – – – | 0.12 kg a.i./ha | 120         | Overall spray |
| Hemp seeds            | FR            | F       | Weeds                             | EC        | 240 g/L    | Foliar treatment – spraying | 19-29      | 1 – – – – | 0.12 kg a.i./ha | 90          | Overall spray |
| Castor beans          | FR            | F       | Weeds                             | EC        | 240 g/L    | Foliar treatment – spraying | 19-29      | 1 – – – – | 0.12 kg a.i./ha | 90          | Overall spray |
| Sugar beets           | NL, FR        | F       | Couch-grass                       | EC        | 120 g/L    | Foliar treatment – spraying | 12-33      | 1 – – – – | 0.3 kg a.i./ha | 56          | Overall spray. Less critical GAPs reported by BE; CZ; DE and UK |
| Chicory roots         | NL            | F       | Agropyron repens                  | EC        | 120 g/L    | Foliar treatment – spraying | 1         | 1 – – – – | 0.3 kg a.i./ha | 56          | Post-emergence |
| Alfalfa (for forage)  | FR            | F       | Annual grasses                    | EC        | 240 g/L    | Foliar treatment – spraying | 12-19      | 1 – – – – | 0.12 kg a.i./ha | 40          | FR proposed extrapolation to clover, trefoil and vetch for forage |
### Critical outdoor GAPs for northern Europe

| Crop and/or situation | MS or country | F/G/I (a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (d) | Remarks |
|-----------------------|---------------|-----------|------------------------------------|-------------|-------------|-------------------------------|---------|---------|
|                       |               |           |                                    |             |             |                               |         |         |
| Clover (for forage)   | FR            | F         | Annual grasses                     | EC          | Foliar treatment – spraying | 12–19 | 1 | – | – | 0.12 kg a.i./ha | 40 | See alfalfa (for forage) NEU |
| Peas (for forage)     | BE            | F         | Couch-grass                        | EC          | Foliar treatment – spraying | 1 | – | – | – | 0.375 kg a.i./ha | 60 | Twice 0.1875 kg a.i./ha |
| Trefoil (for forage)  | FR            | F         | Annual grasses                     | EC          | Foliar treatment – spraying | 12–19 | 1 | – | – | 0.12 kg a.i./ha | 40 | See alfalfa (for forage) NEU |
| Vetch (for forage)    | FR            | F         | Annual grasses                     | EC          | Foliar treatment – spraying | 12–19 | 1 | – | – | 0.12 kg a.i./ha | 40 | See alfalfa (for forage) NEU |
| Fodder beets          | BE            | F         | Couch-grass                        | EC          | Foliar treatment – spraying | 1 | – | – | – | 0.375 kg a.i./ha | 90 | Twice 0.1875 kg a.i./ha Overall spray. Less critical GAPs reported by DE; CZ and by FR a different GAP (BBCH 12–33; 1 × 300 g a.s./ha; PHI = 60 days) and four residue trials |

### Notes

- GAP: good agricultural practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; EC: emulsifiable concentrate; KL: Combi-pack liquid/liquid; a.i.: active ingredient; a.s.: active substance.
- (a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
- (b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
- (c): 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.
- (d): PHI: minimum preharvest interval.
## Critical outdoor GAPs for southern Europe

| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|------------|--------------------------------|------------|---------|
|                       |                         |                                   |             |            |                                |            |         |
| Table grapes          | EL, IT                  | F                                 | Weeds       | Foliar treatment – spraying | 0–85 1     | – – 0.48 kg a.i./ha            | 21         |         |
| Wine grapes           | EL, IT                  | F                                 | Weeds       | Foliar treatment – spraying | 0–85 1     | – – 0.48 kg a.i./ha            | 21         |         |
| Potatoes              | EL, IT, PT              | F                                 | Weeds       | EC 240 g/L Foliar treatment – spraying | 12–33 1   | – – 0.36 kg a.i./ha            | 60         | Less critical GAPs reported by FR (BBCH 12–33; 1 × 300 g a.s./ha; PHI = 60 days) |
| Carrots               | IT, EL, FR              | F                                 | SORHA       | EC 240 g/L Foliar treatment – spraying | 12–45 1   | – – 0.24 kg a.i./ha            | 40         | PT less critical GAP (BBCH 12–33; 1 × 240 g a.s./ha; PHI = 56 days) |
| Jerusalem artichokes  | FR                      | F                                 | Perennial grasses | EC 240 g/L Foliar treatment – spraying | 12–45 1   | – – 0.24 kg a.i./ha            | 40         |         |
| Parsnips              | FR                      | F                                 | Perennial grasses | EC 240 g/L Foliar treatment – spraying | 12–45 1   | – – 0.24 kg a.i./ha            | 40         |         |
| Parsley roots         | FR                      | F                                 | Perennial grasses | EC 240 g/L Foliar treatment – spraying | 12–45 1   | – – 0.24 kg a.i./ha            | 40         |         |
### Critical outdoor GAPs for southern Europe

| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|------------------------------------|-------------|-------------|--------------------------------|------------|---------|
|                       |                         |                                    | Type(1)     | Concentration kind | Method growth stages & season(2) | Number min-max | Interval between application (min) | Water L/ha min-max | g a.s./ha min-max |                        |
| Garlic                | FR                      | F                                  | Weeds       | Foliar treatment – general | 12–45 | 1 | – – | 0.12 kg a.i./ha | 56 | Overall spray. More critical GAP by ES (early post-emergence; 2 × 190 g a.s./ha) not supported by trials |
| Onions                | IT, PT                  | F                                  | Weeds       | Foliar treatment – general | 12–45 | 1 | – – | 0.24 kg a.i./ha | 56 | Overall spray. Less critical GAPs by EL (BBCH 12–45; 1 × 180 g a.s./ha; PHI = 56 days); ES different GAP (early post-emergence; 2 × 190 g a.s./ha) not supported by trials |
| Tomatoes              | EL, IT                  | F                                  | Weeds       | Foliar treatment – general | 12–29 | 1 | – – | 0.36 kg a.i./ha | 30 | Overall spray. Less critical GAPs reported by ES |
| Chervil               | FR                      | F                                  | Weeds       | Foliar treatment – spraying | 16 | 1 | – – | 0.12 kg a.i./ha | 60 | |
| Chives                | FR                      | F                                  | Weeds       | Foliar treatment – spraying | 16 | 1 | – – | 0.12 kg a.i./ha | 60 | |
| Celery leaves         | FR                      | F                                  | Weeds       | Foliar treatment – spraying | 16 | 1 | – – | 0.12 kg a.i./ha | 60 | |
| Crop and/or situation | NEU, SEU, MS or country | F Group of pests controlled | Preparation | Type(s) | Conc. a.s. | Method kind | PHI (days) | Remarks |
|-----------------------|-------------------------|----------------------------|-------------|---------|-----------|-------------|----------|---------|
| Parsley               | FR                      | F                          | Weeds       | EC      | 240 g/L   | Foliar treatment – spraying | 16 – 1   | – –  0.12 kg a.i./ha 60 |
| Sage                  | FR                      | F                          | Weeds       | EC      | 240 g/L   | Foliar treatment – spraying | 16 – 1   | – –  0.12 kg a.i./ha 60 |
| Rosemary              | FR                      | F                          | Weeds       | EC      | 240 g/L   | Foliar treatment – spraying | 16 – 1   | – –  0.12 kg a.i./ha 60 |
| Thyme                 | FR                      | F                          | Weeds       | EC      | 240 g/L   | Foliar treatment – spraying | 16 – 1   | – –  0.12 kg a.i./ha 60 |
| Basil                 | FR                      | F                          | Weeds       | EC      | 240 g/L   | Foliar treatment – spraying | 16 – 1   | – –  0.12 kg a.i./ha 60 |
| Laurel                | FR                      | F                          | Weeds       | EC      | 240 g/L   | Foliar treatment – spraying | 16 – 1   | – –  0.12 kg a.i./ha 60 |
| Tarragon              | FR                      | F                          | Weeds       | EC      | 240 g/L   | Foliar treatment – spraying | 16 – 1   | – –  0.12 kg a.i./ha 60 |
| Beans (with pods)     | FR                      | F                          | Weeds       | EC      | 240 g/L   | Foliar treatment – general | 12 – 19  1 | – –  0.12 kg a.i./ha 30 Overall spray. Additional trials adequately reported by FR |
| Peas (with pods)      | FR                      | F                          | Weeds       | EC      | 240 g/L   | Foliar treatment – spraying | 12 – 39  1 | – –  0.12 kg a.i./ha 30 |
### Critical outdoor GAPs for southern Europe

| Crop and/or situation | NEU, SEU, MS or country | F or G or I(e) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|----------------|-----------------------------------|-------------|------------|-------------------------------|-----------|---------|
| Globe artichokes      | IT, EL                  | F              | Cyndra, Agrre                      | EC 240 g/L | Foliar treatment – spraying  | 12–51 1     |            | 0.36 kg a.i./ha 40 Overall spray |
| Beans (dry)           | ES                      | F              | Weeds                             | Foliar treatment – general 9 2 |            | 0.19 kg a.i./ha 100 Overall spray. Early post-emergence. The use is not supported by residue trials |
| Peas (dry)            | ES                      | F              | Weeds                             | Foliar treatment – general 9 2 |            | 0.19 kg a.i./ha 100 Overall spray. Early post-emergence. The use is not supported by residue trials |
| Lupins (dry)          | ES                      | F              | Weeds                             | Foliar treatment – general 9 2 |            | 0.19 kg a.i./ha 100 Overall spray. Early post-emergence. The use is not supported by residue trials |
| Sesame seeds          | FR                      | F              | Weeds                             | EC 240 g/L | Foliar treatment – spraying 12–32 1 |            | 0.12 kg a.i./ha 120 Overall spray. Extrapolation from rape seed proposed by FR |
| Sunflower seeds       | EL, IT, PT              | F              | Weeds                             | Foliar treatment – general 12–19 1 |            | 0.36 kg a.i./ha 100 Overall spray. Residue trials reported by FR and PT. Less critical GAPs reported by ES, FR |
| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------------------|----------------------------------|-------------|------------|-----------------------------|------------|---------|
|                       | F G or I(e)               |                                  | Type(f)     | Conc. a.s. | Method kind | Range of growth stages & season(g) | Number min-max | Interval between application (min) | g a.s./ hL min-max | Water L/ha min-max | g a.s./ ha min-max |                   |
| Rapeseeds             | EL, FR                   | F                                 | Foliar treatment – general | 12–30 | 1         | – – | 0.12 kg a.i./ha | 120 Overall spray. Additional residue trials provided by EL and FR. A different GAP (early post-emergence; 2 × 190 g a.s./ha) not supported by trials is authorised in ES |
| Soya beans            | EL, IT                   | F                                 | Foliar treatment – general | 12–19 | 1         | – – | 0.3 kg a.i./ha | 60 Overall spray. Less critical GAPs reported by FR (BBCH 12–19; 1 × 120 g a.s./ha; PHI = 60 days) |
| Cotton seeds          | EL                       | F                                 | Foliar treatment – spraying | 12–19 | 1         | – – | 0.36 kg a.i./ha | 100 Overall spray |
| Pumpkin seeds         | FR                       | F                                 | Foliar treatment – spraying | 19–29 | 1         | – – | 0.12 kg a.i./ha | 90 Overall spray |
| Safflower seeds       | FR                       | F                                 | Foliar treatment – spraying | 19–29 | 1         | – – | 0.12 kg a.i./ha | 90 Overall spray |
| Borage seeds          | FR                       | F                                 | Foliar treatment – spraying | 19–29 | 1         | – – | 0.12 kg a.i./ha | 90 Overall spray. Proposed extrapolation from rape seeds |
## Critical outdoor GAPs for southern Europe

| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Type(s) | Conc. a.s. | Method kind | Range of growth stages & season(s) | Number min–max | Interval between application (min) | g a.s./hL min–max | Water L/ha min–max | g a.s./ha min–max | PHI (days) | Remarks |
|-----------------------|-------------------------|-----------------------------------|---------|-----------|-------------|---------------------------------|----------------|----------------------------------|-----------------|-----------------|-----------------|------------|---------|
| Gold of pleasure seeds| FR                      | Annual grasses                    | EC      | 240 g/L   | Foliar treatment – spraying   | 12–32             | 1                                | –               | –               | 0.12 kg a.i./ha | 120        |         |
| Hemp seeds            | FR                      | Annual grasses                    | EC      | 240 g/L   | Foliar treatment – spraying   | 19–29             | 1                                | –               | –               | 0.12 kg a.i./ha | 90         |         |
| Castor beans          | FR                      | Annual grasses                    | EC      | 240 g/L   | Foliar treatment – spraying   | 19–29             | 1                                | –               | –               | 0.12 kg a.i./ha | 90         |         |
| Rice                  | EL, ES, IT             | Weeds                             |         |           | Soil treatment – spraying     | 0–0               | 1                                | –               | –               | 0.18 kg a.i./ha | 56         | Overall spray. Application before sowing |
| Sugar beets           | EL, IT                 | Weeds                             | EC      | 240 g/L   | Foliar treatment – general    | 12–33             | 1                                | –               | –               | 0.36 kg a.i./ha | 56         | Overall spray. Less critical GAPs reported by ES (early post-emergence, 2 × 190 g.a.s./ha) |
| Alfalfa (for forage)  | EL, IT                 | Weeds                             |         |           | Foliar treatment – general    | 12–19             | 1                                | –               | –               | 0.24 kg a.i./ha | 40         | Overall spray. Supported by overdosed trials on alfalfa. Less critical GAP in FR (BBCH 12–19; 1 × 120 g a.s./ha; PHI = 40 days) |
| Clover (for forage)   | FR                     | Annual grasses                    | EC      | 240 g/L   | Foliar treatment – spraying   | 12–19             | 1                                | –               | –               | 0.12 kg a.i./ha | 40         | Overall spray |
## Critical outdoor GAPs for southern Europe

| Crop and/or situation | NEU, SEU, MS or country | F or G or I(e) | Pests or Group of pests controlled | Preparation | Method kind | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|------------------------|----------------|------------------------------------|-------------|------------|------------|-------------------------------|-----------|---------|
| Trefoil (for forage)  | FR                     | F              | Annual grasses                     | EC          | Foliar treatment – spraying | 240 g/L | 12–19 | 1 | – | – | 0.12 kg a.i./ha | 40 | Overall spray |
| Vetch (for forage)    | FR                     | F              | Annual grasses                     | EC          | Foliar treatment – spraying | 240 g/L | 12–19 | 1 | – | – | 0.12 kg a.i./ha | 40 | Overall spray |
| Fodder beets          | IT                     | F              | *Sorghum halepense*, *Echinochloa crus-galli*, *Setaria, Avena spp.*, *Digitaria sanguinalis*, *Lolium spp.*, *Alopecurus myosuroides*, *Phalaris*, *Panicum dichotomiflorum*, *Poa*, *Triticum*, *Hordeum spp.* | EC          | Foliar treatment – spraying | 240 g/L | 1 | – | – | 0.36 kg a.i./ha | 56 | 300–600 L/ha. (application post-emergence of weeds) |

**GAP:** good agricultural practice; **NEU:** northern European Union; **SEU:** southern European Union; **MS:** Member State; **EC:** emulsifiable concentrate; **a.i.:** active ingredient; **a.s.:** active substance.

(e): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(f): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(g): 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.

(h): PHI: minimum preharvest interval.
| Crop and/or situation | NEU, SEU, MS or country | F or G or I(i) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (l) | Remarks |
|-----------------------|-------------------------|----------------|-----------------------------------|-------------|----------------|-------------------------------|----------------|---------|
| Spinaches BE I        | Weeds                   | EC             | 120 g/L                           | Foliar      | 12–14          | 1                             | –              | 0.12 kg a.i./ha | See spinach NEU |
| Beans (with pods) BE  | I                       | Weeds          | EC 120 g/L                        | Foliar      | 1              | –                             | 0.12 kg a.i./ha | 60      |

GAP: good agricultural practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; EC: emulsifiable concentrate; a.s.: active substance; a.i.: active ingredient. 
(i): Outdoor or field use (F), greenhouse application (G) or indoor application (I). 
(j): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide. 
(k): 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. 
(l): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) |
|---------------------------------|-------------|---------|----------------|---------------|
| Root crops                      | Carrots     | Foliar, 2 × 280 g a.s./ha | 20           |
| Leaffy crops                    | Carrots     | Foliar, 1 × 624–638 g a.s./ha | 31, 56       |
| Pulses/oilseeds                | Spinach     | Foliar, 1 × 500 g a.s./ha | 14, 28       |
| Soybean                         | Foliar, 2 × 280 g a.s./ha | 20           |
| Cotton                          | Foliar, 2 × 280 g a.s./ha | 70           |
| (Netherlands, 2005, 2009, 2016) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|-------------------------------------|-------------|---------|----------------|-----------|
| Root/tuber crops                    | Carrot      | Bare soil, 1.1 kg a.s./ha | 30, 120, 366 |
| Leafy crops                         | Lettuce     | Bare soil, 1.1 kg a.s./ha | 30, 120, 366 |
| Cereal (small grain)                | Wheat       | Bare soil, 1.1 kg a.s./ha | 30, 120, 366 |
| (Netherlands, 2005)                |

| Processed commodities (hydrolysis study) | Conditions | Investigated? |
|-----------------------------------------|------------|---------------|
| Pasteurisation (20 min, 90°C, pH 4)     | Yes        |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes        |
| Sterilisation (20 min, 120°C, pH 6)     | Yes        |
| (France, 2017)                         |

Can a general residue definition be proposed for primary crops? Yes (tentative)

Rotational crop and primary crop metabolism similar? Yes

Residue pattern in processed commodities similar to residue pattern in raw commodities? Inconclusive

Plant residue definition for monitoring (RD-Mo)

For raw plant commodities:
- Sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim

For processed commodities: inconclusive (pending on submission of additional hydrolysis studies)

Plant residue definition for risk assessment (RD-RA)

Residue definition for risk assessment one (tentative):
- Sum of clethodim, clethodim sulfoxide, clethodim sulfone and metabolites M14R/M15R, M16R/M17R and M18R/M19R, expressed as clethodim is tentatively proposed

Residue definition for risk assessment two (tentative):
- M14A/M15A

For processed commodities: inconclusive

Conversion factor (monitoring to risk assessment)

Root and tuber vegetables and pulses and oilseeds: 2.5 (EFSA, 2011)

Other plant commodities: tentatively extrapolated to fruit and cereal crops (based on leafy crops metabolism study)
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

| High water, high acid, high oil and dry commodities: |
|------------------------------------------------------|
| - LC-MS/MS method, LOQ of 0.005 mg/kg for clethodim, clethodim sulfone and clethodim sulfoxide; **combined LOQ of enforcement of 0.014 mg/kg (rounded to 0.02 mg/kg)**; validated in sugar beet roots and leaves, soybean and proteinaceous peas. ILV (sugar beet roots, soybean and grapes) and confirmatory method available (Netherlands, 2009, 2016; EFSA, 2011) |
| - LC-MS/MS method, LOQ of 0.005 mg/kg for clethodim, clethodim sulfoxide and clethodim sulfone, respectively; **combined LOQ of enforcement of 0.014 mg/kg (rounded to 0.02 mg/kg)**; validated in high acid (validated in grape bunches) and dry (wheat grain) commodities supported by a confirmatory method validated in high oil (oilseed rape) and water (sugar beet leaves) at the same LOQ (France, 2017) |
| - LC-MS/MS method; LOQ of 0.005 mg/kg for clethodim in high acid (validated in lemon) and high water (validated in cucumber) commodities and in addition with a LOQ of 0.01 mg/kg in oranges (high acid) and zucchini (high water) and in high fat (almond) and dry (wheat) commodities, respectively; clethodim sulfoxide validated in zucchini, orange juice at a LOQ of 0.005 mg/kg and at a LOQ of 0.05 mg/kg in wheat flour and cashew nuts, respectively. Clethodim sulfone was validated at a LOQ of 0.005 mg/kg in all four matrices (zucchini, orange juice, wheat flour, cashew nuts) (EURLs, 2017). During the MSC, the EURL informed on additional successful validation of the method for clethodim in wheat, rye, oat and rice at 0.005 mg/kg (EFSA, 2018b) |

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; LC-MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category               | Commodity                  | T (°C)  | Stability (Months) | Comment                                                                 |
|-----------------------------------|------------------------|----------------------------|---------|-------------------|--------------------------------------------------------------------------|
|                                  | High water content     | Sugar beet root            | -20     | 11                | Clethodim (equivalents)\(^{(a)}\) and 5-OH clethodim sulfone (equivalents)\(^{(b)}\) (Netherlands, 2016) |
|                                  |                        | Sugar beet tops            | -20     | 9                 |                                                                           |
|                                  |                        |                            | -18     |                   | Clethodim not stable (Netherlands, 2016)                                 |
|                                  |                        |                            | -18     | 9                 | Clethodim sulfoxide, clethodim sulfone, M17R, M18R (Netherlands, 2016)  |
|                                  |                        | Alfalfa                    | -18     |                   | Clethodim not stable (Netherlands, 2016)                                 |
|                                  |                        |                            | -18     | 6                 | Clethodim sulfoxide (Netherlands, 2016)                                  |
|                                  |                        |                            | -18     | 6                 | Clethodim sulfone (Netherlands, 2016)                                   |
|                                  | High oil content       | Oil seed rape              | -18     | 9                 | Clethodim (Netherlands, 2016)                                            |
|                                  |                        |                            | -18     | 9                 | Clethodim sulfoxide, clethodim sulfone, M17R, M18R (Netherlands, 2016)  |
|                                  | Dry/high protein       | Dry peas                   | -18     | 9                 | Clethodim (Netherlands, 2016)                                            |
|                                  |                        |                            |         | 9                 | Clethodim sulfoxide, clethodim sulfone, M17R, M18R (Netherlands, 2016)  |
|                                  | High acid content      | Grapes                     | -18     | 9                 | Clethodim sulfoxide, clethodim sulfone, M17R, M18R (Netherlands, 2016)  |

\(^{(a)}\): Clethodim and clethodim-like metabolites containing the 5-(2-ethylthiopropyl) cyclohexene-3-one moiety are converted to DME and \(^{(b)}\): 5-OH clethodim and like metabolites containing the 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moiety to DME-OH.
### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials

| Crop                                      | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | Calculated MRL (mg/kg) | HR<sub>Mo</sub> (mg/kg)<sup>(b)</sup> | STMR<sub>Mo</sub> (mg/kg)<sup>(c)</sup> | CF<sup>(d)</sup> |
|-------------------------------------------|---------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|------------------------|----------------------------------------|----------------------------------------|------------|
| Wine and table grapes                     | SEU           | Mo.: 8 × < 0.014                                                                                   | GAP-compliant trials on wine grapes; last two on bunches (Netherlands, 2012, 2016; France, 2017; Greece, 2017) MRL<sub>OECD</sub> = 0.01 | 0.02<sup>*</sup><sup>(e)</sup> (tentative) | 0.01                                  | 0.01                                  |            |
|                                           |               | RA1.: –                                                                                           |                                             | RA1.: –                                             | 19                                  |                                       |            |
|                                           |               | RA2.: –                                                                                           |                                             | RA2.: –                                             | tbd                                  |                                       |            |
| Strawberries                              | NEU           | Mo.: < 0.014; 0.024; 0.036; 0.056                                                                | GAP-compliant trials on strawberries (Netherlands, 2012, 2016) MRL<sub>OECD</sub> = 0.1 | 0.15<sup>(f)</sup> (tentative) | 0.06                                  | 0.03                                  | 0.15<sup>(f)</sup> |
|                                           |               | RA1.: –                                                                                           |                                             | RA1.: –                                             | 19                                  |                                       |            |
|                                           |               | RA2.: –                                                                                           |                                             | RA2.: –                                             | tbd                                  |                                       |            |
| Cane fruits (blackberries, raspberries (red and yellow), blueberries) | NEU | –                                                                                                   |                                                                                           | No trials available | –                                  | –                                  | –             |
| Other small fruits and berries (cranberries, currants (black, red and white), gooseberries (green, red and yellow), rose hips, elderberries) | NEU | –                                                                                                   |                                                                                           | No trials available | –                                  | –                                  | –             |
| Potatoes                                  | NEU           | Mo.: 0.032; 0.033; 0.0414; 0.043; 0.054; 0.065; 0.071; 0.077; 0.087; 0.112; 0.124; 0.162; 0.197; 0.43 | GAP-compliant trials on potatoes (Netherlands, 2012, 2017; Greece, 2017, Italy, 2017) MRL<sub>OECD</sub> = 0.53 | 0.6                                  | 0.43                                  | 0.07                                  | 2.5          |
|                                           |               | RA1.: –                                                                                           |                                             | RA1.: –                                             | 2.5                                  |                                       |            |
|                                           |               | RA2.: –                                                                                           |                                             | RA2.: –                                             | tbd                                  |                                       |            |
| Crop | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | Calculated MRL (mg/kg) | HR\textsubscript{Mo} (mg/kg)\textsuperscript{(b)} | STMR\textsubscript{Mo} (mg/kg)\textsuperscript{(c)} | CF\textsuperscript{(d)} |
|------|---------------|--------------------------------------------------------------------------------|---------------------------------------------|------------------------|-----------------------------|-----------------------------|------------------|
| SEU  | Mo.: 0.018; 0.032; 0.035; 0.041; 0.046; 0.066; 0.075; 0.079; 0.0915; 0.133; 0.114; 0.205; 0.216; 0.247 | GAP-compliant trials on potatoes (Netherlands, 2012, 2016, 2017; Greece, 2017; Italy, 2017; Portugal, 2017) MRL\textsubscript{OECD} = 0.4 | 0.4 | 0.25 | 0.08 | |
|      | RA1.: –       |                                                                                       |                                             |                        |                             |                             | 2.5              |
|      | RA2.: –       |                                                                                       |                                             |                        |                             |                             |                  |
| NEU  | Mo.: 0.012; 0.024; 0.036; 0.039; 0.048; 0.056; 0.063; 0.086; 0.099 | GAP-compliant trials on carrots (Netherlands, 2012, 2016). Extrapolated to celeriacs, horse radishes, Jerusalem artichokes, parsnips, parsley roots and salsifies MRL\textsubscript{OECD} = 0.16 | 0.2 | 0.10 | 0.05 | |
|      | RA1.: –       |                                                                                       |                                             |                        |                             |                             | 2.5              |
|      | RA2.: –       |                                                                                       |                                             |                        |                             |                             | tbd              |
| SEU  | Mo.: < 0.014; 0.019; 0.019; 0.024; 0.026; 0.026; 0.026; 0.048; 0.101 | GAP-compliant trials on carrots. (Netherlands, 2012, 2016; Portugal, 2017). Extrapolated to Jerusalem artichokes, parsnips and parsley roots. No authorisations on celeriacs, horse radishes, salsifies, swedes and turnips MRL\textsubscript{OECD} = 0.14 | 0.15 | 0.10 | 0.03 | |
|      | RA1.: –       |                                                                                       |                                             |                        |                             |                             | 2.5              |
|      | RA2.: –       |                                                                                       |                                             |                        |                             |                             | tbd              |
| NEU  | Mo.: 0.012; 0.024; 0.036; 0.039; 0.048; 0.056; 0.063; 0.086; 0.099 | Trials on carrots (1 × 240 g a.s./ha; 40 days) (Netherlands, 2012, 2016). Extrapolated to swedes and turnips MRL\textsubscript{OECD} = 0.16 | 0.2 | 0.10 | 0.05 | |
|      | RA1.: –       |                                                                                       |                                             |                        |                             |                             | 2.5              |
|      | RA2.: –       |                                                                                       |                                             |                        |                             |                             | tbd              |
| Crop                        | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | Calculated MRL (mg/kg) | HR<sub>Mo</sub> (mg/kg)<sup>(b)</sup> | STMR<sub>Mo</sub> (mg/kg)<sup>(c)</sup> | CF<sup>(d)</sup> |
|-----------------------------|-----------------------------|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------|------------------------|---------------------------------|-------------------------------------|-----------|
| Onions, garlic, shallots    | NEU                         | Mo.: 4 × < 0.014; 0.014; 0.019; 0.02; 0.02; 0.026; 0.031; 0.032; 0.049 GAP-compliant trials on onions (Netherlands, 2012, 2016). Extrapolated to garlic and shallots MRL<sub>OECD</sub> = 0.07 | 0.07                                       | 0.05                   | 0.02               |                                     | 2.5       |
|                            |                             | RA1.: –                                               |                                             |                        |                   |                                     |           |
|                            |                             | RA2.: –                                               |                                             |                        |                   |                                     | tbd       |
|                            | SEU                         | Mo.: 4 × < 0.014; 0.015 Trials on onions with application rate of 248 – 262 g a.s./ha (Netherlands, 2012, 2016; Portugal, 2017). Tentatively extrapolated to garlic with 1 × 120 g a.s./ha application rate. No authorisation on shallots (SEU) MRL<sub>OECD</sub> = 0.02 | 0.03<sup>(g)</sup> (tentative) | 0.02               | 0.01                  | 2.5       |
|                            |                             | RA1.: –                                               |                                             |                        |                   |                                     |           |
|                            |                             | RA2.: –                                               |                                             |                        |                   |                                     | tbd       |
| Spring onions/green onions and Welsh onions | NEU                         | Mo.: 4 × < 0.014 GAP-compliant trials on spring onions (Netherlands, 2012) MRL<sub>OECD</sub> = 0.01 | 0.02*                                       | 0.01                   | 0.01               |                                     | 2.5       |
|                            |                             | RA1.: –                                               |                                             |                        |                   |                                     |           |
|                            |                             | RA2.: –                                               |                                             |                        |                   |                                     | tbd       |
| Tomatoes                   | SEU                         | Mo.: 0.029; 0.034; 0.043; 0.05; 0.05; 0.052; 0.06; 0.073 GAP-compliant trials on tomatoes (Netherlands, 2012) MRL<sub>OECD</sub> = 0.15 | 0.15                                       | 0.07                   | 0.05               |                                     | 19        |
|                            |                             | RA1.: –                                               |                                             |                        |                   |                                     |           |
|                            |                             | RA2.: –                                               |                                             |                        |                   |                                     | tbd       |
### Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)

| Crop | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | Calculated MRL (mg/kg) | HR_{Mo} (mg/kg)(b) | STMR_{Mo} (mg/kg)(c) | CF(d) |
|------|------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------|-------------------|--------------------|-------|
| Broccoli, cauliflowers | NEU | – | No residue trials available | – | – | – | – |
| Brussels sprouts | NEU | – | No trials available | – | – | – | – |
| Head cabbages | NEU | Mo.: 0.047; 0.057; 0.058; 0.064; 0.083; 0.085; 0.105; 0.142; 0.165; 0.173; 0.174; 0.213; 0.349; 0.598 | GAP-compliant trials on head cabbages (Netherlands, 2012, 2016; France, 2017) MRL_{OECD} = 0.76 | 0.8 | 0.60 | 0.12 | – |
| Spinaches | NEU | – | No valid trials on spinach available | – | – | – | – |
| EU | – | No trials available | – | – | – | – |
| Witloofs/Belgian endives | NEU | – | No trials available | – | – | – | – |
| Chives, chervil, celery leaves, parsley, sage, rosemary, thyme, basil, edible flowers, laurel/bay leaf, tarragon | NEU | Mo.: < 0.17 | Overdosed trial on chives (1 × 180 g a.s./ha; PHI = 21 days), residue analysed with common moiety method, expressed as clethodim. (Netherlands, 2012) | – | – | – | – |
| SEU | Mo.: < 0.014; < 0.014; < 0.17 | Trials on chives to a more critical GAP (first two with 1 × 180 g a.s./ha, PHI = 21 days; second trial 1 × 200 g a.s./ha, PHI = 21 days). Last trial residues analysed as DME and DME-OH sulfone with common moiety method (Netherlands, 2012). Tentatively extrapolated to herbs and edible flowers MRL_{OECD} = 0.17 | 0.2*(h) (tentative) | 0.17 | 0.01 | – | – |
| Crop                                | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | Calculated MRL (mg/kg) | HR_{Mo}(mg/kg) | STMR_{Mo}(mg/kg) | CF(d) |
|-------------------------------------|------------------|------------------------------------------------------------------------------------------------|----------------------------------------|------------------------|--------------|-----------------|-------|
| Beans (with pods)                   | NEU              | Trials with shorter PHI of 39-43 days<br>M_{o.}: < 0.014; 0.016<br>Overdosed trials (1 × 321–386 g a.s./ha and 1 × 161–184 g a.s./ha; PHI = 40-43 days):<br>M_{o.}: 4 × < 0.014; 0.016; 0.031; 0.147 | Trials on beans with pods (Netherlands, 2012; France, 2017)<br>MRL_{OECD} = 0.22 | 0.3(i) (tentative) | 0.15 | 0.02 | 19 |
|                                    |                  | RA1.: –                                                                 | RA2.: –                                |                        |              |                 |       |
|                                    | SEU              | M_{o.}: 0.021; 0.022; 0.050; 0.077; 0.150; 0.166; 0.178; 0.224 | Overdosed trials on beans with pods (application rate of 170–210 instead of 120 g a.s./ha) (Netherlands, 2012; France, 2017)<br>MRL_{OECD} = 0.42 | 0.5(i) (tentative) | 0.22 | 0.11 | 2.5 |
|                                    |                  | RA1.: –                                                                 | RA2.: –                                |                        |              |                 |       |
|                                    | EU               | –                                                                                   | No trials available (Belgium, 2017) | –                     | – | – | – |
| Beans and peas (without pods)      | NEU              | M_{o.}: 0.107; 0.107; 0.278; 0.513; 0.94; 1.065; 1.205; 1.255; 1.279; 1.325; 1.677; 2.039 | Overdosed trials on peas (without pods); (1 × 231–327 g a.s./ha; PHI 29–31 days) (Netherlands, 2012, 2016). Extrapolated to beans without pods<br>MRL_{OECD} = 3.45 | 4(i) (tentative) | 2.04 | 1.14 | 2.5 |
|                                    |                  | RA1.: –                                                                 | RA2.: –                                |                        |              |                 |       |
| Peas (with pods) and fresh lentils  | NEU              | Trials with shorter PHI (PHI 29–31 days)<br>M_{o.}: 0.016; 0.029; 0.033; 0.076; 0.2 | Overdosed trials on beans with pods (Netherlands, 2012; France, 2017). Extrapolated tentatively to<br>MRL_{OECD} = 0.35 | 0.3(i) (tentative) | 0.20 | 0.03 | tbd |
|                                    |                  | RA1.: –                                                                 | RA2.: –                                |                        |              |                 |       |
| Crop                          | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | Calculated MRL (mg/kg) | HRMo(b) | STMRMo(c) | CF(d) |
|------------------------------|---------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|------------------------|---------|----------|-------|
| SEU                          |               | Overdosed (1 × 178 or 183 g a.s./ha; PHI 28, 30 days): Mo.: 0.021; 0.05                               | Recommended trials on lentils and peas with pods. MRLOECD = 0.3 |                        |         |          | 2.5   |
| RA1.: –                      |               |                                                |                                             |                        |         |          |       |
| RA2.: –                      |               |                                                |                                             |                        |         |          |       |
| SEU                          |               | Mo.: 0.021; 0.022; 0.050; 0.077; 0.150; 0.166; 0.178; 0.224                                      | Overdosed trials on beans with pods (application rate of 170–210 instead of 120 g a.s./ha) (Netherlands, 2012; France, 2017). Tentatively extrapolated to peas (with pods). No authorisation on fresh lentils (SEU) MRLOECD = 0.42 |                        | 0.22    | 0.11     |       |
| RA1.: –                      |               |                                                |                                             |                        |         |          | 2.5   |
| RA2.: –                      |               |                                                |                                             |                        |         |          |       |
| Asparagus                    | NEU           | –                                              | No trials on asparagus available           |                        | –       | –        | –     |
| Globe artichokes             | SEU           | –                                              |                                              |                        | –       | –        | –     |
| RA1.: –                      |               |                                                |                                             |                        |         |          | –     |
| RA2.: –                      |               |                                                |                                             |                        |         |          | –     |
| Bean (dry)                   | NEU           | Trials on dry peas: Mo.: 0.13; 0.452; 0.198; 0.197; 0.562; 0.441   | Combined data set of GAP-compliant trials on dry peas and dry beans (Netherlands, 2012, 2016) MRLOECD = 1.01 |                        | 1       | 0.56     | 0.20  |
| RA1.: –                      |               |                                                |                                             |                        |         |          | 2.5   |
| RA2.: –                      |               |                                                |                                             |                        |         |          |       |
| SEU                          |               | –                                              | No GAP-compliant trials available           |                        | –       | –        | –     |
| Crop                                      | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | Calculated MRL (mg/kg) | HR\textsubscript{Mo} (mg/kg)\textsuperscript{(b)} | STMR\textsubscript{Mo} (mg/kg)\textsuperscript{(c)} | CF\textsuperscript{(d)} |
|------------------------------------------|---------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|------------------------|-----------------------------------------------|-----------------------------------------------|------------------|
| Peas (dry), Lupins/lupini beans (dry)    | NEU           | Mo.: < 0.06; < 0.06; < 0.06                                                                | Overdosed trials on dry peas; analysed as DME and DME-OH sulfone, calculated as clethodim (Germany, 2017). Tentatively extrapolated to lupins MRL\textsubscript{OECD} = 0.06  | 0.06*\textsuperscript{(f)} (tentative)      | 0.06                                          | 0.06                                          | 2.5              |
|                                          |               | RA1.: –                                                                                     |                                             |                        |                                               |                                               |                  |
|                                          |               | RA2.: –                                                                                     |                                             |                        |                                               |                                               |                  |
|                                          | SEU           | –                                                                                           | No GAP-compliant trials available           | –                      | –                                             | –                                             | tbd              |
| Linseeds                                 | NEU           | Mo.: 3 × < 0.014; 0.32                                                                     | GAP-compliant trials on linseeds (Netherlands, 2012) MRL\textsubscript{OECD} = 0.7 | 0.9                    | 0.32                                          | 0.01                                          | 2.5              |
|                                          |               | RA1.: –                                                                                     |                                             |                        |                                               |                                               |                  |
|                                          |               | RA2.: –                                                                                     |                                             |                        |                                               |                                               |                  |
| Poppy seeds                              | NEU           | Mo.: 8 × < 0.014                                                                           | Overdosed trials on winter rape (2 × 240 + 1 × 120 g a.s./ha) (Netherlands, 2012, 2016). Tentatively extrapolated to poppy seeds | 0.02*                   | 0.01                                          | 0.01                                          | 2.5              |
|                                          |               | RA1.: –                                                                                     |                                             |                        |                                               |                                               |                  |
|                                          |               | RA2.: –                                                                                     |                                             |                        |                                               |                                               |                  |
| Sesame, pumpkin, safflower seeds, borage seeds, hemp seeds, castor beans | NEU           | Mo.: 4 × < 0.014; 0.017; 0.022; 0.030; 0.0847                                               | GAP-compliant trials on spring rape seed (Netherlands, 2005, 2016). Extrapolated to borage, hemp seed and castor beans. No authorisation on sesame, pumpkin and safflower seeds in NEU MRL\textsubscript{OECD} = 0.12 | 0.2                    | 0.08                                          | 0.02                                          | 2.5              |
|                                          |               | RA1.: –                                                                                     |                                             |                        |                                               |                                               |                  |
|                                          |               | RA2.: –                                                                                     |                                             |                        |                                               |                                               |                  |

\textsuperscript{(a)} Crop is indoor (i) or outdoor (o) if applicable.

\textsuperscript{(b)} HR\textsubscript{Mo} = Hazard ratio for Mo.

\textsuperscript{(c)} STMR\textsubscript{Mo} = Safety threshold multiple of recommended residue (Mo).

\textsuperscript{(d)} CF = Conversion factor.

\textsuperscript{(e)} OECD = Organisation for Economic Co-operation and Development.

\textsuperscript{(f)} Tentative value.
### Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)

| Crop                              | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)                                                                                                                                                                                                 | Recommendations/comments (OECD calculations)                                                                 | Calculated MRL (mg/kg) | HR$_{Mo}$ (mg/kg) | STMR$_{Mo}$ (mg/kg) | CF(d) |
|-----------------------------------|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------------------------|------------------|-------------------|-------|
| SEU                               | Overdosed trials on rape seeds (2 × 240 + 1 × 120 g a.s./ha): Mo.: 3 × < 0.014 Overdosed trials on sunflower seeds (468–499 mg a.s./ha): Mo.: 5 × < 0.014; 0.019; 0.038; 0.038; 0.07 | Combined data set of trials on rape seeds sunflower seeds (Netherlands, 2012, 2016). Extrapolated to pumpkin, borage, safflower, hemp seeds and castor beans MRL$_{OECD}$ = 0.1 | 0.1$^{(i)}$ (tentative) | 0.07            | 0.01              |       |
| RA1.: --                          |               |                                                                                                                                  |                                                                                                             |                       |                  |                   | 2.5   |
| RA2.: --                          |               |                                                                                                                                  |                                                                                                             |                       |                  |                   | tbd    |
| Sunflower seeds, cotton seeds     | NEU           | Mo.: 9 × < 0.014; 0.0196; 0.021; 0.028; 0.035; 0.134                                                                                                                                         | Overdosed trials on sunflower seeds (472–496 g a.s./ha) (Netherlands, 2012, 2016). No authorisation for cotton seeds NEU MRL$_{OECD}$ = 0.15 | 0.15$^{(i)}$ (tentative) | 0.13          | 0.01              |       |
| RA1.: --                          |               |                                                                                                                                  |                                                                                                             |                       |                  |                   | 2.5   |
| RA2.: --                          |               |                                                                                                                                  |                                                                                                             |                       |                  |                   | tbd    |
| SEU                               | Overdosed trials on sunflower seeds (468–499 g a.s./ha) (Netherlands, 2012, 2016). Tentatively extrapolated to cotton seeds MRL$_{OECD}$ = 0.1 |                                                                                                               |                                                                                                             | 0.1$^{(i)}$ (tentative) | 0.07            | 0.01              |       |
| RA1.: --                          |               |                                                                                                                                  |                                                                                                             |                       |                  |                   | 2.5   |
| RA2.: --                          |               |                                                                                                                                  |                                                                                                             |                       |                  |                   | tbd    |
| Rapeseeds/canola seeds            | NEU           | Mo.: 8 × < 0.014                                                                                                               | Overdosed trials on winter rape (2 × 240 + 1 × 120 g a.s./ha) (Netherlands, 2012, 2016) MRL$_{OECD}$ = 0.01 | 0.02$^*$$^{(i)}$ (tentative) | 0.01            | 0.01              |       |
| RA1.: --                          |               |                                                                                                                                  |                                                                                                             |                       |                  |                   | 2.5   |
| RA2.: --                          |               |                                                                                                                                  |                                                                                                             |                       |                  |                   | tbd    |
## Crop

| Region/indoor(s) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | Calculated MRL (mg/kg) | HR\textsubscript{Mo} (mg/kg)\(^{(b)}\) | STMR\textsubscript{Mo} (mg/kg)\(^{(c)}\) | CF\(^{(d)}\) |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SEU             | Mo.: 14 × < 0.014 Overdosed trials on winter rape; eight with 2 × 235–250 and 1 × 110–120 g a.s./ha and six with 1 × 188–208 g a.s./ha; 1 trial PHI 83 days (Netherlands, 2012, 2016; France, 2017; Greece, 2017) MRL\textsubscript{OECD} = 0.01 | 0.02\(^{(i)}\) (tentative) | 0.01 | 0.01 | 2.5 |
|                 | RA1.: –                                                                                                                                                                                                  | RA2.: –                                                                                                                                                                                                  | 2.5 |
| Soya beans      | Mo.: < 0.014; 0.052; 0.259; 0.388; 0.438; 0.45; 0.466; 0.933; 1.253; 1.267 GAP-compliant trials on soya beans (289–325 g a.i./ha) (Netherlands, 2012, 2016) MRL\textsubscript{OECD} = 2.36 | 3 | 1.27 | 0.44 | tbd |
|                 | RA1.: –                                                                                                                                                                                                  | RA2.: –                                                                                                                                                                                                  | tbd |
| Mustard seeds, Gold of pleasure seeds | Overdosed trials (2 × 235.2–262 g a.s./ha, 1 × 121–126 g a.s./ha; PHI: 114–132 days): Mo.: 8 × < 0.014 Overdosed trials (2 × 235.2–262 g a.s./ha and 1 × 121–126 g a.s./ha; PHI: 85–90 days): Mo.: 4 × < 0.014; 0.016; 0.017; 0.022; 0.039 Trials on winter rape (Netherlands, 2012). Tentatively extrapolated to Gold of Pleasure seeds MRL\textsubscript{OECD} = 0.04 | 0.05\(^{(i)}\) (tentative) | 0.04 | 0.01 | 2.5 |
|                 | RA1.: –                                                                                                                                                                                                  | RA2.: –                                                                                                                                                                                                  | tbd |
| SEU             | Overdosed trials (2 x 235–250 and 1 x 110–120 g a.s./ha) Mo.: 8 × < 0.014 Overdosed trials (1 x 188–208 g a.s./ha; | Overdosed trials on winter rape (Netherlands, 2012, 2016; France, 2017; Greece, 2017) MRL\textsubscript{OECD} = 0.01. | 0.02\(^{(i)}\) (tentative) | 0.01 | 0.01 | tbd |
| Crop                              | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                 | Calculated MRL (mg/kg) | HR<sub>Mo</sub> (mg/kg)<sup>(b)</sup> | STMR<sub>Mo</sub> (mg/kg)<sup>(c)</sup> | CF<sup>(d)</sup> |
|----------------------------------|------------------|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|------------------------|---------------------------------------|----------------------------------------|----------------|
|                                  |                  | PHI 83 days)                                                                                   | Extrapolated to Gold of Pleasure seeds. No authorisation for mustard seeds in SEU MRL<sub>OECD</sub> = 0.01 |                        |                                      |                                        |                |
|                                  |                  | Mo.: 6 × < 0.014                                                                               |                                                                                                           | RA1.: –                |                                      |                                        |                |
|                                  |                  |                                                                                               |                                                                                                           | RA2.: –                |                                      |                                        |                |
| Rice grains                       | SEU              | Mo.: < 0.014; < 0.014                                                                          | Overdosed trials (3 replicates with 293; 313 g a.i./ha) on rice grain (Netherlands, 2012)                  | –                     |                                      |                                        |                |
|                                  |                  |                                                                                               |                                                                                                           | RA1.: –                |                                      |                                        |                |
|                                  |                  |                                                                                               |                                                                                                           | RA2.: –                |                                      |                                        |                |
| Rice straw                        | SEU              | Mo.: < 0.014; < 0.014                                                                          | Overdosed trials on rice straw (293; 313 g a.i./ha) (Netherlands, 2012, 2016)                             | –                     |                                      |                                        |                |
|                                  |                  |                                                                                               |                                                                                                           | RA1.: –                |                                      |                                        |                |
|                                  |                  |                                                                                               |                                                                                                           | RA2.: –                |                                      |                                        |                |
| Beetroots, fodder beet roots      | NEU              | Mo.: 8 × < 0.014; 0.028; 0.038; 0.043                                                           | GAP-compliant trials on sugar beet roots 1 × 310–335 g a.s./ha, PHI = 54–56 days; tentatively extrapolated to beetroots and fodder beet roots (Netherlands, 2005, 2012, 2016; Italy, 2017) MRL<sub>OECD</sub> = 0.06 | 0.07(i)               | 0.04                                  | 0.01                                  |                |
|                                  |                  |                                                                                               |                                                                                                           | RA1.: –                |                                      |                                        |                |
|                                  |                  |                                                                                               |                                                                                                           | RA2.: –                |                                      |                                        |                |
| Sugar beet roots, chicory roots   | NEU              | Mo.: 8 × < 0.014; 0.028; 0.038; 0.043                                                           | GAP-compliant trials on sugar beet roots 1 × 310–335 g a.s./ha, PHI = 54–56                                | 0.07                  | 0.04                                  | 0.01                                  |                |

(a) Crop-specific supervised residue trials, (b) HR<sub>Mo</sub> = Maximum residue level, (c) STMR<sub>Mo</sub> = Safety Threshold Multiple Residue level, (d) CF = Conversion Factor
| Crop Details                                    | Region/in(door(a) |
|-----------------------------------------------|-------------------|
| Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) |
|                                               | Calculated MRL (mg/kg) | HR_{Mo} (mg/kg)(b) | STMR_{Mo} (mg/kg)(c) | CF(d) |
|                                               | days; PHI for beetroots 100 days and 90 days for fodder beets (Netherlands, 2005, 2012, 2016; Italy, 2017) MRL_{OECD} = 0.06 | |
| RA1.: –                                       | 2.5 |
| RA2.: –                                       | tbd |
| SEU Mo.: 8 × < 0.014                          | Overdosed trials on sugar beets (367–473 g a.s./ha, PHI = 56 days) (Netherlands 2012, 2016, Italy, 2017). No authorisations for chicory roots in SEU MRL_{OECD} = 0.01 | 0.02* | 0.01 | 0.01 |
| RA1.: –                                       | 2.5 |
| RA2.: –                                       | tbd |
| Sugar beet tops, fodder beet tops; turnip tops | NEU Mo.: 0.169; 0.0745; 0.024; 0.041; 0.022; 0.018; 0.015; 0.022 | GAP-compliant trials on sugar beet leaves (PHI 54–56) (Netherlands, 2005, 2012, 2016; Italy, 2017). Tentatively extrapolated to turnip tops MRL_{OECD} = 0.22 | 0.3 | 0.17 | 0.03 |
| RA1.: –                                       | 2.5 |
| RA2.: –                                       | tbd |
| SEU Mo.: 7 × < 0.014                          | GAP-compliant trials on sugar beet leaves (Netherlands, 2005, 2012, 2016; Italy, 2017). No authorisation for turnips (SEU) MRL_{OECD} = 0.04 | 0.05 | 0.03 | 0.01 |
| RA1.: –                                       | 2.5 |
| RA2.: –                                       | tbd |
| Crop                          | Region/ indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/ comments (OECD calculations) | Calculated MRL (mg/kg) | HR_{Mo}^{(b)} (mg/kg) | STMR_{Mo}^{(c)} (mg/kg) | CF^{(d)} |
|------------------------------|-------------------|--------------------------------------------------------------------------------------------------|------------------------------------------------|------------------------|--------------------------|-------------------------|-----------|
| Alfalfa, clover, trefoil and vetch forage | NEU               | Mo.: < 0.014; 0.015; 0.015; 0.023; 0.091; 0.172                                               | Overdosed trials on alfalfa green material with twice the application rate (Netherlands, 2012, 2016). Tentatively extrapolated to clover, trefoil and vetch forage MRL_{OECD} = 0.31 | 0.4^{(i)} (tentative) | 0.17 | 0.02 | 2.5 |
|                              |                   | RA1.: –                                                                                           |                                                 |                        | RA2.: –                                                               |                        |           |
|                              |                   | SEU                                                 | GAP-compliant trial on alfalfa forage (Netherlands, 2012, 2016). Extrapolated to clover, trefoil and vetch forage MRL_{OECD} = 0.64 | 0.7 | 0.47 | 0.01 | tbd |
|                              |                   | RA1.: –                                                                                           |                                                 |                        | RA2.: –                                                               |                        |           |
| Pea vines                    | NEU               | –                                                                                                 | No trials available                           |                        | –                        | –                       | 2.5       |
|                              |                   | RA1.: –                                                                                           |                                                 |                        | RA2.: –                                                               |                        |           |

GAP: good agricultural practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Tbd: to be determined; Mo: monitoring; RA: risk assessment; a.s.: active substance; PHI: preharvest interval; a.i.: active ingredient.

*: Indicates that the MRL is proposed at the limit of quantification.
(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.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Conversion factor (CF) for risk assessment as derived from the metabolism study based on residue definition for risk assessment 1 (sum of clethodim, clethodim sulfoxide, clethodim sulfone and metabolites M14RM15R, M16R/M17R and M18R/M19R, expressed as clethodim) noting that a conversion factor for residue definition 2 cannot be derived based on the available information.
(e): Residues were all below the LOQ however fruit crops are not supported by a metabolism study and the proposed RD for monitoring may not be a good marker in this case.
(f): MRL proposal is derived from a reduced number of trials.
(g): The MRL proposal is tentative for garlic since trials on onion were done with twice the application rate.
(h): Trials analysed according to the RD definition for enforcement are insufficient to indicate no residue situation, one additional trial analysed with common moiety method.
(i): Trials compliant with a more critical GAP as indicated in the comments.
B.1.2.2. Residues in succeeding crops

| Confined rotational crop study (quantitative aspect) | Individual compounds are not expected to be present in significant levels (above 0.01 mg/kg) in rotational crops when clethodim is applied according to bare soil at 1,100 g a.s./ha (2.9N of the cGAP for beans, 3.1N of cGAP (beetroots) of this review) |
| Field rotational crop study | Not available and not required |

cGAP: critical good agricultural practice.

B.1.2.3. Processing factors

| Processed commodity | Number of studies\(^{(a)}\) | Processing factor (PF) | CF\(_{PF}\)\(^{(b)}\) |
|---------------------|-----------------------------|------------------------|-------------------|
|                     |                             | Individual values       | Median PF         |
| Sugar beets, dehydrated pulp | 1\(^{(a)}\) | – | – |
| Sugar beets, molasses | 1 | 2.8 | 2.8 |
| Sugar beets, refined sugar | 1\(^{(a)}\) | – | – |
| Sugar beets, sliced roots | 1\(^{(a)}\) | – | – |
| Potato, starch | 1 | 0.08 | 0.08 |
| Potato, French fries | 1 | 0.15 | 0.15 |
| Potato, boiling | 1 | 0.11 | 0.11 |

\(^{(a)}\): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
\(^{(b)}\): Conversion factor for risk assessment in the processed commodity could not be derived.

B.2. Residues in livestock

| Relevant groups | Dietary burden expressed in mg/kg bw per day | mg/kg DM | Most critical diet\(^{(a)}\) | Most critical commodity\(^{(a)}\) | Trigger exceeded (Y/N) |
|-----------------|---------------------------------------------|----------|-----------------------------|---------------------------------|------------------------|
|                 | Med. | Max. | Med. | Max. | Cattle (dairy) | Cabbage, heads, leaves | Yes |
| Cattle (all diets) | 0.506 | 1.02 | 16.45 | 29.72 | Cattle (dairy) | Cabbage, heads, leaves | Yes |
| Cattle (dairy only) | 0.506 | 1.02 | 13.71 | 26.51 | Cattle (dairy) | Cabbage, heads, leaves | Yes |
| Sheep (all diets) | 0.496 | 0.738 | 14.88 | 22.15 | Sheep (ram/ewe) | Cabbage, heads, leaves | Yes |
| Sheep (ewe only) | 0.496 | 0.738 | 14.88 | 22.15 | Sheep (ram/ewe) | Cabbage, heads, leaves | Yes |
| Swine (all diets) | 0.198 | 0.388 | 8.59 | 16.80 | Swine (breeding) | Cabbage, heads, leaves | Yes |
| Poultry (all diets) | 0.160 | 0.394 | 2.34 | 5.76 | Poultry (layer) | Cabbage, heads, leaves | Yes |
| Poultry (layer only) | 0.160 | 0.394 | 2.34 | 5.76 | Poultry (layer) | Cabbage, heads, leaves | Yes |

bw: body weight; DM: dry matter.
\(^{(a)}\): Calculated for the maximum dietary burden.
B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | N rate/comment |
|--------------------------------|--------|-------------------------|----------------|----------------|
| Laying hen                    | 2.1    | 5                       | 2.06N rate/maximum burden poultry layers |
|                               | 51     | 5                       | 50N rate/maximum burden poultry layers |
| Lactating goat                | 1.2    | 3                       | 1.63N rate/maximum dietary burden cattle |
| Netherlands (2005)            |        |                         |                 |                |

- Time needed to reach a plateau concentration in milk and eggs (days): 2 days in milk. Plateau in eggs was not reached after 4 days.
- Metabolism in rat and ruminant similar: Yes.
- Animal residue definition for monitoring (RD-Mo): Sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim (tentative).
- Animal residue definition for risk assessment (RD-RA): Sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim (tentative).
- Conversion factor (monitoring to risk assessment): 1.
- Fat soluble residues (Yes/No): Yes.
- Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs): HPLC-MS/MS, muscle, fat, liver, kidney, milk, eggs; combined LOQ = 0.05 mg/kg, clethodim, clethodim sulfoxide, clethodim sulfone as sum. ILV not available ((Reed, 2002) in Netherlands (2005)). FR provided validated HPLC-MS/MS in milk, meat, liver, fat and eggs with a combined LOQ of 0.03 mg/kg (LOQ of 0.01 mg/kg for each of clethodim, clethodim sulfoxide and clethodim sulfone); ILV available (France, 2017).

bw: body weight; HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (Months) | Comment |
|-------------------------------------|--------|-----------|--------|--------------------|---------|
|                                     | Bovine | Muscle    | –20    | 5                  | Clethodim, S-methyl clethodim sulfoxide, 5-OH clethodim sulfone |
|                                     | Bovine | Fat       | –20    | 5                  | As above |
|                                     | Bovine | Liver     | –20    | 5                  | As above |
|                                     | Bovine | Kidney    | –20    | 5                  | As above |
|                                     | Bovine | Milk      | –20    | 5                  | As above |
|                                     | Poultry| Muscle    | –18    | 1.5                | As above |
|                                     | Poultry| Fat       | –18    | 1.5                | As above |
|                                     | Poultry| Gizzard   | –18    | 1.5                | As above |
|                                     | Poultry| Liver     | –18    | 1.5                | As above |
|                                     | Poultry| Egg       | –18    | 2                  | As above |
|                                     | Netherlands (2005); EFSA (2011) |          |        |                    |         |
B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) |
|------------------|---------------------------------------------|------------------------------------------|
|                  | Mean | Highest | STMR<sup>(a)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) |                  |
| Cattle (all diets) |      |         |                            |                         |                  |
| Closest feeding level (1.93 mg/kg bw; 1.89 × N rate)<sup>(c)</sup> |      |         |                            |                         |                  |
| Muscle           | < 0.05 | < 0.05 | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |
| Fat              | < 0.05 | < 0.05 | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |
| Liver            | 0.09  | 0.12   | < 0.05 | 0.08   | 0.08<sup>(f)</sup> (tentative) |
| Kidney           | 0.15  | 0.17   | < 0.05 | 0.09   | 0.09<sup>(f)</sup> (tentative) |
| Cattle (dairy only) |      |         |                            |                         |                  |
| Muscle           |      |         |                            |                         |                  |
| Fat              |      |         |                            |                         |                  |
| Liver            |      |         |                            |                         |                  |
| Milk<sup>(d)</sup> | 0.02 | 0.03   | < 0.03 | < 0.03 | 0.03<sup>*</sup><sup>(f)</sup> (tentative) |
| Sheep (all diets)<sup>(e)</sup> |      |         |                            |                         |                  |
| Closest feeding level (1.93 mg/kg bw; 2.95 × N rate)<sup>(c)</sup> |      |         |                            |                         |                  |
| Muscle           | < 0.05 | < 0.05 | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |
| Fat              | < 0.05 | < 0.05 | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |
| Liver            | 0.09  | 0.12   | < 0.05 | 0.06   | 0.07<sup>(f)</sup> (tentative) |
| Kidney           | 0.15  | 0.17   | < 0.05 | 0.06   | 0.07<sup>(f)</sup> (tentative) |
| Sheep (dairy only)<sup>(e)</sup> |      |         |                            |                         |                  |
| Milk<sup>(d)</sup> | 0.02 | 0.03   | < 0.03 | < 0.03 | 0.03<sup>*</sup><sup>(f)</sup> (tentative) |
| Swine<sup>(e)</sup> |      |         |                            |                         |                  |
| Closest feeding level (0.66 mg/kg bw; 1.70 × N rate)<sup>(c)</sup> |      |         |                            |                         |                  |
| Muscle           | < 0.05 | < 0.05 | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |
| Fat              | < 0.05 | < 0.05 | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |
| Liver            | 0.06  | 0.06   | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |
| Kidney           | < 0.05 | 0.051  | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |
| Poultry (all diets)<sup>(e)</sup> |      |         |                            |                         |                  |
| Closest feeding level (1.03 mg/kg bw; 2.61 × N rate)<sup>(c)</sup> |      |         |                            |                         |                  |
| Muscle           | < 0.05 | < 0.05 | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |
| Fat              | < 0.05 | < 0.05 | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |
| Liver            | < 0.05 | < 0.05 | < 0.05 | < 0.05 | 0.05<sup>(f)</sup> (tentative) |

<sup>(a)</sup> STMR = Simple Target Residue

<sup>(b)</sup> HR = Harmonised Reference Value

<sup>(c)</sup> Rat is in mg/kg bw

<sup>(d)</sup> Cattle milk

<sup>(e)</sup> Dairy animals (cows, sheep, goats, pigs)

<sup>(f)</sup> Tentative MRL
### B.3. Consumer risk assessment

#### B.3.1. Indicative consumer risk assessment without consideration of the existing CXLs

| ADI | 0.16 mg/kg bw per day (EFSA, 2011) |
| --- | --- |
| Highest IEDI, according to EFSA PRIMo | 12.7% ADI (FR, toddler) according to RD1 |
| Assumptions made for the calculations | Residue definition one (RD1): The calculation is based on the median residue levels in the raw agricultural commodities  For root and tuber vegetables, pulses and oilseeds a tentative conversion factor of 2.5 and for all other crop groups a tentative conversion factor of 19 was applied  For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL multiplied by the respective tentative CF for an indicative calculation  The contributions of commodities where no GAP was reported were not included in the calculation in the framework of this review  
Residue definition two (RD2): In the absence of a final conclusion on the toxicological properties of metabolite M14A/M15A, a (tentative) conversion factor cannot be derived and a consumer risk assessment cannot be performed |
| ARfD | Not applicable mg/kg bw (EFSA, 2011) |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; CF: conversion factor for enforcement residue definition to risk assessment residue definition; GAP: Good Agricultural Practice; ARfD: acute reference dose; IESTI: international estimated short-term intake.
B.3.2. Indicative consumer risk assessment with consideration of the existing CXLs

| ADI | 0.16 mg/kg bw per day (EFSA, 2011) |
|-----|----------------------------------|
| Highest IEDI, according to EFSA PRIMO | 27.6% ADI (WHO, cluster diet B) according to RD1 |

Assumptions made for the calculations

The residue definition in place of the CXLs is not compatible with the proposed residue definitions for the EU. For those commodities having a CXL higher than the EU MRL, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR (except for rapeseeds, soya beans and cotton seeds where the CXL value was considered), multiplied by the tentative conversion factors of 2.5 (root and tuber vegetables, pulses and oilseeds) and 19 (all other crop groups) for risk assessment according to RD1.

| ARfD | Not applicable mg/kg bw (EFSA, 2011) |
|-----|------------------------------------|

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMO: (EFSA) Pesticide Residues Intake Model; CXL: codex maximum residue limit; MRL: maximum residue level; RD1: residue definition 1; ARfD: acute reference dose.

B.4. Proposed MRLs

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment |
|-------------|-----------|------------------------|---------------------|-------------|---------|
|             | Enforcement residue definition (existing): Clethodim (sum of sethoxydim and clethodim including degradation products calculated as sethoxydim) | Enforcement residue definition (proposed): Sum of clethodim, clethodim sulfoxide and clethodim sulfone, expressed as clethodim |
| 0151010 | Table grapes | 1 | – | – | Further consideration needed(a) |
| 0151020 | Wine grapes | 0.5 | – | – | Further consideration needed(a) |
| 0152000 | Strawberries | 0.5 | – | – | Further consideration needed(a) |
| 0153010 | Blackberries | 0.1 | – | – | Further consideration needed(b) |
| 0153030 | Raspberries (red and yellow) | 0.1 | – | – | Further consideration needed(b) |
| 0154010 | Blueberries | 0.1 | – | – | Further consideration needed(b) |
| 0154020 | Cranberries | 0.5 | – | – | Further consideration needed(b) |
| 0154030 | Currants (black, red and white) | 0.1 | – | – | Further consideration needed(b) |
| 0154040 | Gooseberries (green, red and yellow) | 0.1 | – | – | Further consideration needed(b) |
| 0154050 | Rose hips | 0.1 | – | – | Further consideration needed(b) |
| 0154080 | Elderberries | 0.1 | – | – | Further consideration needed(b) |
| 0211000 | Potatoes | 0.5 | 0.5 | – | Further consideration needed(c) |
| 0213010 | Beetroots | 0.5 | – | – | Further consideration needed(a) |
| 0213020 | Carrots | 0.5 | – | – | Further consideration needed(a) |
| 0213030 | Celeriacs/turnip rooted celeries | 0.5 | – | – | Further consideration needed(a) |
| 0213040 | Horseradishes | 0.5 | – | – | Further consideration needed(a) |
| 0213050 | Jerusalem artichokes | 0.5 | – | – | Further consideration needed(a) |
| 0213060 | Parsnips | 0.5 | – | – | Further consideration needed(a) |
| 0213070 | Parsley roots/Hamburg roots parsley | 0.5 | – | – | Further consideration needed(a) |
| 0213090 | Salsifis | 0.5 | – | – | Further consideration needed(a) |
| 0213100 | Swedes/rutabagas | 0.5 | – | – | Further consideration needed(a) |
| Code number | Commodity                                                                 | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|---------------------------------------------------------------------------|-------------------------|----------------------|-----------------------|---------|
| 0213110     | Turnips                                                                   | 0.5                     | –                    | Further consideration needed(a) |
| 0220010     | Garlic                                                                    | 0.5                     | 0.5                  | Further consideration needed(c) |
| 0220020     | Onions                                                                    | 0.5                     | 0.5                  | Further consideration needed(c) |
| 0220030     | Shallots                                                                  | 0.5                     | –                    | Further consideration needed(a) |
| 0220040     | Spring onions/green onions and Welsh onions                              | 0.5                     | –                    | Further consideration needed(a) |
| 0231010     | Tomatoes                                                                  | 1                       | 1                    | Further consideration needed(c) |
| 0241010     | Broccoli                                                                  | 0.5                     | –                    | Further consideration needed(b) |
| 0241020     | Cauliflowers                                                               | 0.5                     | –                    | Further consideration needed(b) |
| 0242010     | Brussels sprouts                                                          | 0.5                     | –                    | Further consideration needed(b) |
| 0242020     | Head cabbages                                                             | 0.5                     | –                    | Further consideration needed(a) |
| 0252010     | Spinaches                                                                  | 0.5                     | –                    | Further consideration needed(b) |
| 0255000     | Witloofs/Belgian endives                                                  | 0.5                     | –                    | Further consideration needed(b) |
| 0256010     | Chervil                                                                    | 0.5                     | –                    | Further consideration needed(a) |
| 0256020     | Chives                                                                     | 0.5                     | –                    | Further consideration needed(a) |
| 0256030     | Celery leaves                                                              | 0.5                     | –                    | Further consideration needed(a) |
| 0256040     | Parsley                                                                    | 0.5                     | –                    | Further consideration needed(a) |
| 0256050     | Sage                                                                       | 0.5                     | –                    | Further consideration needed(a) |
| 0256060     | Rosemary                                                                   | 0.5                     | –                    | Further consideration needed(a) |
| 0256070     | Thyme                                                                      | 0.5                     | –                    | Further consideration needed(a) |
| 0256080     | Basil and edible flowers                                                  | 0.5                     | –                    | Further consideration needed(a) |
| 0256090     | Laurel/bay leave                                                          | 0.5                     | –                    | Further consideration needed(a) |
| 0256100     | Tarragon                                                                   | 0.5                     | –                    | Further consideration needed(a) |
| 0260010     | Beans (with pods)                                                         | 0.5                     | 0.5*                 | Further consideration needed(c) |
| 0260020     | Beans (without pods)                                                      | 0.5                     | –                    | Further consideration needed(a) |
| 0260030     | Peas (with pods)                                                          | 0.5                     | –                    | Further consideration needed(a) |
| 0260040     | Peas (without pods)                                                       | 0.5                     | –                    | Further consideration needed(a) |
| 0260050     | Lentils                                                                    | 0.5                     | –                    | Further consideration needed(a) |
| 0270010     | Asparagus                                                                  | 0.5                     | –                    | Further consideration needed(b) |
| 0270050     | Globe artichokes                                                          | 0.5                     | –                    | Further consideration needed(a) |
| 0300010     | Beans (dry)                                                                | 2                       | 2                    | Further consideration needed(c) |
| 0300030     | Peas (dry)                                                                 | 2                       | 2                    | Further consideration needed(c) |
| 0300040     | Lupins/lupini beans (dry)                                                 | 0.5                     | –                    | Further consideration needed(a) |
| 0401010     | Linseeds                                                                   | 0.1                     | –                    | Further consideration needed(a) |
| 0401020     | Peanuts                                                                    | 5                       | 5                    | Further consideration needed(g) |
| 0401030     | Poppy seeds                                                                | 0.1                     | –                    | Further consideration needed(a) |
| 0401040     | Sesame seeds                                                               | 0.1                     | –                    | Further consideration needed(a) |
| 0401050     | Sunflower seeds                                                           | 0.5                     | 0.5                  | Further consideration needed(c) |
| 0401060     | Rapeseeds/canola seeds                                                    | 1                       | 0.5                  | Further consideration needed(c) |
| 0401070     | Soya beans                                                                 | 10                      | 10                   | Further consideration needed(c) |
| 0401080     | Mustard seeds                                                             | 0.1                     | –                    | Further consideration needed(a) |
| 0401090     | Cotton seeds                                                               | 0.5                     | 0.5                  | Further consideration needed(c) |
| 0401100     | Pumpkin seeds                                                             | 0.1                     | –                    | Further consideration needed(a) |
| 0401110     | Safflower seeds                                                           | 0.1                     | –                    | Further consideration needed(a) |
| 0401120     | Borage seeds                                                               | 0.1                     | –                    | Further consideration needed(a) |
| 0401130     | Gold of pleasure seeds                                                    | 0.1                     | –                    | Further consideration needed(a) |
| 0401140     | Hemp seeds                                                                 | 0.1                     | –                    | Further consideration needed(a) |
| 0401150     | Castor beans                                                               | 0.1                     | –                    | Further consideration needed(a) |
| Code number | Commodity          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Outcome of the review | Comment                                                                 |
|-------------|--------------------|-------------------------|----------------------|-------------|-----------------------|--------------------------------------------------------------------------|
| 0500060     | Rice               | 0.1                     | –                    | –           | Further consideration needed(b) |                                                                          |
| 0900010     | Sugar beet roots   | 0.5                     | 0.1                  | –           | Further consideration needed(c) |                                                                          |
| 0900030     | Chicory roots      | 0.1                     | –                    | –           | Further consideration needed(a) |                                                                          |
| 1011010     | Swine muscle       | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1011020     | Swine fat tissue   | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1011030     | Swine liver        | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1011040     | Swine kidney       | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1012010     | Bovine muscle      | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1012020     | Bovine fat tissue  | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1012030     | Bovine liver       | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1012040     | Bovine kidney      | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1013010     | Sheep muscle       | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1013020     | Sheep fat tissue   | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1013030     | Sheep liver        | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1013040     | Sheep kidney       | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1014010     | Goat muscle        | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1014020     | Goat fat tissue    | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1014030     | Goat liver         | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1014040     | Goat kidney        | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1015010     | Equine muscle      | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1015020     | Equine fat tissue  | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1015030     | Equine liver       | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1015040     | Equine kidney      | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1016010     | Poultry muscle     | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1016020     | Poultry fat tissue | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1016030     | Poultry liver      | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1016040     | Poultry kidney     | 0.2                     | 0.2*                 | –           | Further consideration needed(c) |                                                                          |
| 1020010     | Cattle milk        | 0.05*                   | 0.05*                | –           | Further consideration needed(c) |                                                                          |
| 1020020     | Sheep milk         | 0.05*                   | 0.05*                | –           | Further consideration needed(c) |                                                                          |
| 1020030     | Goat milk          | 0.05*                   | 0.05*                | –           | Further consideration needed(c) |                                                                          |
| 1020040     | Horse milk         | 0.05*                   | 0.05*                | –           | Further consideration needed(c) |                                                                          |
| 1030000     | Bird eggs          | 0.05*                   | 0.05*                | –           | Further consideration needed(c) |                                                                          |
|             | Other commodities  |                         |                      |             | Further consideration needed(e) |                                                                          |
|             | of plant and       | Regulation              |                      |             |                       |                                                                          |
|             | animal origin      | (EC) No 839/2008        |                      |             |                       |                                                                          |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.

(a): GAP evaluated at EU level is not fully supported by data and an overall risk assessment could not be performed; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-I in Appendix E).
(b): GAP evaluated at EU level is not supported by data and an overall risk assessment could not be performed; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-I in Appendix E).
(c): GAP evaluated at EU level is not fully supported by data and an overall risk assessment could not be performed; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-II in Appendix E).
(d): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix E).
(e): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### PRIMo(EU)

| Clethodim |
|-----------|
| Status of the active substance: | Included |
| Code no. | 0.014 |
| LOQ (mg/kg bw): | Proposed LOQ |
| ADI (mg/kg bw per day): | 0.16 |
| Source of ADI: | EFSA |
| Year of evaluation: | 2011 |
| ARfD (mg/kg bw): | 0.16 |
| Source of ARfD: | EFSA |
| Year of evaluation: | 2011 |

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI | No of diets exceeding ADI |
|--------------------------------|--------------------------|---------------------------|
|                                | minimum – maximum        | 5                         |
|                                | 37.1                      | 5                         |
| WHO Cluster diet B             | 20.2                      | 37.1                      |
| FR toddler                    | 6.6                       | 23.7                      |
| NL child                       | 4.4                       | 23.7                      |
| WHO cluster diet E            | 6.1                       | 19.1                      |
| WHO Cluster diet F            | 6.6                       | 18.6                      |
| WHO regional European diet    | 7.2                       | 16.7                      |
| DE child                       | 5.9                       | 14.9                      |
| PT General population         | 6.1                       | 14.7                      |
| IE adult                       | 6.1                       | 13.9                      |
| FR infant                      | 4.2                       | 12.6                      |
| UK infant                      | 4.1                       | 12.4                      |
| NL general                     | 2.3                       | 12.3                      |
| SE general population 90th percentile | 5.0                    | 12.2                      |
| UK Toddler                    | 3.9                       | 12.0                      |
| IT kids/toddler               | 9.4                       | 11.6                      |
| IT child                      | 6.4                       | 10.7                      |
| IT adult                      | 7.6                       | 10.3                      |
| UK vegetarian                 | 4.1                       | 9.2                       |
| PL general population         | 5.8                       | 8.6                       |
| ES adult                      | 5.1                       | 8.4                       |
| FR all population             | 2.8                       | 7.7                       |
| UK Adult                      | 2.9                       | 6.9                       |
| LT adult                      | 4.1                       | 6.3                       |
| DK child                      | 3.5                       | 5.6                       |
| DK adult                      | 2.7                       | 4.8                       |
| FI adult                      | 2.8                       | 4.5                       |

### Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of clethodim is unlikely to present a public health concern.
The acute risk assessment is based on the ADI as no ARfD was available.

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 variability factor of 3.

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

### Unprocessed commodities

| No of commodities for which ARfD/ADI is exceeded (IFESTI 1): | 7 |
| --- | --- |
| No of commodities for which ARfD/ADI is exceeded (IFESTI 2): | 6 |
| Highest % of ARfD/ADI | commodities pTMRL/threshold MRL (mg/kg) |
| --- | --- |
| 894.0 Tomatoes | 24.62/2.75 |
| 619.5 Cauliflower | 15/2.42 |
| 590.1 Head cabbage | 17.94/3.04 |
| 434.9 Witloof | 15/4.44 |
| 211.9 Spinach | 15/7.07 |
| 193.3 Potatoes | 1.075/1.04 |

### Processed commodities

| No of commodities (IFESTI 1): | 1 |
| No of commodities (IFESTI 2): | 0 |

### Conclusion:

For clethodim, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 6 commodities.

For processed commodities, the ARfD/ADI was exceeded in one or several cases.
Clethodim

Status of the active substance: Included

LOQ (mg/kg bw): 0.014

Toxicological endpoint

ADI (mg/kg bw per day): 0.16

Source of ADI: EFSA

Year of evaluation: 2011

ARfD (mg/kg bw): n.n.

Source of ARfD: EFSA

Year of evaluation: 2011

No of diets exceeding ADI:

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

Review of the existing MRLs for clethodim
Acute risk assessment is not necessary.

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 variability factor of 3.

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

### Unprocessed commodities

| IESTI 1 | IESTI 2 | IESTI 1 | IESTI 2 |
|---------|---------|---------|---------|
| No of critical MRLs (IESTI 1) | --- | No of critical MRLs (IESTI 2) | --- |
| Highest % of ARfD/ADI | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | pTMRL/ threshold MRL (mg/kg) |

### Processed commodities

| IESTI 1 | IESTI 2 | IESTI 1 | IESTI 2 |
|---------|---------|---------|---------|
| No of critical MRLs (IESTI 1) | --- | No of critical MRLs (IESTI 2) | --- |
| Highest % of ARfD/ADI | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | pTMRL/ threshold MRL (mg/kg) |

### Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of clethodim residues is unlikely to present a public health concern.

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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 variability factor of 3. **Threshold MRL** is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

| IESTI 1 | IESTI 2 | IESTI 1 | IESTI 2 |
|---------|---------|---------|---------|
| No of critical MRLs (IESTI 1) | --- | No of critical MRLs (IESTI 2) | --- |
| Highest % of ARfD/ADI | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | pTMRL/ threshold MRL (mg/kg) |

### No of commodities for which ARfD/ADI is exceeded

| IESTI 1 | IESTI 2 | IESTI 1 | IESTI 2 |
|---------|---------|---------|---------|
| --- | --- | --- | --- |
| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | --- |
| pTMRL/ threshold MRL (mg/kg) | pTMRL/ threshold MRL (mg/kg) | pTMRL/ threshold MRL (mg/kg) | pTMRL/ threshold MRL (mg/kg) |

---

1) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

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Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of clethodim residues is unlikely to present a public health concern.
### Appendix D – Input values for the exposure calculations

#### D.1. Livestock dietary burden calculations

| Feed commodity | Median dietary burden | Maximum dietary burden |
|----------------|-----------------------|------------------------|
|                | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment |
| Potato, culls  | 0.19                  | STMR \times CF\textsuperscript{(c)} | 1.08                  | HR \times CF\textsuperscript{(c)} |
| Potato, process waste | 3.85 | STMR \times 2\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 3.85                  | STMR \times 2\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Potato, dried pulp | 7.32 | STMR \times 3\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 7.32                  | STMR \times 3\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Carrot, culls | 0.12                  | STMR \times CF\textsuperscript{(c)} | 0.25                  | HR \times CF\textsuperscript{(c)} |
| Swede, roots  | 0.12                  | STMR \times CF\textsuperscript{(c)} | 0.25                  | HR \times CF\textsuperscript{(c)} |
| Turnip, roots | 0.12                  | STMR \times CF\textsuperscript{(c)} | 0.25                  | HR \times CF\textsuperscript{(c)} |
| Cabbage, heads, leaves | 2.35 | STMR \times CF\textsuperscript{(c)} | 11.36                 | HR \times CF\textsuperscript{(c)} |
| Bean, seed (dry) | 0.49 | STMR \times CF\textsuperscript{(c)} | 0.49                  | STMR \times CF\textsuperscript{(c)} |
| Cowpea, seed  | 0.49                  | STMR \times CF\textsuperscript{(c)} | 0.49                  | STMR \times CF\textsuperscript{(c)} |
| Pea (Field pea), seed (dry) | 0.15 | STMR \times CF\textsuperscript{(c)} | 0.15                  | STMR \times CF\textsuperscript{(c)} |
| Lupin, seed | 0.15                  | STMR \times CF\textsuperscript{(c)} | 0.15                  | STMR \times CF\textsuperscript{(c)} |
| Lupin seed, meal | 0.17 | STMR \times 1\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 0.17                  | STMR \times 1\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Flaxseed/Linseed, meal | 0.07 | STMR \times 2\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 0.07                  | STMR \times 2\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Sunflower, meal | 0.07 | STMR \times 2\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 0.07                  | STMR \times 2\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Canola (Rape seed), meal | 0.04 | STMR\textsuperscript{(a)} \times CF\textsuperscript{(c)} | 0.04                  | STMR\textsuperscript{(a)} \times CF\textsuperscript{(c)} |
| Rape, meal | 0.04                  | STMR\textsuperscript{(a)} \times CF\textsuperscript{(c)} | 0.04                  | STMR\textsuperscript{(a)} \times CF\textsuperscript{(c)} |
| Soybean, seed | 1.11                  | STMR \times CF\textsuperscript{(c)} | 1.11                  | STMR \times CF\textsuperscript{(c)} |
| Soybean, meal | 1.44                  | STMR \times 1\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 1.44                  | STMR \times 1\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Soybean, hulls | 14.43                | STMR \times 13\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 14.43                 | STMR \times 13\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Cotton, undelinted seed | 0.04 | STMR \times CF\textsuperscript{(c)} | 0.04                  | STMR \times CF\textsuperscript{(c)} |
| Cotton, meal | 0.04                  | STMR \times 1.25\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 0.04                  | STMR \times 1.25\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Safflower, meal | 0.07 | STMR \times 2\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 0.07                  | STMR \times 2\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Beet, sugar, dried pulp | 0.63 | STMR \times 18\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 0.63                  | STMR \times 18\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Beet, sugar, ensiled pulp | 0.11 | STMR \times 3\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 0.11                  | STMR \times 3\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Beet, sugar, molasses | 0.98 | STMR \times 28\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 0.98                  | STMR \times 28\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Alfalfa, forage (green) | 0.05 | STMR \times CF\textsuperscript{(c)} | 1.18                  | HR \times CF\textsuperscript{(c)} |
| Alfalfa, hay (fodder) | 0.12 | STMR \times 2.5\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 2.95                  | HR \times 2.5\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Alfalfa, meal | 0.12                  | STMR \times 2.5\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 2.95                  | HR \times 2.5\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Alfalfa, silage | 0.05 | STMR \times 1\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 1.30                  | HR \times 1\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Clover, forage | 0.05 | STMR \times CF\textsuperscript{(c)} | 1.18                  | HR \times CF\textsuperscript{(c)} |
| Clover, hay | 0.14                  | STMR \times 3\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 3.54                  | HR \times 3\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Clover, silage | 0.05 | STMR \times 1\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 1.18                  | HR \times 1\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Trefoil, forage | 0.05 | STMR \times CF\textsuperscript{(c)} | 1.18                  | HR \times CF\textsuperscript{(c)} |
| Trefoil, hay | 0.13                  | STMR \times 2.8\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 3.30                  | HR \times 2.8\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
| Vetch, forage | 0.05 | STMR \times CF\textsuperscript{(c)} | 1.18                  | HR \times CF\textsuperscript{(c)} |
| Vetch, hay | 0.13                  | STMR \times 2.8\textsuperscript{(b)} \times CF\textsuperscript{(c)} | 3.30                  | HR \times 2.8\textsuperscript{(b)} \times CF\textsuperscript{(c)} |
### Feed commodity

| Feed commodity          | Median dietary burden | Maximum dietary burden |
|-------------------------|-----------------------|-----------------------|
|                         | Input value (mg/kg)   | Comment               | Input value (mg/kg)   | Comment               |
| Beet, mangel, roots     | 0.04                  | STMR × CF<sup>(c)</sup> | 0.11                | HR × CF<sup>(c)</sup> |
| Beet, mangel, tops      | 0.08                  | STMR × CF<sup>(c)</sup> | 0.42                | HR × CF<sup>(c)</sup> |
| Beet, sugar, tops       | 0.08                  | STMR × CF<sup>(c)</sup> | 0.42                | HR × CF<sup>(c)</sup> |
| Turnip, tops (leaves)   | 0.08                  | STMR × CF<sup>(c)</sup> | 0.42                | HR × CF<sup>(c)</sup> |

STMR: supervised trials median residue; CF: conversion factor for enforcement to risk assessment residue definition; HR: highest residue.

*: Indicates that the input value is proposed at the limit of quantification.

(a): For oilseed meals and rice bran, no default processing factor was applied because clethodim is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

(b): For feed items, in the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities.

(c): According to residue definition for risk assessment one, a tentative conversion factor of 2.5 was applied for root and tuber vegetables, pulses and oilseeds and of 19 for all other commodities.

### D.2. Indicative consumer risk assessment without consideration of the existing CXLs

| Commodity                          | Chronic risk assessment |
|------------------------------------|-------------------------|
|                                    | Input value (mg/kg)     | Comment                  |
| **Risk assessment residue definition for plant commodities (tentative) RD1:** Sum of clethodim, clethodim sulfoxide, clethodim sulfone and metabolites M14R/M15R, M16R/M17R and M18R/M19R, expressed as clethodim |
| Table grapes                       | 0.27                    | STMR × CF (tentative)    |
| Wine grapes                        | 0.27                    | STMR × CF (tentative)    |
| Strawberries                       | 0.57                    | STMR × CF (tentative)    |
| Blackberries                       | 1.9                     | EU MRL × CF (tentative)  |
| Raspberries (red and yellow)       | 1.9                     | EU MRL × CF (tentative)  |
| Blueberries                        | 1.9                     | EU MRL × CF (tentative)  |
| Cranberries                        | 9.5                     | EU MRL × CF (tentative)  |
| Currants (black, red and white)    | 1.9                     | EU MRL × CF (tentative)  |
| Gooseberries (green, red and yellow)| 1.9                | EU MRL × CF (tentative)  |
| Rose hips                          | 1.9                     | EU MRL × CF (tentative)  |
| Elderberries                       | 1.9                     | EU MRL × CF (tentative)  |
| Potatoes                           | 0.19                    | STMR × CF (tentative)    |
| Beetroots                          | 0.04                    | STMR × CF (tentative)    |
| Carrots                            | 0.12                    | STMR × CF (tentative)    |
| Celeriacs/turnip rooted celeries    | 0.12                    | STMR × CF (tentative)    |
| Horseradishes                      | 0.12                    | STMR × CF (tentative)    |
| Jerusalem artichokes               | 0.12                    | STMR × CF (tentative)    |
| Parsnips                           | 0.12                    | STMR × CF (tentative)    |
| Parsley roots/Hamburg roots parsley| 0.12                    | STMR × CF (tentative)    |
| Salsifies                          | 0.12                    | STMR × CF (tentative)    |
| Swedes/rutabagas                   | 0.12                    | STMR × CF (tentative)    |
| Turnips                            | 0.12                    | STMR × CF (tentative)    |
| Garlic                             | 0.05                    | STMR × CF (tentative)    |
| Onions                             | 0.05                    | STMR × CF (tentative)    |
| Shallots                           | 0.05                    | STMR × CF (tentative)    |
| Spring onions/green onions and Welsh onions | 0.04 | STMR × CF (tentative) |
| Tomatoes                           | 0.95                    | STMR × CF (tentative)    |
| Commodity                              | Input value (mg/kg) | Comment               |
|----------------------------------------|---------------------|-----------------------|
| Broccoli                              | 9.5                 | EU MRL x CF (tentative) |
| Cauliflowers                          | 9.5                 | EU MRL x CF (tentative) |
| Brussels sprouts                      | 9.5                 | EU MRL x CF (tentative) |
| Head cabbages                         | 2.34                | STMR x CF (tentative)  |
| Spinaches                             | 9.5                 | EU MRL x CF (tentative) |
| Witloofs/Belgian endives              | 9.5                 | EU MRL x CF (tentative) |
| Chervil                                | 3.23                | STMR x CF (tentative)  |
| Chives                                | 3.23                | STMR x CF (tentative)  |
| Celery leaves                         | 3.23                | STMR x CF (tentative)  |
| Parsley                               | 3.23                | STMR x CF (tentative)  |
| Rosemary                              | 3.23                | STMR x CF (tentative)  |
| Thyme                                 | 3.23                | STMR x CF (tentative)  |
| Basil and edible flowers              | 3.23                | STMR x CF (tentative)  |
| Laurel/bay leave                      | 3.23                | STMR x CF (tentative)  |
| Tarragon                              | 3.23                | STMR x CF (tentative)  |
| Beans (with pods)                     | 0.28                | STMR x CF (tentative)  |
| Beans (without pods)                  | 2.84                | STMR x CF (tentative)  |
| Peas (with pods)                      | 0.28                | STMR x CF (tentative)  |
| Peas (without pods)                   | 2.84                | STMR x CF (tentative)  |
| Lentils (fresh)                       | 0.08                | STMR x CF (tentative)  |
| Asparagus                             | 9.5                 | EU MRL x CF (tentative) |
| Globe artichokes                      | 0.39                | STMR x CF (tentative)  |
| Beans (dry)                           | 0.49                | STMR x CF (tentative)  |
| Peas (dry)                            | 0.15                | STMR x CF (tentative)  |
| Lupins/lupini beans (dry)             | 0.15                | STMR x CF (tentative)  |
| Linseeds                              | 0.04                | STMR x CF (tentative)  |
| Poppy seeds                           | 0.04                | STMR x CF (tentative)  |
| Sesame seeds                          | 0.04                | STMR x CF (tentative)  |
| Sunflower seeds                       | 0.04                | STMR x CF (tentative)  |
| Rapeseeds/canola seeds                | 0.04                | STMR x CF (tentative)  |
| Soya beans                            | 1.11                | STMR x CF (tentative)  |
| Mustard seeds                         | 0.04                | STMR x CF (tentative)  |
| Cotton seeds                          | 0.04                | STMR x CF (tentative)  |
| Pumpkin seeds                         | 0.04                | STMR x CF (tentative)  |
| Safflower seeds                       | 0.04                | STMR x CF (tentative)  |
| Borage seeds                          | 0.04                | STMR x CF (tentative)  |
| Gold of pleasure seeds                | 0.04                | STMR x CF (tentative)  |
| Hemp seeds                            | 0.04                | STMR x CF (tentative)  |
| Castor beans                          | 0.04                | STMR x CF (tentative)  |
| Rice grains                           | 1.9                 | EU MRL x CF (tentative) |
| Sugar beet roots                      | 0.04                | STMR x CF (tentative)  |
| Chicory roots                         | 0.04                | STMR x CF (tentative)  |

**Risk assessment residue definition for animal commodities (tentative):** Sum of clethodim, clethodim sulfoxide, clethodim sulfone, expressed as clethodim

| Commodity        | Input value (mg/kg) | Comment                                          |
|------------------|--------------------|--------------------------------------------------|
| Swine meat       | 0.05               | 0.8 x STMR muscle + 0.2 x STMR fat (tentative)   |
| Swine fat tissue | 0.05               | STMR (tentative)                                 |
## Chronic risk assessment

| Commodity          | Input value (mg/kg) | Comment                                      |
|--------------------|---------------------|----------------------------------------------|
| Swine liver        | 0.05                | STMR (tentative)                             |
| Swine kidney       | 0.05                | STMR (tentative)                             |
| Bovine meat        | 0.05                | $0.8 \times \text{STMR muscle} + 0.2 \times \text{STMR fat}$ (tentative) |
| Bovine fat tissue  | 0.05                | STMR (tentative)                             |
| Bovine liver       | 0.05                | STMR (tentative)                             |
| Bovine kidney      | 0.05                | STMR (tentative)                             |
| Sheep meat         | 0.05                | $0.8 \times \text{STMR muscle} + 0.2 \times \text{STMR fat}$ (tentative) |
| Sheep fat tissue   | 0.05                | STMR (tentative)                             |
| Sheep liver        | 0.05                | STMR (tentative)                             |
| Sheep kidney       | 0.05                | STMR (tentative)                             |
| Goat meat          | 0.05                | $0.8 \times \text{STMR muscle} + 0.2 \times \text{STMR fat}$ (tentative) |
| Goat fat tissue    | 0.05                | STMR (tentative)                             |
| Goat liver         | 0.05                | STMR (tentative)                             |
| Goat kidney        | 0.05                | STMR (tentative)                             |
| Equine meat        | 0.05                | $0.8 \times \text{STMR muscle} + 0.2 \times \text{STMR fat}$ (tentative) |
| Equine fat tissue  | 0.05                | STMR (tentative)                             |
| Equine liver       | 0.05                | STMR (tentative)                             |
| Equine kidney      | 0.05                | STMR (tentative)                             |
| Poultry meat       | 0.05                | $0.9 \times \text{STMR muscle} + 0.1 \times \text{STMR fat}$ (tentative) |
| Poultry fat tissue | 0.05                | STMR (tentative)                             |
| Poultry liver      | 0.05                | STMR (tentative)                             |
| Cattle milk        | 0.03*               | STMR (tentative)                             |
| Sheep milk         | 0.03*               | STMR (tentative)                             |
| Goat milk          | 0.03*               | STMR (tentative)                             |
| Horse milk         | 0.03*               | STMR (tentative)                             |
| Birds eggs         | 0.05                | STMR (tentative)                             |

STMR: supervised trials median residue; CF: conversion factor for enforcement to risk assessment residue definition; MRL: maximum residue level.

*: Indicates that the input value is proposed at the limit of quantification.

### D.3. Indicative consumer risk assessment with consideration of the existing CXLs

| Commodity          | Input value (mg/kg) | Comment                                      |
|--------------------|---------------------|----------------------------------------------|
| Table grapes       | 0.27                | $\text{STMR} \times \text{CF}$ (tentative)   |
| Wine grapes        | 0.27                | $\text{STMR} \times \text{CF}$ (tentative)   |
| Strawberries       | 0.57                | $\text{STMR} \times \text{CF}$ (tentative)   |

Risk assessment residue definition for plant commodities (tentative) RD1: Sum of clethodim, clethodim sulfoxide, clethodim sulfone and metabolites M14R/M15R, M16R/M17R and M18R/M19R, expressed as clethodim
| Commodity                          | Input value (mg/kg) | Comment                  |
|-----------------------------------|--------------------|--------------------------|
| Blackberries                      | 1.9                | EU MRL × CF (tentative)  |
| Raspberries (red and yellow)      | 1.9                | EU MRL × CF (tentative)  |
| Blueberries                       | 1.9                | EU MRL × CF (tentative)  |
| Cranberries                       | 9.5                | EU MRL × CF (tentative)  |
| Currants (black, red and white)   | 1.9                | EU MRL × CF (tentative)  |
| Gooseberries (green, red and yellow) | 1.9            | EU MRL × CF (tentative)  |
| Rose hips                         | 1.9                | EU MRL × CF (tentative)  |
| Elderberries                      | 1.9                | EU MRL × CF (tentative)  |
| Potatoes                          | 0.19               | STMR × CF (tentative)    |
| Beetroot                          | 0.04               | STMR × CF (tentative)    |
| Carrots                           | 0.12               | STMR × CF (tentative)    |
| Celeriacs/turnip rooted celery     | 0.12               | STMR × CF (tentative)    |
| Horseradishes                     | 0.12               | STMR × CF (tentative)    |
| Jerusalem artichokes              | 0.12               | STMR × CF (tentative)    |
| Parsnips                          | 0.12               | STMR × CF (tentative)    |
| Parsley roots/Hamburg roots parsley | 0.12           | STMR × CF (tentative)    |
| Salsifies                         | 0.12               | STMR × CF (tentative)    |
| Swedes/rutabagas                  | 0.12               | STMR × CF (tentative)    |
| Turnips                           | 0.12               | STMR × CF (tentative)    |
| Garlic                            | 0.25               | STMR × CF (CXL tentative) |
| Onions                            | 0.25               | STMR × CF (CXL tentative) |
| Shallots                          | 0.05               | STMR × CF (tentative)    |
| Spring onions/green onions and Welsh onions | 0.04           | STMR × CF (tentative)    |
| Tomatoes                          | 6.65               | STMR × CF (CXL tentative) |
| Broccoli                          | 9.5                | EU MRL × CF (tentative)  |
| Cauliflowers                      | 9.5                | EU MRL × CF (tentative)  |
| Brussels sprouts                  | 9.5                | EU MRL × CF (tentative)  |
| Head cabbages                     | 2.35               | STMR × CF (tentative)    |
| Spinaches                         | 9.5                | EU MRL × CF (tentative)  |
| Witloofs/Belgian endives          | 9.5                | EU MRL × CF (tentative)  |
| Chervil                           | 3.23               | STMR × CF (tentative)    |
| Chives                            | 3.23               | STMR × CF (tentative)    |
| Celery leaves                     | 3.23               | STMR × CF (tentative)    |
| Parsley                           | 3.23               | STMR × CF (tentative)    |
| Sage                              | 3.23               | STMR × CF (tentative)    |
| Rosemary                          | 3.23               | STMR × CF (tentative)    |
| Thyme                             | 3.23               | STMR × CF (tentative)    |
| Basil and edible flowers          | 3.23               | STMR × CF (tentative)    |
| Laurel/bay leave                  | 3.23               | STMR × CF (tentative)    |
| Tarragon                          | 3.23               | STMR × CF (tentative)    |
| Beans (with pods)                 | 0.28               | STMR × CF (tentative)    |
| Beans (without pods)              | 2.84               | STMR × CF (tentative)    |
| Peas (with pods)                  | 0.28               | STMR × CF (tentative)    |
| Peas (without pods)               | 2.84               | STMR × CF (tentative)    |
| Lentils (fresh)                   | 0.08               | STMR × CF (tentative)    |
| Asparagus                         | 9.5                | EU MRL × CF (tentative)  |
| Globe artichokes                  | 0.39               | STMR × CF (tentative)    |
| Beans (dry)                       | 2.00               | STMR × CF (CXL tentative) |
| Commodity                          | Input value (mg/kg) | Comment                                      |
|-----------------------------------|--------------------|----------------------------------------------|
| Peas (dry)                        | 0.20               | STMR × CF (CXL tentative)                    |
| Lupins/lupini beans (dry)         | 0.15               | STMR × CF (tentative)                        |
| Linseeds                          | 0.04               | STMR × CF (tentative)                        |
| Poppy seeds                       | 0.04               | STMR × CF (tentative)                        |
| Sesame seeds                      | 0.04               | STMR × CF (tentative)                        |
| Sunflower seeds                   | 0.15               | STMR × CF (CXL tentative)                    |
| Rapeseeds/canola seeds            | 1.25               | CXL × CF (tentative)                         |
| Soya beans                        | 25.00              | CXL × CF (tentative)                         |
| Mustard seeds                     | 0.04               | STMR × CF (tentative)                        |
| Cotton seeds                      | 1.25               | CXL × CF (tentative)                         |
| Pumpkin seeds                     | 0.04               | STMR × CF (tentative)                        |
| Safflower seeds                   | 0.04               | STMR × CF (tentative)                        |
| Borage seeds                      | 0.04               | STMR × CF (tentative)                        |
| Gold of pleasure seeds            | 0.04               | STMR × CF (tentative)                        |
| Hemp seeds                        | 0.04               | STMR × CF (tentative)                        |
| Castor beans                      | 0.04               | STMR × CF (tentative)                        |
| Rice grains                       | 1.9                | EU MRL × CF (tentative)                      |
| Sugar beet roots                  | 0.08               | STMR × CF (CXL tentative)                    |
| Chicory roots                     | 0.04               | STMR × CF (tentative)                        |
| Peanuts                           | 3.25               | STMR × CF (CXL tentative)                    |

**Risk assessment residue definition for animal commodities:** sum of clethodim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as clethodim

| Commodity          | Input value (mg/kg) | Residue definition                                                                 |
|--------------------|--------------------|-----------------------------------------------------------------------------------|
| Swine meat         | 0.2*               | 0.8 × STMR muscle + 0.2 × STMR fat (CXL tentative)                                 |
| Swine fat tissue   | 0.2*               | STMR (CXL tentative)                                                              |
| Swine liver        | 0.2*               | STMR (CXL tentative)                                                              |
| Swine kidney       | 0.2*               | STMR (CXL tentative)                                                              |
| Bovine meat        | 0.2*               | 0.8 × STMR muscle + 0.2 × STMR fat (CXL tentative)                                 |
| Bovine fat tissue  | 0.2*               | STMR (tentative)                                                                 |
| Bovine liver       | 0.2*               | STMR (CXL tentative)                                                              |
| Bovine kidney      | 0.2*               | STMR (CXL tentative)                                                              |
| Sheep meat         | 0.2*               | 0.8 × STMR muscle + 0.2 × STMR fat (CXL tentative)                                 |
| Sheep fat tissue   | 0.2*               | STMR (CXL tentative)                                                              |
| Sheep liver        | 0.2*               | STMR (CXL tentative)                                                              |
| Sheep kidney       | 0.2*               | STMR (CXL tentative)                                                              |
| Goat meat          | 0.2*               | 0.8 × STMR muscle + 0.2 × STMR fat (CXL tentative)                                 |
| Goat fat tissue    | 0.2*               | STMR (CXL tentative)                                                              |
| Goat liver         | 0.2*               | STMR (CXL tentative)                                                              |
| Goat kidney        | 0.2*               | STMR (CXL tentative)                                                              |
| Equine meat        | 0.2*               | 0.8 × STMR muscle + 0.2 × STMR fat (CXL tentative)                                 |
| Equine fat tissue  | 0.2*               | STMR (CXL tentative)                                                              |
| Equine liver       | 0.2*               | STMR (CXL tentative)                                                              |
| Equine kidney      | 0.2*               | STMR (CXL tentative)                                                              |
| Poultry meat       | 0.2*               | 0.9 × STMR muscle + 0.1 × STMR fat (CXL tentative)                                 |

www.efsa.europa.eu/efsajournal 79 EFSA Journal 2019;17(5):5706
| Commodity       | Input value (mg/kg) | Comment               |
|-----------------|---------------------|-----------------------|
| Poultry fat tissue | 0.2*               | STMR (CXL tentative)  |
| Poultry liver   | 0.2*               | STMR (CXL tentative)  |
| Cattle milk     | 0.05*              | STMR (CXL tentative)  |
| Sheep milk      | 0.05*              | STMR (CXL tentative)  |
| Goat milk       | 0.05*              | STMR (CXL tentative)  |
| Horse milk      | 0.05*              | STMR (CXL tentative)  |
| Birds eggs      | 0.05               | STMR (CXL tentative)  |

STMR: supervised trials median residue; CF: conversion factor for enforcement to risk assessment residue definition; MRL: maximum residue level; CXL: codex maximum residue limit.

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

1. GAP or DB > 0.1 mg/kg QM in EU?
   - Yes: MRL And RA derived in section 3?
     - Yes: MRL fully supported by data?
       - Yes: Risk identified?
         - Yes: Median/highest values are included in the RA.
         - No: Fall-back MRL available?
           - Yes: MRL is recommended.
           - No: Recommendations resulting from EU authorisations and import tolerances
             (A) Specific LOQ or default MRL?
               (B) Specific LOQ or default MRL?
               (C) Specific LOQ or default MRL?
               (D) Maintain current EU MRL?
               (E) Establish tentative EU MRL?
               (F) Specific LOQ or default MRL?
               (G) Specific LOQ or default MRL?
               (H) MRL is recommended.
     - No: Specific LOQ or default MRL?
   - No: Specific LOQ or default MRL?

Consumer risk assessment for GAPs evaluated at EU level – EU scenarios

Not considered for the RA

Current EU MRL is included in the RA.

Tentative median/highest values are included in the RA.

Fall-back MRL available?

Risk identified?

Median/highest values are included in the RA.

Fall-back MRL available?

Recommendations resulting from EU authorisations and import tolerances

(A) Specific LOQ or default MRL?
(B) Specific LOQ or default MRL?
(C) Specific LOQ or default MRL?
(D) Maintain current EU MRL?
(E) Specific LOQ or default MRL?
(F) Establish tentative EU MRL?
(G) Specific LOQ or default MRL?
(H) MRL is recommended.

Comparison with CXLs
### Appendix F – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-----------------------------------------------|---------------------------------|
| clethodim                       | (5RS)-2-[(1EZ)-1-[(2E)-3-chloroallyloxyimino] propyl]-5-[(2RS)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one CC/C=C=N/O(C=C(C=O))CC1=C(O)CC(CC(C)SC)CCCl=O | ![Clethodim](https://example.com/structure1.png) |
| clethodim sulfoxide             | (5RS)-2-[(1EZ)-N-[(2E)-3-chloro-2-propen-1-yl] oxy]propanimidoyl]-5-[(2RS)-2-(ethylsulfonyl)propyl]-3-hydroxy-2-cyclohexen-1-one CC/C=C=N/O(C=C(C=O))CC1=C(O)CC(CC(C)SC(=O)CC)CC1=O | ![Clethodim Sulfoxide](https://example.com/structure2.png) |
| clethodim glucoside (M26)       | (5RS)-2-[(1EZ)-N-[(2E)-3-chloro-2-propen-1-yl] oxy]propanimidoyl]-5-[(2RS)-2-(ethylsulfonyl)propyl]-3-hydroxy-2-cyclohexen-1-one CC/C=C=N/O(C=C(C=O))CC1=C(O)CC(CC(C)SC(=O)CC)CC1=O | ![Clethodim Glucoside](https://example.com/structure3.png) |
| clethodim sulfone               | (5RS)-2-[(1EZ)-N-[(2E)-3-chloro-2-propen-1-yl] oxy]propanimidoyl]-5-[(2RS)-2-(ethylsulfonyl)propyl]-3-hydroxy-2-cyclohexen-1-one CC/C=C=N/O(C=C(C=O))CC1=C(O)CC(CC(C)SC(=O)CC)CC1=O | ![Clethodim Sulfone](https://example.com/structure4.png) |
| Clethodim-5 hydroxy sulfone     | (5RS)-2-[(1EZ)-N-[(2E)-3-chloro-2-propen-1-yl] oxy]propanimidoyl]-5-[(2RS)-2-(ethylsulfonyl)propyl]-3,5-dihydroxy-2-cyclohexen-1-one OC1(CC(C)SC(=O)(=O)CC)CC1=C(O)CC(C=O)C1C(C(C(=O)Cl)N)C(C)CC1=O | ![Clethodim-5 Hydroxy Sulfone](https://example.com/structure5.png) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-----------------------------|-----------------------------------------------|---------------------------------|
| M14A/M15A                  | (2E)-3-chloro-2-propen-1-yl D-glucopyranoside | ![Structure](attachment:1). |
|                            | OC[C@H]1OC(OC[C=C(Cl)[C@H][O][C@H]1O)] [C@H]1O | ![Structure](attachment:1). |
|                            | SBZOAPJFZBPEC-1OFWEACVSA-N                     | ![Structure](attachment:1). |
| M14R/M15R                  | (2EZ)-3-[(2RS)-2-(ethylsulfonyl)propyl]-2-pentenedioic acid | ![Structure](attachment:1). |
|                            | CCS(=O)C(C)CC(CC(=O)=C/C(=O)O)                | ![Structure](attachment:1). |
|                            | IGPCBPCYKNJX-UCFFFAOYSA-N                     | ![Structure](attachment:1). |
| M16R/M17R                  | 3-[(2RS)-2-(ethylsulfonyl)propyl]pentanedioic acid | ![Structure](attachment:1). |
|                            | CCS(=O)C(C)CC(CC(=O)O)CC(=O)O                  | ![Structure](attachment:1). |
|                            | QGEHELRAWAXGBZ-UHFFFAOYSA-N                   | ![Structure](attachment:1). |
| M18R/M19R                  | 3-[(2RS)-2-(ethylsulfonyl)propyl]pentanedioic acid | ![Structure](attachment:1). |
|                            | CCS(=O)(=O)C(C)CC(CC(=O)=O)CC(=O)O             | ![Structure](attachment:1). |
|                            | LWWJRPFUULSJCD-UHFFFAOYSA-N                   | ![Structure](attachment:1). |
| clethodim imine sulfone    | (5RS)-5-[(2RS)-2-(ethylsulfonyl)propyl]-3-hydroxy-2-propanimidoyl-2-cyclohexen-1-one | ![Structure](attachment:1). |
|                            | CCC(=N)C1=CC(C)=C(=O)O                         | ![Structure](attachment:1). |
|                            | HCZLGHBOKCINFL-UHFFFAOYSA-N                    | ![Structure](attachment:1). |
| clethodim imine sulfoxide  | (5RS)-5-[(2RS)-2-(ethylsulfonyl)propyl]-3-hydroxy-2-propanimidoyl-2-cyclohexen-1-one | ![Structure](attachment:1). |
|                            | CCC(=N)C1=CC(C)=C(=O)O                         | ![Structure](attachment:1). |
|                            | CWWXBEOBWOJDQS-UHFFFAOYSA-N                   | ![Structure](attachment:1). |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-----------------------------|-------------------------------------|--------------------------------|
| M22R                        | (5RS)-5-[(2RS)-2-(ethylsulfanyl)propyl]-3,5-dihydroxy-2-propanimidoyl-2-cyclohexen-1-one | ![M22R Structural Formula](image1) |
|                            | OC1(C(C(S(=O)CC)CC(=O)=C(C(=O)C1)C(=N)CC) | VYZUUEJPHVXBB-J-UHFFFAOYSA-N |
|                            | clethodim oxazole                    | ![Clethodim Oxazole Structural Formula](image2) |
|                            | (6RS)-2-ethyl-6-[(2RS)-2-(ethylthio)propyl]-6,7-dihydro-1,3-benzoazol-4(5H)-one | ![Clethodim Oxazole Structural Formula](image3) |
|                            | CC(SCC)CC1Cc2oc(nc2C(=O)C1)CC          | WHFXMHVIMZTIO-R-UHFFFAOYSA-N |
|                            | clethodim oxazole sulfoxide          | ![Clethodim Oxazole Sulfoxide Structural Formula](image4) |
|                            | (6RS)-2-ethyl-6-[(2RS)-2-(ethylsulfonyl)propyl]-6,7-dihydro-1,3-benzoazol-4(5F)-one | ![Clethodim Oxazole Sulfoxide Structural Formula](image5) |
|                            | CCS(=O)(C(C)CC1Cc2oc(nc2C(=O)C1)CC) | IVZPFBARUICDR-UHFFFAOYSA-N |
|                            | clethodim oxazole sulfone            | ![Clethodim Oxazole Sulfone Structural Formula](image6) |
|                            | (6RS)-2-ethyl-6-[(2RS)-2-(ethylsulfonyl)propyl]-6,7-dihydro-1,3-benzoazol-4(5F)-one | ![Clethodim Oxazole Sulfone Structural Formula](image7) |
|                            | CCS(=O)(C(C)CC1Cc2oc(nc2C(=O)C1)CC) | LUZIJNAGJNDHZ-UHFFFAOYSA-N |
|                            | Clethodim trione                     | ![Clethodim Trione Structural Formula](image8) |
|                            | (5RS)-5-[(2RS)-2-(ethylthio)propyl]-3-hydroxy-2-propionyl-2-cyclohexen-1-one | ![Clethodim Trione Structural Formula](image9) |
|                            | CCC(=O)C1=CC(=O)CC(CC(SCC)CC1=O | CQCIJXERGZLE0-UHFFFAOYSA-N |

SMILES: simplified molecular-input line-entry system; IUPAC: International Union of Pure and Applied Chemistry; InChiKey: International Chemical Identifier Key.

(a): The metabolite name in bold is the name used in the conclusion.

(b): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).

(c): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).