Review of the existing maximum residue levels for fluopicolide 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 fluopicolide. To assess the occurrence of fluopicolide 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 as well as the import tolerances and European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Some information required by the regulatory framework was missing and a possible acute risk to consumers was identified. Hence, the consumer risk assessment is considered indicative only, some MRL proposals derived by EFSA still require further consideration by risk managers and measures for reduction of the consumer exposure should also be considered.

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Keywords: fluopicolide, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, fungicide

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Summary

Fluopicolide was included in Annex I to Directive 91/414/EEC on 1 June 2010 by Commission Directive 2010/15/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 Regulations (EU) No 541/2011 and 2017/1527.

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.

As the basis for the MRL review, on 15 September 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 13 October 2017 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS) United Kingdom to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 5 February 2018. On the basis of all the data submitted by Member States and by the European Union Reference Laboratories for Pesticide Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file were provided by the RMS to EFSA on 20 April 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURL, and taking into account the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in February 2019 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 7 March 2019 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of fluopicolide in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement should be set as fluopicolide only. As regards risk assessment, two residue definitions are set: fluopicolide and metabolite 2,6-dichlorobenzamide, separately. These residue definitions are also applicable to processed commodities. Fully validated analytical methods for enforcement of fluopicolide in the four main plant matrices are available and fully applicable in routine according to the EURLs.

For fluopicolide (which is the only residue definition for monitoring purpose), the available data were considered sufficient to derive MRL proposals as well as risk assessment values in all commodities under evaluation. For blackberries, tomatoes, broccoli, cauliflower, lamb’s lettuces/corn salads, cresses and other sprouts and shoots, land cresses, red mustards, baby leaf crops (including brassica species) and escaroles/broad-leaved endives, the MRLs were derived on tentative basis due to major data gaps identified for these crops. With regard to 2,6-dichlorobenzamide (which is relevant for risk assessment purpose only), risk assessment values (at least tentative) could also be derived for all commodities.

It was noted that significant residue levels of fluopicolide and 2,6-dichlorobenzamide may be expected in rotational crops. Based on the available data no risk mitigation measure could be proposed by EFSA to avoid residue uptake in rotational crops. For fluopicolide, MRL proposals and risk assessment values were derived to accommodate residues from rotational crops in cereal straw (in view of the future need to set MRLs in feed items) and in valerian root. For 2,6-dichlorobenzamide, tentative risk assessment values could be derived to consider residues arising from rotational crops in cereal straw, leafy vegetables and valerian root.

Fluopicolide is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for the two residue definitions relevant for risk assessment (fluopicolide and 2,6-dichlorobenzamide, separately), for different groups of livestock according to OECD guidance. For fluopicolide, the dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Regarding 2,6-dichlorobenzamide, the calculated dietary burdens were found to exceed the trigger value of 0.1 mg/kg DM for all groups of livestock except poultry. Behaviour of residues was therefore assessed in all commodities of animal origin.
The metabolism of fluopicolide residues in livestock was investigated in lactating cows and laying hens at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement should be set as fluopicolide only. As regards risk assessment, two residue definitions are set: fluopicolide and metabolite 2,6-dichlorobenzamide, separately. Validated analytical methods for enforcement of fluopicolide in milk, muscle, fat, liver and kidney are available and EURLs confirmed the applicability in routine for milk and meat. However, an independent laboratory validation (ILV) was found to be missing and an analytical method for enforcement in eggs were found to be missing (data gaps).

Livestock feeding study on dairy cows and metabolism study on laying hens were used to derive MRL and risk assessment values in milk, eggs, and tissues of ruminants and 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.

EFSA performed separate consumer risk assessments for fluopicolide (RD-RA1) and for 2,6-dichlorobenzamide (RD-RA2). Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo.

As regards fluopicolide, the highest chronic exposure considering all authorised used reported in this review represented 2.4% of the acceptable daily intake (ADI; WHO Cluster diet B) and the highest acute exposure amounted to 58.3% of the acute reference dose (ARfD; scarole, broad-leaf endive). Apart from the MRLs evaluated in the framework of this review, internationally recommended codex maximum residue limits (CXLs) have also been established for fluopicolide. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and exceedances of the ARfD were identified for the existing CXLs in scarole (broad-leaf endive) (825.7%), kale (638.5%), celery (357.1%), Chinese cabbage (350.7%), lettuce (254.1%), spinach (213.5%), beet leaves (chard) (165.8%), purslane (142.7%) and head cabbage (114.0%). Excluding these CXLs from the calculation, the highest chronic exposure represented 3.3% of the ADI (WHO Cluster diet B) and the highest acute exposure amounted to 58.3% of the ARfD (scarole, broad-leaf endive).

As regards 2,6-dichlorobenzamide, a comprehensive risk assessment was performed taking into account residues for this metabolite assessed in this review (primary crops and rotational crops) as well as residues of 2,6-dichlorobenzamide which are associated to the CXLs of fluopicolide (assessed by JMPR). The highest chronic exposure was calculated for the French toddler, representing 1.3% of the ADI, and the highest acute exposure was calculated for scarole (broad-leaf endive), representing 2.0% of the ARfD.
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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.

Flupiculide was included in Annex I to Council Directive 91/414/EEC on 1 June 2010 by means of Commission Directive 2010/15/EU\(^3\) which 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 Regulations (EU) No 541/2011\(^6\) and 2017/1527.\(^7\) Therefore, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Directive 91/414/EEC, Flupiculide was evaluated by United Kingdom, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA conclusion (EFSA, 2009b). The approval of Flupiculide is restricted to uses as fungicide.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, 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 Regulation (EC) No 1107/2009 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.

As the basis for the MRL review, on 15 September 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 13 October 2017 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 18 Member States provided feedback on their national authorisations of Flupiculide. Based on the GAP data submitted, the designated RMS United Kingdom was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the critical GAPs by 5 February 2018.

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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 2010/15/EU of 8 March 2010 amending Council Directive 91/414/EEC to include flupiculide as active substance. OJ L 58, 9.3.2010, p. 5-7.
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) 2017/1527 of 6 September 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances cyflufenamid, flupiculide, heptamaloxyloglucan and malathion. OJ L 231, 7.9.2017, p. 3-5.
On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked United Kingdom to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were submitted to EFSA on 20 April 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limits (CXLs)), EFSA prepared in February 2019 a draft reasoned opinion, which was circulated to Member States for commenting via a written procedure. All comments received by 7 March 2019 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (United Kingdom, 2018) taking into account also the information provided by Member States during the collection of data, the additional evaluation reports submitted by Belgium (2018), the Czech Republic (2017, 2018), Germany (2018), Hungary (2018), Italy (2018) and the EURL report on analytical methods (EURL, 2018) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2019a) and the Member States consultation report (EFSA, 2019b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA PRIMo and the PROFiles as well as the GAP overview file listing all authorised uses and import tolerances are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is 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

Fluopicolide is the ISO common name for 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl] benzamide (IUPAC).

The chemical structure of the active substance and its main metabolites are reported in Appendix F. The EU MRLs for fluopicolide are established in Annex IIIA of Regulation (EC) No 396/2005. CXLs for fluopicolide were also established by the CAC. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).
Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

| Procedure | Legal implementation | Remarks |
|-----------|----------------------|---------|
| MRL applications | Commission Regulation (EU) 2018/832 | Modification of the existing maximum residue level for flupicolid in chards (EFSA, 2018) |
| | Commission Regulation (EU) 2016/1003 | Modification of the existing maximum residue level for flupicolid in blackberries, spinaches and purslanes (EFSA, 2015b) |
| | Commission Regulation (EU) 2016/486 | Modification of the existing maximum residue level for flupicolid in valerian (EFSA, 2015a) |
| | Commission Regulation (EU) 2015/1101 | Modification of the existing MRLs for flupicolid in radishes, onions, kale and potatoes (EFSA, 2012a) |
| | Commission Regulation (EU) 2015/846 | Modification of the existing MRL for flupicolid in Chinese cabbage (EFSA, 2014) |
| | Commission Regulation (EU) No 737/2014 | Modification of the existing MRLs for flupicolid in hops and certain root and tuber vegetables (EFSA, 2013b) |
| | Commission Regulation (EU) No 251/2013 | Modification of the existing MRLs for flupicolid in various vegetable crops (carrots, radishes and sugar beet) (EFSA, 2012b) |
| | Commission Regulation (EU) No 812/2011 | Modification of the current MRLs for flupicolid in various commodities (onions, tomatoes, cucurbits (edible peel), flowering brassica, head brassica, kohlrabi, lettuce and leek) (EFSA, 2011) |
| | Commission Regulation (EC) No 1050/2009 | Reasoned opinion of EFSA on the setting of an import tolerance for flupicolid on peppers (EFSA, 2009a) |
| Implementation of CAC 2010 | Commission Regulation (EU) No 520/2011 | Scientific report of EFSA. Scientific and technical support for preparing a EU position in the 42nd Session of the Codex Committee on Pesticide Residues (CCPR) (EFSA, 2010) |

MRL: maximum residue level.
(a): Commission Regulation (EU) 2018/832 of 5 June 2018 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, flupicolid, folpet, fosetyl, maneb, manebestrob, mecaptan, metazachlor, propamocarb, propargite, pyrimethanil, sulfurfluor and trifloxystrobin in or on certain products. OJ L 140, 6.6.2018, p. 38–86.
(b): Commission Regulation (EU) 2016/1003 of 17 June 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, ametoctradin, amisulbrom, bupirimate, clofentezine, ethephon, ethirimol, fenoxycarb, metalaxyl-M, pendimethalin and tebufenozide in or on certain products. OJ L 167, 24.6.2016, p. 46–103.
(c): Commission Regulation (EU) 2016/486 of 29 March 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyazofamid, cyproconazole, difenoconazole, fenamidone, flubendiamide, flupicolid, folpet, fosetyl, maneb, manebestrob, mecaptan, metazachlor, propamocarb, propargite, pyrimethanil, sulfurfluor and trifloxystrobin in or on certain products. OJ L 176, 6.7.2012, p. 1–37.
(d): Commission Regulation (EU) 2015/1101 of 8 July 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyazofamid, cyproconazole, difenoconazole, fenamidone, flubendiamide, flupicolid, folpet, fosetyl, maneb, manebestrob, mecaptan, metazachlor, propamocarb, propargite, pyrimethanil, sulfurfluor and trifloxystrobin in or on certain products. OJ L 90, 6.4.2016, p. 1–66.
(e): Commission Regulation (EU) No 592/2012 of 4 July 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, captan, cyprodinil, flupicolid, hexythiazox, isoprotiolane, metaldehyde, oxadixyl and phosphet in or on certain products. OJ L 176, 6.7.2012, p. 1–37.
(f): Commission Regulation (EU) 2015/846 of 28 May 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, amitraz, amisolbrom, bupirimate, clodentazine, ethophon, ethirimol, flupicolid, imazapic, propamocarb, pyraclostrobin and tau-fluvalinate in or on certain products. OJ L 90, 6.4.2016, p. 1–66.
(g): Commission Regulation (EU) No 737/2014 of 24 June 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, chloromequat, cyfluafenamid, cyfluthrin, dicamba, flupicolid, flutriafol, fosetyl, indoxacarb, isoprotiolane, mandipropamid, metaldehyde, metconazole, phosmet, picloram, propamid, pyriproxyfen, saflufenacil, spinosad and trifloxystrobin in or on certain products. OJ L 202, 10.7.2014, p. 1–63.
(h): Commission Regulation (EU) No 251/2013 of 22 March 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, bifenthrate, captan, fluazinam, flupicolid, folpet, kresoxim-methyl, penthiopyrad, proquinazid, pyridate and tembotrione in or on certain products. OJ L 88, 27.3.2013, p. 1–49.
(i): Commission Regulation (EU) No 812/2011 of 10 August 2011 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, flupicolid, mandipropamid, metrafenone, nicotine and spirotetramat in or on certain products. OJ L 208, 13.8.2011, p. 1–22.
For the purpose of this MRL review, all the uses of fluopicolide currently authorised within the EU and in third countries as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in two PROFiles (one for each residue definition for risk assessment) and considered in the assessment. The details of the authorised critical GAPs for fluopicolide are given in Appendix A.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (United Kingdom, 2018);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2006, 2008);
- the conclusion on the peer review of the pesticide risk assessment of the active substance fluopicolide (EFSA, 2009b);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2009b, 2014);
- the previous reasoned opinions on fluopicolide (EFSA, 2009a, 2011, 2012a,b, 2013a,b, 2014, 2015a,b, 2018);
- Additional evaluation reports provided by Belgium (2018), the Czech Republic (2017, 2018), Germany (2018), Hungary (2018), Italy (2018) and Lithuania (2018).

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–g, 2000, 2010a,b, 2017, and 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 fluopicolide was investigated after foliar treatment in fruits crops, root crops and leafy crops and for soil treatment (drenching) in leafy crops (United Kingdom, 2006) and assessed in the framework of the peer review (EFSA, 2009b). In addition, a metabolism investigating seed treatment in oilseed crops was recently assessed in the framework of zonal assessment (Czech Republic, 2017). In all studies, fluopicolide was radiolabelled in the phenyl and pyridinil rings of the molecule except for the soil drench application on lettuce (only phenyl labelled). Following foliar or soil applications, plant metabolism was found to be limited with fluopicolide being the major component of the total radioactive residues (TRR) at harvest (lettuce/foliar: 96% of TRR; lettuce/soil: 72% of TRR; grapes: 91.2% of TRR; potato tubers: 70% of TRR). The metabolite 2,6-dichlorobenzamide, also referred to metabolite M-01 or BAM (see Appendix F), was identified in significant amounts in potato tubers (up to 25.4% TRR) and in lettuce grown after soil drench application (up to 19.8% TRR). Two other compounds were identified in potato tubers: metabolite M-05 and M-09.

(j): Commission Regulation (EC) No 1050/2009 of 28 October 2009 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, acetamiprid, clofazamine, cyflufenamid, emamectin benzoate, famoxadone, fenbutanil oxide, flufenoxuron, fluopicolide, indoxacarb, ipoxynyl, mepanipyrim, prothioconazole, pyridalyl, thiacloprid and trifloxystrobin in or on certain products. OJ L 290, 6.11.2009, p. 7–55.

(k): Commission Regulation (EU) No 520/2011 of 25 May 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benalaxyl, boscalid, buprofezin, carbofuran, carbosulfan, cypermethrin, fluopicolide, hexitiazox, indoxacarb, metaflumizone, methoxyfenozide, paraxat, prochloraz, spirodiclofen, prothioconazole and zoxamide in or on certain products. OJ L 140, 27.5.2011, p. 2–47.
M-02 (up to 12% TRR) and M-06 (up to 2.4% TRR). The results suggested that the most important part of the degradation occurs in soil with subsequent uptakes of metabolites from soil.

The metabolism of fluopicolide was investigated in oilseed rape following seed treatment, at an application rate 10 times higher than the one currently authorised on oilseed crops. In general, fairly low levels of radioactivity were detected in crop samples, from 0.06 mg eq./kg (seeds) to 0.011 mg eq./kg (forage). In all crop samples, the major residue was the parent compound: 83–88% of the TRR in forage and 40–77.5% of the TRR in seeds. The only metabolite identified as significant level was 2,6-dichlorobenzamide (M-01), representing 11.5% of the TRR (0.012 mg/kg) in forage and up to 37.3% of TRR (0.021 mg/kg) in seeds. All other metabolites were detected in much lower amounts (≤ 4.1% of TRR and ≤ 0.002 mg/kg) (Czech Republic, 2017).

The metabolic pathway of fluopicolide was found to be similar in the four crop groups, involving hydrolysis of the amide bond to form metabolites 2,6-dichlorobenzamide (M-01) and M-02 and hydroxylation of the phenyl ring to form metabolite M-06.

1.1.2. Nature of residues in rotational crops

Fluopicolide is authorised on crops that may be grown in rotation. The field DT₉₀ reported in the soil degradation studies evaluated in the framework of the peer review was 1,184 days for fluopicolide (EFSA, 2009b). Furthermore, the metabolite 2,6-dichlorobenzamide is also persistent in soil, with a maximum field DT₉₀ of 1,046 days. Therefore, the assessment of residues in rotational crops is triggered.

It is noted that considering the critical GAPs reported in this review, the maximal net annual application rate (assumed to reach the soil) is expected to be 270 g/ha.⁹ Considering the DT₉₀ reported above and assuming a soil mixing depth of 20 cm and soil bulk density 1.5 g/cm³, the total soil concentration of fluopicolide (predicted environmental concentration (PEC) soil total) resulting from the multiannual use of fluopicolide at the critical GAP (PEC plateau background) plus from the maximal seasonal application rate is calculated as 0.15 mg/kg (immediately after application), 0.11 mg/kg (after 28 days) and 0.10 mg/kg (after 100 days). Similarly, the total soil concentration of metabolite 2,6-dichlorobenzamide (M01) is calculated as 0.08 mg/kg (immediately after application), 0.08 mg/kg (after 28 days) and 0.072 mg/kg (after 100 days).

One confined rotational crop study performed with fluopicolide radiolabelled on the phenyl and pyridinyl rings is available (United Kingdom, 2006) and was previously assessed in the framework of the peer review (EFSA, 2009b). Fluopicolide was applied at a rate of 400 g a.s./ha onto bare soil. Crops were planted at nominal plant-back intervals (PBI) of 29, 133 and 365 days after treatment (DAT). Crops planted at each interval consisted of root crops (radish), leafy crops (lettuce) and cereals (wheat). Total residue levels measured in soil samples at planting for a PBI 29 days are in the same range (0.07–0.14 mg eq./kg) as the PEC soil total calculated for parent at PBI of 28 days (0.11 mg/kg). However, as detailed soil analysis of parent compound and its metabolites were not reported in this study, it is not possible to assert whether the PEC soil total is covered for each compound. Nevertheless, the present study is deemed applicable to depict the metabolism of fluopicolide in rotational crops.

Translocation of residues was observed in all crops at all PBIs. Highest TRR were observed at PBI 29 days, in wheat straw (up to 13.6 mg eq./kg), radish tops (up to 6.71 mg eq./kg), wheat grain (up to 2.6 mg eq./kg) and lettuce (up to 1.01 mg eq./kg). Although total radioactivity tends to decline over time, significant levels were also found at the PBI of 365 days (up to 2 mg/kg in radish tops, 1.0 mg eq./kg in wheat straw and 0.62 mg eq./kg in lettuce).

Overall, the metabolism was found to be similar but much more extensive than in primary crops. In lettuce, radish tops and roots, fluopicolide, metabolites 2,6-dichlorobenzamide (M-01) and M-02 were identified as the major components of the total radioactive residues. At a PBI of 29 days, parent compound, metabolite 2,6-dichlorobenzamide (M-01) and M-02 are all individually significantly present (i.e. > 10% TRR and or > 0.05 mg/kg) in all crops samples, with the sole exception of wheat grain where M-01 was not found. It is noted that even after 1 year, significant residues of fluopicolide, metabolites M-01 and M-02 were observed in different samples. At PBI of 365 days, fluopicolide was quantified up to 0.28 mg/kg (27.5% TRR) in wheat straw, M-01 up to 0.53–1.76 mg eq./kg in lettuce and radish tops (87% TRR) and M-02 up to 0.11 mg eq./kg in radish tops (27.1% TRR).

⁹ Based on the critical GAP authorised on onions: 3 × 100 g a.s./ha at BBCH 10–49 (only 10% crop interception). It is noted that the critical GAP authorised on potatoes 5 × 100 g a.s./ha per year (from BBCH 20 to 95; PHI 7 days) is restricted to 400 g a.s./ha every 36 months (see northern outdoor GAP); this GAP is not considered as the critical GAP as regards rotational crops because foliar interception (90% at BBCH 95) is higher than for onions.
Other metabolites were also identified in particular crop matrices, such as metabolite M-04 (wheat straw and forage) and metabolite M-05 (wheat and lettuce). Low concentrations of metabolite M-08 and metabolite M-09 were also found in wheat straw.

As observed in primary crops, the metabolic pathway of fluopicolide in rotational crops involves hydrolysis of the amide bond to mainly form metabolites 2,6-dichlorobenzamide (M-01) and M-02. Further degradation compounds were also observed in certain plant compartments. However, during the peer review, it was concluded that all these compounds presented a lower toxicity compared to the parent compound (EFSA, 2009b). It is concluded that the metabolism of fluopicolide in rotational crops does not present any specificity compared to the metabolic pathway observed in primary crops.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed (United Kingdom, 2006). Studies were conducted with radiolabelled fluopicolide on the pyridinyl 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). Fluopicolide was stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2009b).

It is noted that the effect of processing under hydrolytic conditions on the potential degradation of the metabolite 2,6-dichlorobenzamide (M01) was not investigated while it is a significant degradation product in primary crops (see Section 1.1.1). EFSA considers this, however, only a minor deficiency having regard to the low residue levels of 2,6-dichlorobenzamide recovered in primary crops under consideration and to the very low consumer exposure calculated for this compound (1.3% acceptable daily intake (ADI), 2% acute reference dose (ARfD); see also Section 3.2).

1.1.4. Methods of analysis in plants

During the peer review, a modified version of the multi-residues analytical method DFG-S19 based on gas chromatography (GC) coupled to mass spectrometry (MS) detection was validated for the determination of fluopicolide in commodities with high water content (limit of quantification (LOQ) of 0.02 mg/kg), high acid content (LOQ of 0.1 mg/kg) and dry content (LOQ of 0.02 mg/kg). This primary method is fully validated and is supported by an independent laboratory validation (ILV) (EFSA, 2009b).

For high water and high acid content commodities, an additional analytical method for the determination of fluopicolide, based on high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS), was also reported and validated in the framework of a previous MRL application (Germany, 2010 assessed in EFSA, 2011). The method is sufficiently validated with a LOQ of 0.01 mg/kg for matrices with high water (cabbage) and high acid content (grapes) and a ILV was provided.

For high oil content commodities, the multi-residue Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method (HPLC-MS/MS method) described in the European Standard EN 15662:2008 was found to be applicable for the determination of fluopicolide with a LOQ of 0.01 mg/kg (EFSA, 2015b).

For hops, a matrix which is considered difficult to analyse, an liquid chromatography with tandem mass spectrometry (LC-MS/MS) analytical method for fluopicolide was presented in the framework of a previous MRL application (EFSA, 2013b). The hop cones were extracted with acetone/water, quantification is performed by LC-MS/MS on a RP18 column and monitoring the MS/MS transition m/z 383→173. The validated LOQ was 0.05 mg/kg. However, a confirmatory method and an ILV are still missing and are therefore required (data gap).

During the completeness check, the EURLs informed EFSA that fluopicolide could be enforced in routine analysis in the four main plant matrices. QuEChERS multi-residue analytical methods are applicable for high water and high acid content commodities (LOQ of 0.002 mg/kg) and dry commodities (LOQ of 0.01 mg/kg). A QuOil method is also available for high oil content commodities with a LOQ 0.01 mg/kg (EURLs, 2018).

1.1.5. Stability of residues in plants

The storage stability of parent and its metabolite 2,6-dichlobenzamide (M-01) was investigated in the framework of the peer review (United Kingdom, 2006; EFSA, 2009b) and in new studies reported under this review (Czech Republic, 2017). The storage stability of each compound was separately investigated in matrices with high water content (cabbage), high acid content (grapes), high starch content (wheat grain and potatoes), high oil content (sunflower seed) and specific matrices (wheat straw).
The storage stability was demonstrated for both compounds separately in all matrices: up to 30 months in high water content, high acid content and high starch content commodities, up to 24 months in high oil content commodities and up to 18 months in wheat straw.

1.1.6. Proposed residue definitions

The metabolic pathway of flupicuolide was found to be similar in the four crop groups investigated. The metabolism in rotational crops is similar to the metabolism observed in primary crops and the processing of flupicuolide is not expected to modify the nature of residues. The available studies indicate that parent compound and its metabolite 2,6-dichlorobenzamide (M01) are the most important components of the residue. The parent compound is a relevant marker in all primary crops as well as in rotational crops and therefore the residue definition for enforcement is proposed as parent compound flupicuolide for all plant commodities. Fully validated analytical methods for enforcement of flupicuolide in the four main plant matrices are available and are fully applicable in routine according to the EURLs. The metabolite 2,6-dichlorobenzamide (M01) is not specific to flupicuolide as it is also the main degradation product of another active substances (dichlobenil and chlorthiamide) which are not authorised in the EU. Therefore, this compound was not proposed in the residue definition for enforcement.

As regards dietary risk assessment purposes, the parent flupicuolide and its metabolite 2,6-dichlorobenzamide (also referred to as BAM or M-01) are the only compounds of toxicological relevance. The other metabolites found in lower amount in primary crops and/or in rotational crops were all regarded as less toxic than the parent compound (EFSA, 2009b). It is noted that specific ADI and ARfD were set for 2,6-dichlorobenzamide and that flupicuolide and metabolite 2,6-dichlorobenzamide have different toxicological end points (EFSA, 2009b). Therefore, two separate residue definitions are set for risk assessment purpose: flupicuolide (RD-RA1) and metabolite 2,6-dichlorobenzamide (RD-RA2).

The proposed residue definitions are applicable to all commodities that are under assessment in the present review.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of flupicuolide residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (United Kingdom, 2018) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2009b) or in the framework of a previous MRL application (EFSA, 2009a, 2011, 2012a,b, 2013b, 2014, 2015b, 2018). In addition, residues trials separately reported by Belgium (2018), the Czech Republic (2017, 2018), Germany (2018), Hungary (2018), Italy (2018) and Lithuania (2018) were also considered. All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated (except for 4 of the northern trials performed on tomatoes for which additional information is required; see details below). Decline of residues during storage of the trial samples is therefore not expected.

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, 2017).

For all commodities except blackberries, the available trials provide residue data for flupicuolide and for metabolite 2,6-dichlorobenzamide (M-01). Since these two compounds should be assessed separately, the residue levels related to the corresponding residue definitions (RD-Mo and RA-RA1: flupicuolide and RD-RA2: 2,6-dichlorobenzamide) were reported in two separate tables (see Appendices B.1.2.1 and B.1.2.2, respectively). The available residue trials are sufficient to derive MRL and risk assessment values (at least tentative) for flupicuolide in all crops under evaluation. Furthermore, risk assessment values (at least tentative) could also be derived for 2,6-dichlorobenzamide in all commodities. The following considerations are made by EFSA:

- **Blackberries:** The available residue trials (four northern European Union (NEU) and four indoor) are sufficient to derive MRL and risk assessment values for flupicuolide. However, only
five of these trials provide analysis for metabolite 2,6-dichlorobenzamide (two NEU and three indoor). Therefore, only tentative risk assessment value for 2,6-dichlorobenzamide can be derived from the indoor GAP. Two additional trials compliant with the northern outdoor GAP and one additional trial compliant with the indoor GAP analysing for 2,6-dichlorobenzamide are desirable (minor deficiency).

- **Carrots, beetroots, celeriacs/turnip rooted celeries, Horseradishes, Jerusalem artichokes, Parsnips, Parsley roots/Hamburg roots parsley, Salsifies, Swedes/rutabagas, Turnips and radishes (import tolerance):** It is noted that a MRL for the whole group of root and tuber vegetables was previously derived based on a combined data set of trials performed on carrots, sugar beet and radishes (EFSA, 2013b). However, according to the most updated EU guidance document on extrapolations (European Commission, 2017), a MRL for the whole group of root and tuber vegetables should only be extrapolated from trials performed on carrots. Therefore, the MRL for carrots, beetroots, celeriac/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, salsifies, swedes/rutabagas and turnips is now directly derived from the trials performed on carrots. Since only seven trials are available, one additional trial on carrots would be desirable to comply with the new guidance (minor deficiency). The MRL for radish is simply derived from the 6 trials performed on radish and compliant with the GAP for import tolerance.

- **Tomatoes:** Eight trials analysed for the parent and metabolite M-01 compliant with the northern GAP are available. However, for four of these trials, reported by the Czech Republic (2018), the validity of the analytical method used and the storage conditions of the samples between harvest and analysis were not clearly reported. These trials are therefore considered indicative and only tentative MRL and risk assessment values can be derived from the available data set. The Member State Czech Republic is invited to provide the missing information on the validity of the analytical method used in the trials and the storage conditions of the samples between harvest and analysis (data gap).

- **Cucumbers and courgettes:** MRL and risk assessment values can be derived from the indoor GAP fully supported by data. For the outdoor GAPs, however, four additional northern trials (either cucumber or courgettes) and four additional southern trials (either cucumber or courgettes), all analysed for the parent and metabolite M-01, are still required (data gaps).

- **Cauliflower:** Tentative MRL and risk assessment values can be derived from the indoor GAP supported by a limited data set (only four trials on cauliflower). However, four additional trials analysed for the parent and metabolite M-01 compliant with indoor GAP on cauliflower are required (data gap).

- **Broccoli:** Tentative MRL and risk assessment values can be derived from the indoor trials performed on cauliflower according to a more critical GAP (three applications instead of one). However, four trials analysed for parent and metabolite M-01 performed on broccoli and compliant with indoor GAP on broccoli are required (data gap).

- **Brussels sprouts:** Although MRL and risk assessment values can be derived from the northern GAP fully supported by data, four trials compliant with the southern GAP and four trials compliant with the indoor GAP, all analysed for parent and metabolite M-01, are still required (data gaps).

- **Head cabbage:** Although MRL and risk assessment values can be derived from the northern GAP fully supported by data, eight trials analysed for parent and metabolite M-01 compliant with the indoor GAP are still required (data gaps).

- **Kale:** Although MRL and risk assessment values can be derived from the northern GAP fully supported by data, four trials analysed for parent and metabolite M-01 compliant with the indoor GAP are still required (data gaps).

- **Kohlrabi:** Although MRL and risk assessment values can be derived from the northern GAP fully supported by data, four trials analysed for parent and metabolite M-01 compliant with the southern GAP are still required (data gaps).

- **Lamb’s lettuces/corn salads, Cresses and other sprouts and shoots, Land cresses, Red mustards, Baby leaf crops (including brassica species):** Tentative MRL and risk assessment values can be derived from eight indoor trials performed on lettuces according to a more critical GAP (three applications instead of two); however, four trials analysed for parent and metabolite M-01 compliant with the indoor GAP are still required (data gap). The same issue is identified for the northern and southern outdoor GAPs. Therefore, four trials compliant with northern GAP and four trials compliant with the southern GAP, all analysed for parent and
metabolite M-01, are also required. It is noted that if the trials are performed on lettuce, open leaf varieties of lettuce should be used. The GAP-compliant southern trials would also support the southern GAPs on Escaroles/broad-leaved endives and on Roman rocket/rucula (see below).

- **Escaroles/broad-leaved endives**: Tentative MRL and risk assessment values can be derived from the southern trials performed on lettuces according to a more critical GAP (three applications instead of two). However, four trials analysed for parent and metabolite M-01 compliant with southern GAP on this crop are required (data gap). It is noted that this data gap is the same as the data gap identified for the southern GAP on lamb’s lettuces (see just above).

- **Lettuces, Roman rocket/rucula, purslane, chards/beet leaves and fresh herbs**: MRL and risk assessment values can be derived from the indoor GAPs fully supported by data. It is noted that for lettuce, Roman rocket and fresh herbs, the northern GAP is not fully supported by data as only two trials performed on open leaf varieties of lettuces are available and that the southern GAPs for Roman rocket, Purslane and chards are supported by trials performed according to a more critical GAP (three applications instead of two). However, as the available data on open leaf varieties show that the outdoor GAPs for all these crops are likely to result in a lower MRL compared to the one derived from the indoor GAPs, no further trials are required.

- **Rapeseeds and mustard seeds**: The number of residue trials supporting the northern GAPs is not compliant with the data requirements for these crops (six trials instead of eight). However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.

It is noted that all required trials in the above bullet points should provide analysis for flupicoline and for the metabolite 2,6-dichlorobenzamide in accordance with the two residue definitions derived under this review (see Section 1.1.6).

### 1.2.2. Magnitude of residues in rotational crops

Two field rotational crop studies were reported and evaluated during the peer review (United Kingdom, 2006; EFSA, 2009b). In these studies, flupicoline was applied on potatoes at a total rate of 400 g a.s./ha. In most of the trials available, these experimental conditions allowed to reach the PEC soil total for flupicoline (0.15 mg/kg soil just after application; see Section 1.1.2). Concerning the metabolite 2,6-dichlorobenzamide, however, the soil concentration remained below 0.01 mg/kg in all trials while the PEC soil total was estimated at 0.08 mg/kg for this compound (see Section 1.1.2).

After harvest of potatoes, different types of rotational crops were planted: cereals (winter and spring wheat), pulses (faba beans) and leafy crops (cabbage). The PBI were of 28–39 days (winter wheat), 174–227 days (spring wheat), 57–227 days (beans) and 33–49 days (cabbage).

Samples were analysed for flupicoline and 2,6-dichlorobenzamide in accordance with the proposed residue definitions. The results of the available residue trials are summarised in Appendix B.1.2.3-b. Wheat straw is the only commodity where flupicoline was found in quantifiable concentrations (up to 0.12 mg/kg). In all other crop samples (food and feed) harvested at maturity, flupicoline was below the LOQ (0.01 mg/kg). The metabolite 2,6-dichlorobenzamide was found in quantifiable concentrations in cabbage (max. 0.04 mg/kg) and wheat straw (max. 0.03 mg/kg). Nevertheless, it has to be noted that the results obtained for 2,6-dichlorobenzamide might be underestimated considering that the soil concentration reached in the study was too low to reflect the PEC soil total for this compound. Results for 2,6-dichlorobenzamide are therefore considered indicative only and further investigations may need to be provided in the future (minor deficiency).

Additional analyses were also performed for metabolites M-02, M-04 and M-05. These compounds were not included in the residue definition because of their toxicological properties (see Section 1.1.6). It is noted that low levels (between 0.01 and 0.10 mg/kg) were found in some samples of wheat grain and straw for these compounds.

From this study, it is concluded that significant amounts of flupicoline are only expected to occur in wheat straw at any PBIs. As cereal straws are not intended for human consumption, there is no need to derive MRL for this commodity. Nevertheless, risk assessment values could be derived from the available data, which can be considered to assess the livestock dietary burden. As for other feed items, a tentative MRL can also be calculated for flupicoline in cereal straw (see Appendix B.1.2.3-b). Significant amounts of 2,6-dichlorobenzamide can be expected in cereal straw and in leafy crops, at any PBIs. Tentative risk assessment values for this compound could be derived from the available data.
(see Appendix B.1.2.3-b), which can be considered to assess the livestock dietary burden (via cereal straw and leafy feed items) and the human dietary exposure (via leafy food commodities).

No residue uptakes of fluopicolide are expected in pulses. The same is expected for metabolite 2,6-dichlorobenzamide but due to the general uncertainty as regards the results for this compound, this remains only a tentative conclusion. It is noted that the above studies did not investigate the potential residues uptakes in root crops while the metabolism studies indicate that such translocations may occur. In the framework of a previous MRL application, studies were conducted with fresh valerian roots (EFSA, 2015a). However, as valerian is a very minor crop, these studies cannot be extrapolated to other root crop commodities. Further rotational crop field trials performed with major root crop representatives may need to be generated in the future to address this point.

A summary of the assessment performed by EFSA (2015a) for valerian root is reported here. In the studies submitted in this previous MRL application, a primary crop (potato) was treated with fluopicolide at a total seasonal application rate of 324–400 g a.s./ha. Valerian was planted as a rotational crop 1 or 2 years after the application on potatoes. A total of 11 trials was available. Valerian root samples harvested at maturity were only analysed for fluopicolide. Information was not provided on the residue levels of the 2,6-dichlorobenzamide metabolite. However, the expected residues for this compound were estimated considering that fluopicolide and 2,6-dichlorobenzamide were observed at similar levels in the confined rotational crops studies and considering the respective molecular weights of fluopicolide and 2,6-dichlorobenzamide (see details in EFSA, 2015a). Results for 2,6-dichlorobenzamide are therefore considered indicative. The results of the available residue trials are summarised in Appendix B.1.2.3-b, noting that residue levels were determined in fresh roots. The residue levels in dried roots were calculated by applying an estimated concentration factor of 8 (see EFSA, 2015a). For fluopicolide, the highest value observed in fresh valerian root was 0.62 mg/kg; the estimated concentration in dried valerian roots is therefore 4.96 mg/kg. These results allowed EFSA to derive a MRL for valerian root (covered by the category ‘herbal infusion from roots’).

### 1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on table and wine grapes (United Kingdom, 2006), tomatoes (EFSA, 2011) and melons (Italy, 2018). Since analyses of fluopicolide and its metabolite 2,6-dichlorobenzamide were performed in all studies, processing factors could be derived for fluopicolide, which is the residue definition valid for enforcement (RD-Mo) and risk assessment (RD-RA1), and for 2,6-dichlorobenzamide, which is valid for risk assessment only (RD-RA2).

An overview of all available processing studies is provided in Appendix B.1.2.4. Robust processing factors (fully supported by data) for fluopicolide (RD-Mo) could be derived for wine, wine grape must, tomato juice and peeled melons. A tentative processing factor (not fully supported by data) was derived for raisins. The same could be done for 2,6-dichlorobenzamide (RD-RA2), noting, however, that in this case the processing factor for tomato juice deemed tentative since supported by one trial only.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

### 1.2.4. Proposed MRLs

For fluopicolide (which is the only residue definition for monitoring purpose), the available data are considered sufficient to derive MRL proposals as well as risk assessment values in all commodities under evaluation (see Appendix B.1.2.1). For tomatoes, broccoli, cauliflower, lamb’s lettuces/corn salads, cresses and other sprouts and shoots, land cresses, red mustards, baby leaf crops (including brassica species) and escaroles/broad-leaved endives, the MRLs were derived on tentative basis due to major data gaps identified for these crops.

Regarding 2,6-dichlorobenzamide (which is relevant for risk assessment purpose only), risk assessment values could be derived for all commodities (see Appendix B.1.2.2). As for fluopicolide, some of those risk assessment values are tentative because of missing residue trials. For information purpose, MRL calculation derived from the available data set were also reported in Appendix B.1.2.2. However, as 2,6-dichlorobenzamide is not relevant for enforcement purpose (see Section 1.1.6), those MRLs are not proposed to risk managers.
It was noted that significant residue levels of fluopicolide and 2,6-dichlorobenzamide may be expected in rotational crops. Based on the available data no risk mitigation measure could be proposed by EFSA to avoid residue uptake in rotational crops. For fluopicolide, it was found that significant uptakes are only expected in valerian roots and cereal straw and no conclusion could be drawn for major root crops. Therefore, MRL proposals and risk assessment values for fluopicolide were derived to consider residues from rotational crops in cereal straw (in view of the future need to set MRLs in feed items) and in valerian root (in line with previous MRL assessment EFSA, 2015a). For 2,6-dichlorobenzamide, only tentative risk assessment values could be derived because field rotational crops residue trials are not expected to cover the PEC soil total. Tentative risk assessment values were derived for cereal straw, leafy vegetables and valerian root. However, since 2,6-dichlorobenzamide is not relevant for enforcement purpose, no MRLs are proposed for this compound.

2. Residues in livestock

Fluopicolide is authorised for use on several crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for the two residue definitions relevant for risk assessment (fluopicolide and 2,6-dichlorobenzamide, separately (Appendix B.2)). The calculations were carried out according to OECD guidance (OECD, 2013), which has also been agreed upon at European level. Livestock dietary burdens were based on residues levels resulting from the critical uses on primary crops (derived in Section 1.2.1) as well as the possible uptake in rotational crops (derived in Section 1.2.2). The input values for all relevant commodities are summarised in Appendix D.1. For fluopicolide, the dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Regarding 2,6-dichlorobenzamide, the calculated dietary burdens were found to exceed the trigger value of 0.1 mg/kg DM for all groups of livestock except poultry. Behaviour of residues was therefore assessed in all commodities of animal origin.

2.1. Nature of residues and methods of analysis in livestock

The metabolism of fluopicolide residues in livestock was investigated in lactating cows and laying hens (United Kingdom, 2006). These studies were assessed in the framework of the peer review (EFSA, 2009b). In all available studies, animals were dosed with radiolabelled fluopicolide (phenyl and pyridinil rings). The studies performed with the highest dose rates (0.385 mg/kg body weight (bw) per day for cows and 0.684 mg/kg bw per day for hens) cover the maximum dietary burdens calculated for fluopicolide in the present review.

In the studies performed with dairy cows, transfer of radioactivity into milk and tissues was low. At the high-dose group (5N compared to dietary burden), a plateau in milk was reached after 4 days (0.01–0.02 mg eq./kg). The only identified radioactive component in milk, muscle and fat was fluopicolide (< 0.01–0.03 mg/kg), up to 76% of the TRR in fat. Total radioactivity was higher in liver and kidney (0.45–0.64 mg eq./kg and 0.2–0.3 mg eq./kg, respectively) where fluopicolide, 3-hydroxy and 4-hydroxy fluopicolide (metabolites M-06 and M-07) and sulfates and glucuronides of hydroxy/dihydroxy fluopicolide were the only metabolites identified. However, none of these compounds account for more than 0.2 mg eq./kg. On cellular fractionation, the non-characterised radioactivity was found to be associated with proteins, amino acids, peptides, lipids and sulfated glucosaminoglycans.

It is noted that studies investigating the livestock metabolism with 2,6-dichlorobenzamide directly fed to animals are not available in the present dossier. Nevertheless, it has to be noted that the livestock dietary burden calculated for 2,6-dichlorobenzamide (exceeding trigger value in ruminant and swine) is more than 10 times lower than the one of fluopicolide, for which the metabolic pathways have been elucidated. Furthermore, in the dossier of dichlobenil (another active substance for which 2,6-dichlorobenzamide is a major metabolite), it is noted that two metabolism studies performed on goat with 2,6-dichlorobenzamide are available. These studies indicated that 2,6-dichlorobenzamide was the main and only toxicologically relevant component of the residues in animal tissues and products (EFSA, 2013a). Therefore, further metabolism studies performed with 2,6-dichlorobenzamide are not deemed necessary.

In the studies performed with laying hens, the majority of radioactivity was excreted, with less than 0.2% TRR found in eggs and 0.3% TRR in tissues. At the high-dose group (40N compared to dietary burden), a plateau in eggs was reached after 8 days. When considering the low-dose group (4N compared to dietary burden), radioactive residues did not exceed 0.02 mg eq./kg in egg yolk and did not exceed 0.01 mg eq./kg in egg white and tissues, with the exception of liver (max. 0.13 mg eq./kg). Further identification was carried out in the study performed with the high dose rate. Fluopicolide was
only identified in eggs and fat (2.5–11% TRR; ≤ 0.01 mg eq./kg). Metabolite 2,6-dichlorobenzamide (M-01) was the only compound accounting for more than 0.02 mg eq./kg (37% TRR; 0.36 mg eq./kg in liver). The other metabolites (M-06 and M-07) and different conjugates (sulfate of hydroxy/dihydroxy fluopicolide and a methyl sulfone conjugate of fluopicolide) were also identified but remained below 0.05 mg eq./kg.

Based on the available data, fluopicolide is the only compound retrieved in all animal commodities, although in very low levels. Apart from metabolite 2,6-dichlorobenzamide, no other metabolite exceeds the level of 0.05 mg/kg (in studies that are overdosed with factors of 5 and 40). Considering that metabolite 2,6-dichlorobenzamide is not a specific marker for fluopicolide, the residue definition for enforcement is proposed as parent compound fluopicolide only, for all livestock commodities. As regards dietary risk assessment purposes two separate residue definitions are set: fluopicolide (RD-RA1) and metabolite 2,6-dichlorobenzamide (RD-RA2), due to the fact that these compounds have different toxicological end points (see also Section 1.1.6).

The storage stability of fluopicolide was demonstrated at –18°C for a period of 4 months in muscle and fat, for a period of 9 months in liver and kidney and for a period of 2 months in milk (United Kingdom, 2006; EFSA, 2009a). The storage stability of metabolite 2,6-dichlorobenzamide was also demonstrated under the same conditions (United Kingdom, 2006; EFSA, 2009a). It is noted that studies investigating the storage stability of fluopicolide and its metabolite 2,6-dichlorobenzamide in eggs are not available. Nevertheless, this is not considered as a data gap as such studies are not needed to support the MRLs derived in eggs (see Section 2.2).

An analytical method for the enforcement of fluopicolide in animal matrices was assessed during the peer review (EFSA, 2009a). A method based on HPLC coupled to MS/MS detection was validated for the determination of fluopicolide in milk (LOQ of 0.01 mg/kg), muscle (LOQ of 0.02 mg/kg) and fat, liver and kidney (LOQ of 0.05 mg/kg). This primary method was fully validated but is not supported by an ILV. An ILV is therefore required (data gap). Furthermore, as this method was not validated in eggs, an analytical method validated in eggs is also required (data gap). According to the EURLs, a screening detection level (SDL) of 0.005 mg/kg is achievable in milk and a SDL of 0.01 mg/kg is achievable in analytical method validated in eggs is also required (data gap). According to the EURLs, a screening detection level (SDL) of 0.005 mg/kg is achievable in milk and a SDL of 0.01 mg/kg is achievable in egg (FAO, 2009b). Nevertheless, since detailed information of this method and its validation are not available, it cannot be considered in the framework of the present review.

2.2. Magnitude of residues in livestock

In the framework of the peer review, a feeding study was performed with dairy cows (United Kingdom, 2006). In this study, fluopicolide was administered using different dosing levels (0.02, 0.06 and 0.20 mg/kg bw per day (reported as 0.5, 1.5 and 5 mg/kg feed). Analysis were performed separately for fluopicolide (RD-Mo and RD-RA1) and for 2,6-dichlorobenzamide (RD-RA2) in milk, muscle, fat, liver and kidney. 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.

This feeding study was used to derive MRLs for fluopicolide and risk assessment values for fluopicolide and 2,6-dichlorobenzamide in milk and tissues of ruminants, in compliance with the latest recommendations on this matter (FAO, 2009b). 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. The available data show that significant levels of fluopicolide and 2,6-dichlorobenzamide are not expected to occur in ruminant commodities.

For poultry, the metabolism study (performed at 40N rate compared to the maximum dietary burden) is sufficient to conclude that residue levels of fluopicolide and 2,6-dichlorobenzamide would remain below the enforcement LOQs in all matrices. Hence, livestock feeding study for poultry are not needed. For the same reasons, studies investigating the storage stability of fluopicolide and its metabolite 2,6-dichlorobenzamide in eggs are also not required.

In conclusion, MRLs and risk assessment values for fluopicolide are proposed at the enforcement LOQ for all livestock commodities. Considering that an ILV is still required for enforcement purposes, these MRLs are considered tentative. Furthermore, as no method is available for enforcement of fluopicolide in eggs, a default LOQ is proposed for eggs at 0.01 mg/kg.
Regarding 2,6-dichlorobenzamide, risk assessment values are also proposed at the LOQ based on the above study. It is noted that there is no feeding study investigating the level of 2,6-dichlorobenzamide when 2,6-dichlorobenzamide is directly fed to animals. Nevertheless, considering that the overall transfer of fluopicolide residues in livestock commodities is extremely low and considering that the livestock exposure to 2,6-dichlorobenzamide is 10 times lower than the exposure to fluopicolide, additional feeding studies performed with 2,6-dichlorobenzamide are not required. It is noted that indicative MRLs were also calculated for 2,6-dichlorobenzamide, which would correspond to LOQs.

3. Consumer risk assessment

As different toxicological reference values were derived for fluopicolide and for its metabolite 2,6-dichlorobenzamide, EFSA performed separate consumer risk assessments for fluopicolide (RD-RA1) and for 2,6-dichlorobenzamide (RD-RA2).

In a first scenario (EU1), only the uses of fluopicolide reported in Appendix A were considered. However, the use of fluopicolide was previously also assessed by the JMPR (FAO, 2009b, 2014) and the CXLs resulting from these assessments which were 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 then also calculated with consideration of the existing CXLs (scenarios CX1 and CX2 in Appendix C).

3.1. Consumer risk assessment for fluopicolide

3.1.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute 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 derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009a). For melons, pumpkins and watermelons the peeling processing factor (\(< 0.25\)) derived in this review was applied. For Valerian roots, potential residue uptakes from rotational crops were considered using risk assessment values derived from the field rotational crops residue trials (see Section 1.2.2). All input values included in the exposure calculations are summarised in Appendix D.2.

The exposure values calculated were compared with the toxicological reference values for fluopicolide, derived by EFSA (2009a). The highest chronic exposure was calculated for WHO Cluster diet B, representing 2.4% of the ADI, and the highest acute exposure was calculated for scarole (broad-leaf endive), representing 58.3% of the ARfD. These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values for fluopicolide. Therefore, the exposure calculation did not indicate a risk to consumers for what regards fluopicolide.

3.1.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals 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 provided in Appendix D.3.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference values derived for fluopicolide. The highest chronic exposure was calculated for Dutch children, representing 11.8% of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for scarole (broad-leaf endive), kale, celery, Chinese cabbage, lettuce, spinach, beet leaves (chard), purslane and head cabbage, representing 825.7%, 638.5%, 357.1%, 350.7%, 254.1%, 213.5%, 165.8%, 142.7%, and 114.0% of the ARfD, respectively. A second exposure calculation was therefore performed, excluding the CXLs for these crops. According to the results of this second calculation, the highest chronic exposure declined to 3.3% of the ADI for WHO Cluster diet B; the highest acute exposure is then calculated for scarole (broad-leaf endive), representing 58.3% of the ARfD.

Based on these calculations, EFSA concludes that the fluopicolide CXLs on scarole (broad-leaf endive), kale, celery, Chinese cabbage, lettuce, spinach, beet leaves (chard), purslane and head..
cabbage are of concern for European consumers. For the remaining CXLs, the exposure calculation did not indicate a risk to consumers for what regards fluopicolide.

3.2. Consumer risk assessment for 2,6-dichlorobenzamide

2,6-Dichlorobenzamide is a metabolite of fluopicolide which has its own toxicological properties. Therefore, separate calculations were performed for this compound using the risk assessment values and the toxicological reference values specifically derived for this compound.

It is noted that 2,6-dichlorobenzamide is not specific to fluopicolide as it is also a major metabolism product of dichlobenil. Nevertheless, the use of dichlobenil is not authorised in the EU. The MRL review for this substance has previously been carried out by EFSA (2013a). Considering that the substance is not authorised, no residues of 2,6-dichlorobenzamide are expected from this source.

Therefore, input values for the exposure calculations were derived considering the residues of 2,6-dichlorobenzamide arising from the use of fluopicolide. It takes into account residues of 2,6-dichlorobenzamide assessed in this review (primary crops and rotational crops) as well residues of 2,6-dichlorobenzamide which are associated to the CXLs of fluopicolide assessed by JMPR (FAO, 2014).

As regards residues of 2,6-dichlorobenzamide assessed in this review, risk assessment values were directly derived from the authorised uses in primary crops for all commodities other than leafy crops and herbal infusions from roots (valerian roots). For leafy crops and valerian roots, the potential uptake from rotational crops was also taken into account using the tentative risk assessment values derived for 2,6-dichlorobenzamide (see Section 3.1.2). Therefore, for all leafy commodities where a GAP is authorised (e.g. broccoli), risk assessment values were derived as the sum of residues from primary crops and rotational crops (see details in Appendix D.4). For leafy commodities where no EU GAP is authorised (e.g. herbal infusions from leaves and herbs) and for valerian root, risk assessment values were directly derived from rotational crops (see details in Appendix D.4).

As regards residues of 2,6-dichlorobenzamide assessed by JMPR (FAO, 2014), the following considerations were done. Only the risk assessment values derived from the use of fluopicolide were taken into account. Therefore, those risk assessment values which were derived from GAPs of dichlobenil (which is not authorised in the EU) were not taken into account. Furthermore, considering that the CXLs of fluopicolide for scarole (broad-leaf endive), kale, celery, Chinese cabbage, lettuce, spinach, beet leaves (chard), purslane and head cabbage are not recommended due to acute concerns with fluopicolide (see also Section 3.1.2), the risk assessment values for 2,6-dichlorobenzamide which are associated to these CXLs should also not be considered in the consumer exposure.

A comprehensive calculation including risk assessment values from EU uses and CXLs was directly performed. In this calculation, risk assessment values derived from the EU uses were compared with the risk assessment values derived by JMPR, in compliance with Appendix E. An overview of the input values used for this exposure calculation is provided in Appendix D.4.

The exposure values calculated were compared with the toxicological reference values for 2,6-dichlorobenzamide, derived by EFSA (2009a). The highest chronic exposure was calculated for the French toddler, representing 1.3% of the ADI, and the highest acute exposure was calculated for scarole (broad-leaf endive), representing 2.0% of the ARfD. These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values for 2,6-dichlorobenzamide. Therefore, the exposure calculation did not indicate a risk to consumers for what regards this compound. Due to the deficiency identified regarding the residues levels of 2,6-dichlorobenzamide in rotational crops, uncertainty remains regarding the results of this calculation. However, considering the large margin of safety and considering that for many leafy commodities a conservative assessment was performed using the risk assessment values derived by JMPR, no concerns are expected regarding the consumer exposure to 2,6-dichlorobenzamide.

Conclusions

The metabolism of fluopicolide in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement should be set as fluopicolide only. As regards risk assessment, two residue definitions are set: fluopicolide and metabolite 2,6-dichlorobenzamide, separately. These residue definitions are also applicable to processed commodities. Fully validated analytical methods for enforcement of fluopicolide in the four main plant matrices are available and fully applicable in routine according to the EURLs.
For fluopicolide (which is the only residue definition for monitoring purpose), the available data were considered sufficient to derive MRL proposals as well as risk assessment values in all commodities under evaluation. For tomatoes, broccoli, cauliflower, lamb’s lettuces/corn salads, cresses and other sprouts and shoots, land cresses, red mustards, baby leaf crops (including brassica species) and escaroles/broad-leaved endives, the MRLs were derived on tentative basis due to major data gaps identified for these crops. Regarding 2,6-dichlorobenzamide (which is relevant for risk assessment purpose only), risk assessment values (at least tentative) could also be derived for all commodities.

It was noted that significant residue levels of fluopicolide and 2,6-dichlorobenzamide may be expected in rotational crops. Based on the available data no risk mitigation measure could be proposed by EFSA to avoid residue uptake in rotational crops. For fluopicolide, MRL proposals and risk assessment values were derived to consider residues from rotational crops in cereal straw (in view of the future need to set MRLs in feed items) and in valerian root. For 2,6-dichlorobenzamide, tentative risk assessment values could be derived to consider residues arising from rotational crops in cereal straw, leafy vegetables and valerian root.

Fluopicolide is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for the two residue definitions relevant for risk assessment (fluopicolide and 2,6-dichlorobenzamide, separately), for different groups of livestock according to OECD guidance. For fluopicolide, the dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Regarding 2,6-dichlorobenzamide, the calculated dietary burdens were found to exceed the trigger value of 0.1 mg/kg DM for all groups of livestock except poultry. Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of fluopicolide residues in livestock was investigated in lactating cows and laying hens at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement should be set as fluopicolide only. As regards risk assessment, two residue definitions are set: fluopicolide and metabolite 2,6-dichlorobenzamide, separately. Validated analytical methods for enforcement of fluopicolide in milk, muscle, fat, liver and kidney are available and EURs assured the applicability in routine for milk and meat. However, an ILV was found to be missing and analytical methods for enforcement in eggs were found to be missing (data gaps).

Livestock feeding study on dairy cows and metabolism study on laying hens were used to derive MRL and risk assessment values in milk, eggs, and tissues of ruminants and 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.

EFSA performed separate consumer risk assessments for fluopicolide (RD-RA1) and for 2,6-dichlorobenzamide (RD-RA2). Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMO.

As regards fluopicolide, the highest chronic exposure considering all authorised uses reported in this review represented 2.4% of the ADI (WHO Cluster diet B) and the highest acute exposure amounted to 58.3% of the ARfD (escarole, broad-leaf endive). Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for fluopicolide. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and exceedances of the ARfD were identified for the existing CXLs in escarole (broad-leaf endive) (825.7%), kale (638.5%), celery (357.1%), Chinese cabbage (350.7%), lettuce (254.1%), spinach (213.5%), beet leaves (chard) (165.8%), purslane (142.7%) and head cabbage (114.0%). Excluding these CXLs from the calculation, the highest chronic exposure represented 3.3% of the ADI (WHO Cluster diet B) and the highest acute exposure amounted to 58.3% of the ARfD (escarole, broad-leaf endive).

As regards 2,6-dichlorobenzamide, a comprehensive risk assessment was performed taking into account residues for this metabolite assessed in this review (primary crops and rotational crops) as well as residues of 2,6-dichlorobenzamide which are associated to the CXLs of fluopicolide (assessed by JMPR). The highest chronic exposure was calculated for the French toddler, representing 1.3% of the ADI, and the highest acute exposure was calculated for escarole (broad-leaf endive), representing 2.0% of the ARfD.

**Recommendations**

MRL recommendations for fluopicolide were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the
Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, some tentative MRLs need to be confirmed by the following data:

- Four trials supporting the southern outdoor GAP on Escarole/broad-leaved endive;
- A confirmatory method and an ILV for hops;
- An ILV for the analytical method validated for the enforcement of fluopicolide in milk, muscle, fat, liver and kidney;
- A fully validated method (including ILV) for the enforcement of fluopicolide in eggs.

It is highlighted, however, that some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Additional residue trials supporting the GAPs on cucumbers and courgettes (4 NEU and 4 southern European Union (SEU)), broccoli (4 indoor), cauliflower (4 indoor), Brussels sprouts (4 SEU and 4 indoor), head cabbage (8 indoor), kale (4 indoor), kohlrabi (4 SEU), lamb’s lettuce, cresses and other sprouts and shoots, land cresses, red mustards, baby leaf crops (incl. brassica species) (4 NEU, 4 SEU and 4 indoor);
- Considering the northern trials supporting the GAP on tomatoes and reported by the Member State Czech Republic, missing information on the validity of the analytical method used and on the storage conditions of the samples between harvest and analysis is required.

If the above-reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level. When generating the residue trials required, it is recommended to perform the residue analysis of both fluopicolide and its metabolite 2,6-dichlorobenzamide as they are both relevant to perform the risk assessment. The available studies investigating the magnitude of residues in rotational crops allow to conclude that no significant residue uptakes of fluopicolide are expected in cereal grains, pulses and leafy vegetables. Nevertheless, in the absence of field rotational crops studies performed on major root crops, no conclusion could be drawn for root crops. It is therefore recommended to generate studies (e.g. rotational crop field trials performed with major root crop) to address this point in the future or to meanwhile consider restrictions of use (e.g. root crops not to be grown in rotation).

Minor deficiencies were also identified in the assessment, but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- A study investigating the effect of processing under hydrolytic conditions on the potential degradation of the metabolite 2,6-dichlorobenzamide;
- A rotational crop field study reflecting the calculated plateau for 2,6-dichlorobenzamide in soil;
- Additional residue trials supporting the GAPs on blackberries (2 NEU and 1 indoor) analysing for metabolite 2,6-dichlorobenzamide;
- One additional trial on carrot supporting the import tolerance GAP on root and tuber vegetables.

It is highlighted that MRLs are only proposed for fluopicolide, which is according to EFSA the only compound relevant for enforcement.

As regards metabolite 2,6-dichlorobenzamide, a separate risk assessment was performed. This risk assessment was subject to uncertainty due to data gaps linked to residues levels of 2,6-dichlorobenzamide in rotational crops. However, considering the large margin of safety observed in the outcome of the calculations no further concerns are expected regarding the consumer exposure to 2,6-dichlorobenzamide. As there are indications that 2,6-dichlorobenzamide is also a metabolite of other active substances (namely dichlobenil and chlorthiamide, both not authorised in the EU), this compound is not deemed as a good marker for enforcement purpose and no MRLs are proposed for 2,6-dichlorobenzamide in the present review. Nevertheless, it is reminded that in the framework of the MRL review for dichlobenil, metabolite 2,6-dichlorobenzamide was considered as the only relevant marker for enforcement against a potential illegal use of dichlobenil. Therefore, risk managers may have interest in setting specific MRLs at the LOQ for 2,6-dichlorobenzamide (BAM). If risk managers decide to do so, the following points need to be considered:
Significant levels of 2,6-dichlorobenzamide are expected to be found due to the authorised uses of fluopicolide within the EU (assessed in this review) and outside the EU (assessed in this review as import tolerance and by Codex as CXL). Therefore, MRLs which would be set at the LOQ for this compound are likely to be exceeded even in the absence of illegal use of non-authorised active substances.

An overview of the potential residue levels of 2,6-dichlorobenzamide (from primary and rotational crops), assessed in the present review as well as by FAO (2014), is provided in Appendix G of the present reasoned opinion. It is noted that the assessment of residue levels of 2,6-dichlorobenzamide in rotational crops is subject to uncertainty due to the deficiencies identified above.

Analysing systematically 2,6-dichlorobenzamide together with fluopicolide may partially help to identify misuses. For example, in the cases where 2,6-dichlorobenzamide would be present at significant levels but fluopicolide would be below the LOQ, this may indicate an illegal use of dichlobenil, provided that 2,6-dichlorobenzamide was not up taken in rotational crops.

An analytical method for enforcement of 2,6-dichlorobenzamide was validated for acidic commodities with a LOQ of 0.01 mg/kg (see MRL review of dichlobenil). However, there was no evidence that 2,6-dichlorobenzamide could be enforced in high water content, high oil content, dry commodities and any commodities of animal origin. Therefore, additional analytical methods may need to be developed and validated for these matrices.

It is noted that the EURLs have routinely monitored metabolite 2,6-dichlorobenzamide by using QuEChERS methods. According to the EURLs, metabolite 2,6-dichlorobenzamide was frequently found in various products from the market (see MSC report EFSA, 2019b).

Table 2: Summary table

| Code number | Commodity                  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Outcome of the review |
|-------------|----------------------------|-------------------------|----------------------|-------------|----------------------|
| 151010      | Table grapes               | 2                       | 2                    | 2           | Recommended[^a]      |
| 151020      | Wine grapes                | 2                       | 2                    | 2           | Recommended[^a]      |
| 153010      | Blackberries              | 3                       | –                    | 3           | Recommended[^b]      |
| 211000      | Potatoes                  | 0.03                    | –                    | 0.03        | Recommended[^b]      |
| 212010      | Cassava roots/manioc      | 0.01                    | –                    | 0.01*       | Recommended[^b]      |
| 212020      | Sweet potatoes            | 0.01                    | –                    | 0.01*       | Recommended[^b]      |
| 212030      | Yams                      | 0.01                    | –                    | 0.01*       | Recommended[^b]      |
| 212040      | Arrowroots                | 0.01                    | –                    | 0.01*       | Recommended[^b]      |
| 213010      | Beetroots                 | 0.15                    | –                    | 0.2         | Recommended[^b]      |
| 213020      | Carrots                   | 0.15                    | –                    | 0.2         | Recommended[^b]      |
| 213030      | Celeriacs/turnip rooted celeries | 0.15                | –                    | 0.2         | Recommended[^b]      |
| 213040      | Horseradishes             | 0.15                    | –                    | 0.2         | Recommended[^b]      |
| 213050      | Jerusalem artichokes      | 0.15                    | –                    | 0.2         | Recommended[^b]      |
| 213060      | Parsnips                  | 0.15                    | –                    | 0.2         | Recommended[^b]      |
| 213070      | Parsley roots/Hamburg roots parsley | 0.15            | –                    | 0.2         | Recommended[^b]      |
| 213080      | Radishes                  | 0.15                    | –                    | 0.2         | Recommended[^b]      |
| 213090      | Salsifies                 | 0.15                    | –                    | 0.2         | Recommended[^b]      |
| 213100      | Swedes/rutabagas          | 0.15                    | –                    | 0.2         | Recommended[^b]      |
| 213110      | Turnips                   | 0.15                    | –                    | 0.2         | Recommended[^b]      |
| 220010      | Garlic                    | 0.3                      | –                    | 0.3         | Recommended[^b]      |
| 220020      | Onions                    | 1                        | 1                    | 1           | Recommended[^c]      |
| 220030      | Shallots                  | 0.3                      | –                    | 0.3         | Recommended[^b]      |
| 220040      | Spring onions/green onions and Welsh onions | 10                 | 10                   | 10          | Recommended[^c]      |

Enforcement residue definition: fluopicolide
| Code number | Commodity                        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|----------------------------------|-------------------------|----------------------|-----------------------|---------|
| 231010      | Tomatoes                         | 1                       | 1                    | 1                     | Recommended (d) |
| 231020      | Sweet peppers/bell peppers       | 1                       | 1                    | 1                     | Recommended (e) |
| 231030      | Aubergines (egg plants)           | 1                       | 1                    | 1                     | Recommended (e) |
| 231040      | Okra, lady's fingers              | 1                       | 1                    | 1                     | Recommended (e) |
| 232010      | Cucumbers                         | 0.5                     | 0.5                  | 0.5                   | Recommended (c) |
| 232020      | Gherkins                          | 0.5                     | 0.5                  | 0.5                   | Recommended (c) |
| 232030      | Courgettes                        | 0.5                     | 0.5                  | 0.5                   | Recommended (c) |
| 233010      | Melons                            | 0.5                     | 0.5                  | 0.5                   | Recommended (c) |
| 233020      | Pumpkins                          | 0.5                     | 0.5                  | 0.5                   | Recommended (c) |
| 233030      | Watermelons                       | 0.5                     | 0.5                  | 0.5                   | Recommended (c) |
| 241010      | Broccoli                          | 2                       | 2                    | 2                     | Recommended (d) |
| 241020      | Cauliflowers                      | 2                       | 2                    | 2                     | Recommended (d) |
| 242010      | Brussels sprouts                  | 0.2                     | 0.2                  | 0.2                   | Recommended (c) |
| 242020      | Head cabbages                     | 0.2                     | 7                    | 0.3                   | Recommended (f) |
| 243010      | Chinese cabbages/pe-tsai          | 2                       | 30                   | 2                     | Recommended (f) |
| 243020      | Kales                             | 2                       | 30                   | 2                     | Recommended (f) |
| 244000      | Kohlrabies                        | 0.03                    | –                    | 0.03                  | Recommended (b) |
| 251010      | Lamb's lettuces/corn salads       | 9                       | 30                   | 30                    | Recommended (d) |
| 251020      | Lettuces                          | 9                       | 30                   | 6                     | Recommended (f) |
| 251030      | Escaroles/broad-leaved endives    | 1.5                     | 30                   | 2                     | Further consideration needed (g) |
| 251040      | Cresses and other sprouts and shoots | 9                       | 30                   | 30                    | Recommended (d) |
| 251050      | Land cresses                      | 9                       | 30                   | 30                    | Recommended (d) |
| 251060      | Roman rocket/rucola               | 9                       | 30                   | 30                    | Recommended (c) |
| 251070      | Red mustards                      | 9                       | 30                   | 30                    | Recommended (d) |
| 251080      | Baby leaf crops (including brassica species) | 9                       | 30                   | 30                    | Recommended (d) |
| 252010      | Spinaches                         | 6                       | 30                   | 6                     | Recommended (f) |
| 252020      | Purslanees                        | 6                       | 30                   | 6                     | Recommended (f) |
| 252030      | Chards/beet leaves                | 6                       | 30                   | 6                     | Recommended (f) |
| 253000      | Vine leaves (grape leaves)        | 0.01*                   | 30                   | 30                    | Recommended (b) |
| 254000      | Water cress                       | 0.01*                   | 30                   | 30                    | Recommended (c) |
| 256010      | Chervil                           | 9                       | 30                   | 30                    | Recommended (c) |
| 256020      | Chives                            | 9                       | –                    | 9                     | Recommended (b) |
| 256030      | Celery leaves                     | 9                       | –                    | 9                     | Recommended (b) |
| 256040      | Parsley                           | 9                       | –                    | 9                     | Recommended (b) |
| 256050      | Sage                              | 9                       | –                    | 9                     | Recommended (b) |
| 256060      | Rosemary                          | 9                       | –                    | 9                     | Recommended (b) |
| 256070      | Thyme                             | 9                       | –                    | 9                     | Recommended (b) |
| 256080      | Basil and edible flowers          | 9                       | –                    | 9                     | Recommended (b) |
| 256090      | Laurel/bay leaf                   | 9                       | –                    | 9                     | Recommended (b) |
| 256100      | Tarragon                          | 9                       | –                    | 9                     | Recommended (b) |
| 270030      | Celery leave                      | 0.01*                   | 20                   | –                     | Further consideration needed (b) |
| 270060      | Leeks                             | 1.5                     | –                    | 1.5                   | Recommended (b) |
| 401060      | Rapeseeds/canola seeds            | 0.01*                   | –                    | 0.01*                 | Recommended (b) |
| Code number | Commodity                              | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                          |
|-------------|----------------------------------------|-------------------------|----------------------|-------------|----------------------------------|
| 401080      | Mustard seeds                          | 0.01*                   | –                    | 0.01*       | Recommended**(b)**               |
| 633000      | Herbal infusions from roots            | 7                       | –                    | 7           | Recommended**(i)**               |
| 700000      | Hops                                   | 0.7                     | –                    | 0.15        | Further consideration needed**(j)**|
| 900010      | Sugar beet roots                       | 0.15                    | –                    | 0.15        | Recommended**(b)**               |
| 1011010     | Swine muscle                           | 0.01*                   | 0.01*                | 0.02*       | Further consideration needed**(k)**|
| 1011020     | Swine fat tissue                       | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1011030     | Swine liver                            | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1011040     | Swine kidney                           | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1012010     | Bovine muscle                          | 0.01*                   | 0.01*                | 0.02*       | Further consideration needed**(k)**|
| 1012020     | Bovine fat tissue                      | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1012030     | Bovine kidney                          | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1012040     | Bovine kidney                          | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1013010     | Sheep muscle                           | 0.01*                   | 0.01*                | 0.02*       | Further consideration needed**(k)**|
| 1013020     | Sheep fat tissue                       | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1013030     | Sheep liver                            | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1013040     | Sheep kidney                           | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1014010     | Goat muscle                            | 0.01*                   | 0.01*                | 0.02*       | Further consideration needed**(k)**|
| 1014020     | Goat fat tissue                        | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1014030     | Goat liver                             | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1014040     | Goat kidney                            | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1015010     | Equine muscle                          | 0.01*                   | 0.01*                | 0.02*       | Further consideration needed**(k)**|
| 1015020     | Equine fat tissue                      | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1015030     | Equine liver                           | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1015040     | Equine kidney                          | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1016010     | Poultry muscle                         | 0.01*                   | 0.01*                | 0.02*       | Further consideration needed**(k)**|
| 1016020     | Poultry fat tissue                     | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1016030     | Poultry liver                          | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed**(k)**|
| 1020010     | Cattle milk                            | 0.02                    | 0.02                 | 0.02        | Further consideration needed**(k)**|
| 1020020     | Sheep milk                             | 0.02                    | 0.02                 | 0.02        | Further consideration needed**(k)**|
| 1020030     | Goat milk                              | 0.02                    | 0.02                 | 0.02        | Further consideration needed**(k)**|
| 1020040     | Horse milk                             | 0.02                    | 0.02                 | 0.02        | Further consideration needed**(k)**|
| 1030000     | Birds eggs                             | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed**(k)**|
|             | Other commodities of plant and/or animal origin | See Reg. 832/2018 | –                    | –           | Further consideration needed**(m)**|

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

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).

(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).

(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-V in Appendix E).

(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination F-VII in Appendix E).

(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).

(f): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination H-VI in Appendix E).

(g): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination F-VI in Appendix E).
(h): There are no relevant authorisations or import tolerances reported at EU level; CXL is supported by data but a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-VI in Appendix E).

(i): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. However, MRL fully supported by data is derived to take into account the uptake in rotational crops (EFSA, 2015a); no risk to consumers is identified (equivalent to combination H-I in Appendix E).

(j): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination F-I in Appendix E).

(k): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination F-III in Appendix E).

(l): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination F-V in Appendix E).

(m): 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
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
BVL Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany
bw body weight
CAC Codex Alimentarius Commission
CAS Chemical Abstract Service
CCPR Codex Committee on Pesticide Residues
CF conversion factor for enforcement residue definition to risk assessment residue definition
cGAP critical GAP
CXL codex maximum residue limit
DALA days after last application
DAR draft assessment report
DAT days after treatment
DB dietary burden
DM dry matter
DT$_{90}$ period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
eq. residue expressed as a.s. equivalent
EURLs European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC–MS gas chromatography with mass spectrometry
GC-MS/MS gas chromatography with tandem mass spectrometry
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)
LC–MS/MS liquid chromatography with tandem mass spectrometry
LOQ limit of quantification
Mo monitoring
MRL maximum residue level
MS Member States
NEDI national estimated daily intake
NESTI national estimated short-term intake
NEU northern European Union
NTMDI national theoretical maximum daily intake
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PEC predicted environmental concentration
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
PROFile (EFSA) Pesticide Residues Overview File
QToF quadrupole time-of-flight

Review of the existing MRLs for fluopicolide
Review of the existing MRLs for fluopicolide

| Acronym | Description |
|---------|-------------|
| QuEChERS | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA | risk assessment |
| RAC | raw agricultural commodity |
| RD | residue definition |
| RMS | rapporteur Member State |
| SANCO | Directorate-General for Health and Consumers |
| SC | suspension concentrate |
| SDL | screening detection level |
| SEU | southern European Union |
| SMILES | simplified molecular-input line-entry system |
| SL | soluble concentrate |
| STMR | supervised trials median residue |
| TMDI | theoretical maximum daily intake |
| TRR | total radioactive residue |
| WG | water-dispersible granule |
| WHO | World Health Organization |
### Appendix A – Summary of authorised uses considered for the review of MRLs

#### A.1. Authorised outdoor uses in northern EU

| Crop and/or situation | MS or country | FG or TI(a) | Pests or Group of pests controlled | Preparation Type(b) | Conc. a.s. | Method kind | Application | PHI (days) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|---------------------|-----------|-------------|-------------|------------|---------|
|                       |               |             |                                   | Preparer            |           |             | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Application rate per treatment | PHA (days)(d) |          |
| Table grapes           | HU            | F           | Downy mildew                      | WG                  | 44.4 g/kg | Foliar treatment – broadcast spraying | 81 1-3     | 10  | –        | –        | 111 g a.i./ha | 28    | –        |
| Wine grapes            | HU            | F           | Downy mildew                      | WG                  | 44.4 g/kg | Foliar treatment – broadcast spraying | 81 1-3     | 10  | –        | –        | 111 g a.i./ha | 28    | –        |
| Blackberries           | DE            | F           | Downy mildew of cane fruit (Peronospora rubi) | WG                  | 44.4 g/kg | Foliar treatment – ultra-low volume spraying | 60-85 2 | 10  | –        | –        | 120 g a.i./ha | 21    | At beginning of infestation and/or when first symptoms become visible |
| Potatoes               | BE            | F           | Mildew                            | SC                  | 62.5 g/L | Foliar treatment – general (see also comment field) | 1-5 7 | –   | –        | –        | 100 g a.i./ha | 7     | Max 0.4 kg fluopicolide/36 months |
| Radishes               | BE            | F           | Mildew, rust                      | SC                  | 62.5 g/L | Foliar treatment – general (see also comment field) | 1-2 10 | –   | –        | –        | 100 g a.i./ha | 14    | Applications/culture; max 0.4 kg fluopicolide/36 months |
| Garlic                 | NL            | F           | Peronospora destructor            | SC                  | 62.5 g/L | Foliar treatment – broadcast spraying | 40 3 7 | –   | –        | –        | 100 g a.i./ha | 7     | Spray volume is 200–800 L/ha |

Note: (a) FG or TI (F=treatment indication, G=growth stage) (b) Type: a.s.–active substance (c) Range of growth stages & season (d) PHI: Preharvest interval (e) Remarks: Any additional information or notes.
| Crop and/or situation | MS or country | FG or T(1) | Pests or Group of pests controlled | Preparation | Method kind | Type(b) | Conc. a.s. | Application | Range of growth stages & season(1) | Number min-max | Interval between application (min) | PHI (days) (d) | Remarks |
|-----------------------|--------------|------------|-----------------------------------|-------------|-------------|---------|------------|-------------|----------------------------------|----------------|-------------------------------|---------------|---------|
| Onions                | SK           | F          |                                   | SC          | Foliar treatment – general (see also comment field) | SC       | 62.5 g/L  |            | 13-49               | 1-3            | 7                            | -             | 100 g a.i./ha                 |
|                       |              |            |                                   |             |                                         |          |            |            |                                   |                |                              | 7             | Max. 300 g fluopicolide/36 months |
| Shallots              | NL           | F          | Peronospora destructor            | SC          | Foliar treatment – broadcast spraying    | SC       | 62.5 g/L  |            | 40                   | 3              | 7                            | -             | 100 g a.i./ha                 |
|                       |              |            |                                   |             |                                         |          |            |            |                                   |                |                              | 7             | Spray volume is 200–800 L/ha    |
| Spring onions        | BE           | F          | Mildew                            | SC          | Foliar treatment – general (see also comment field) | SC       | 66.5 g/L  |            | 1-3                  |                |                              | -             | 100 g a.i./ha                 |
|                       |              |            |                                   |             |                                         |          |            |            |                                   |                |                              | 14            | Max 0.4 kg fluopicolide/36 months |
| Tomatoes              | CZ           | F          | Phytophthora infestans            | SC          | Foliar treatment – broadcast spraying    | SC       | 62.5 g/L  |            | 3                                   | 7              |                              | -             | 100 g a.i./ha                 |
| Cucumbers             | AT           | F          | Pseudoperonospora cubensis        | SC          | Foliar treatment – general (see also comment field) | SC       | 62.5 g/L  |            | n.a.                 | 3              | 7                            | -             | 100 g a.i./ha                 |
|                       |              |            |                                   |             |                                         |          |            |            |                                   |                |                              | 3             | In case of danger of infection and/or after warning service appeal |
| Gherkins              | AT           | F          | Pseudoperonospora cubensis        | SC          | Foliar treatment – general (see also comment field) | SC       | 62.5 g/L  |            | n.a.                 | 3              | 7                            | -             | 100 g a.i./ha                 |
|                       |              |            |                                   |             |                                         |          |            |            |                                   |                |                              | 3             | In case of danger of infection and/or after warning service appeal |
| Crop and/or situation | MS or country | F | G | S | Pests or Group of pests controlled | Preparation | Method kind | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|---|---|---|----------------------------------|-------------|-------------|-------------|--------------------------------|------------|---------|
| Courgettes            | AT            | F |   |   | *Pseudoperonospora cubensis*     | SC          | 62.5 g/L    | Foliar treatment – general (see also comment field) | n.a. | 3 | 7 | – | – | 100g a.i./ha | 3 | In case of danger of infection and/or after warning service appeal |
| Broccoli              | BE            | F |   |   | Mildew, rust                    | SC          | 67.5 g/L    | Foliar treatment – general (see also comment field) | 41–49 | 1–3 | 10 | – | – | 100g a.i./ha | 14 | Applications/culture. Max 0.4 kg fluopicolide/36 months |
| Cauliflowers          | HU            | F |   |   | Downy mildew                    | SC          | 62.5 g/L    | Foliar treatment – broadcast spraying | 41–49 | 1–3 | 10 | – | – | 100g a.i./ha | 14 | – |
| Brussels sprouts      | HU            | F |   |   | Downy mildew                    | SC          | 62.5 g/L    | Foliar treatment – broadcast spraying | 41–49 | 1–3 | 10 | – | – | 100g a.i./ha | 14 | – |
| Head cabbages         | SI            | F |   |   |                                  | SC          | 62.5 g/L    | Foliar treatment – general (see also comment field) | 13–49 | 1–3 | 7 | – | – | 100g a.i./ha | 14 | – |
| Chinese cabbages      | BE            | F |   |   | Mildew, rust                     | SC          | 70.5 g/L    | Foliar treatment – general (see also comment field) | 41–49 | 1–3 | 10 | – | – | 100g a.i./ha | 14 | Applications/culture. Max 0.4 kg fluopicolide/36 months |
| Crop and/or situation | MS or country | FG or I(a) | Pests or Group of pests controlled | Preparation Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Application rate per treatment a.s./hL min-max | Water L/ha min-max | Rate and unit | PHI (days) (d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|----------------------|-----------|------------|----------------------------------|----------------|----------------------------------|------------------------------------------|------------------|-------------|---------------|---------|
| Kales                 | BE            | F           | Mildew, rust                       | SC                   | 72.5 g/L | Foliar treatment – general (see also comment field) | 41-49             | 1-3                             | 10                                      | –                 | –           | 100 g a.i./ha | 14      | Applications/ culture. Max 0.4 kg fluopicolide/ 36 months |
| Kohlrabies            | FI            | F           | *Perunospora parasitica* PEROPA, *Albugo Candica* ALBUCA | SC                   | 62.5 g/L | Foliar treatment – broadcast spraying               | 40-49             | 3                               | –                        | –                 | 100 g a.i./ha | 14      | Minor use |
| Lamb’s lettuces       | FR            | F           | Mildew                            | SC                   | 62.5 g/L | Foliar treatment – broadcast spraying               | 13-51             | 2                               | 10                                      | –                 | 100 g a.i./ha | 14      | –         |
| Lettuces              | HU            | F           | Downy mildew                      | SC                   | 62.5 g/L | Foliar treatment – broadcast spraying               | 19-49             | 1-3                             | 10                                      | –                 | 100 g a.i./ha | 7       | –         |
| Cresses               | FR            | F           | Mildew                            | SC                   | 62.5 g/L | Foliar treatment – broadcast spraying               | 13-51             | 2                               | 10                                      | –                 | 100 g a.i./ha | 14      | –         |
| Land cresses          | FR            | F           | Mildew                            | SC                   | 62.5 g/L | Foliar treatment – broadcast spraying               | 13-51             | 2                               | 10                                      | –                 | 100 g a.i./ha | 14      | –         |
| Roman rocket          | NL            | F           | *Bremia lactucae*                 | SC                   | 62.5 g/L | Foliar treatment – broadcast spraying               | 30                 | 2                               | 10                                      | –                 | 100 g a.i./ha | 7       | –         |
| Crop and/or situation | MS or country | FG or I(a) | Pests or Group of pests controlled | Preparation | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------------|-----------|-----------------------------------|-------------|------------|------------------------------------|----------------|----------------------------------|---------------------------------|---------------|---------|
| Red mustards          | FR            | F         | Mildew                            | SC          | 62.5 g/L   | Foliar treatment – broadcast spraying | 13–51          | 2                                | –                               | 100 g a.i./ha | 14      |
| Baby leaf crops       | FR            | F         | Mildew                            | SC          | 62.5 g/L   | Foliar treatment – broadcast spraying | 13–51          | 2                                | –                               | 100 g a.i./ha | 14      |
| Spinaches             | SI            | F         | SC                                | 62.5 g/L    |            | Foliar treatment – general (see also comment field) | 13–47          | 1–3                              | –                               | 100 g a.i./ha | 14      |
| Purslanes             | BE            | F         | Mildew                            | SC          | 79.5 g/L   | Foliar treatment – general (see also comment field) | 14–47          | 1–3                              | 7                                | 100 g a.i./ha | 14 Max 0.4 kg fluopicolide/36 months |
| Chards                | BE            | F         | Mildew                            | SC          | 75.5 g/L   | Foliar treatment – general (see also comment field) | 14–47          | 1–3                              | 7                                | 100 g a.i./ha | 14 Max 0.4 kg fluopicolide/36 months |
| Chervil               | NL            | F         | Bremia lactucae                   | SC          | 62.5 g/L   | Foliar treatment – broadcast spraying | 30             | 2                                | 10                               | 100 g a.i./ha | 7       |
| Chives                | BE            | F         | Mildew                            | SC          | 77.5 g/L   | Foliar treatment – general (see also comment field) | 40–49          | 1–2                              | –                               | 100 g a.i./ha | 7 Max 0.4 kg fluopicolide/36 months |

(a) FG or I: Crop and/or situation in France, Germany or Ireland. (b) Type: a.s. : active substance. (c) Range of growth stages & season: (d) PHI (days): PHI: Preharvest interval (days). (e) Remarks:
| Crop and/or situation | MS or country | F or I(a) | Pests or Group of pests controlled | Preparation | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Remarks | PHI (days) (d) | Application rate per treatment a.s./hL | Water L/ha min-max | Rate and unit |
|-----------------------|--------------|----------|-----------------------------------|-------------|----------|------------|--------------------------|----------------|-----------------------------|--------|----------------|--------------------------------|-------------------|-------------|
| Celery leaves NL      | F            | Bremia lactucae | SC 62.5 g/L | Foliar treatment – broadcast spraying | 30 | 2 | 10 | – | – | 100 g a.i./ha | 7 – |
| Parsley NL            | F            | Bremia lactucae | SC 62.5 g/L | Foliar treatment – broadcast spraying | 30 | 2 | 10 | – | – | 100 g a.i./ha | 7 – |
| Sage NL               | F            | Bremia lactucae | SC 62.5 g/L | Foliar treatment – broadcast spraying | 30 | 2 | 10 | – | – | 100 g a.i./ha | 7 – |
| Rosemary NL           | F            | Bremia lactucae | SC 62.5 g/L | Foliar treatment – broadcast spraying | 30 | 2 | 10 | – | – | 100 g a.i./ha | 7 – |
| Thyme NL              | F            | Bremia lactucae | SC 62.5 g/L | Foliar treatment – broadcast spraying | 30 | 2 | 10 | – | – | 100 g a.i./ha | 7 – |
| Basil NL              | F            | Bremia lactucae | SC 62.5 g/L | Foliar treatment – broadcast spraying | 30 | 2 | 10 | – | – | 100 g a.i./ha | 7 – |
| Laurel NL             | F            | Bremia lactucae | SC 62.5 g/L | Foliar treatment – broadcast spraying | 30 | 2 | 10 | – | – | 100 g a.i./ha | 7 – |
| Crop and/or situation | MS or country | F Group or situation | 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 application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit |                      |
| Tarragon              | NL            | F                    | Bremia lactucae                     | SC         | 62.5 g/L    | Foliar treatment – broadcast spraying | 30       | 2          | 10                     | –         | –                   | 100 g a.i./ha  | 7                      | –            |
| Leeks                 | BE            | F                    | Mildew                              | SC         | 76.5 g/L    | Foliar treatment – general (see also comment field) | 14-47    | 1-3        | 14                     | –         | –                   | 100 g a.i./ha  | 14 Max 0.4 kg fluopicolide/ 36 months |
| Rapeseeds             | CZ            | F                    | Phoma spp., Alternaria spp., Rhizoctonia spp., Hyaloperonospora brassicae | FS         | 200 g/L     | Seed treatment – general (see also comment field) | 0        | 1          | –                     | –         | –                   | 12 g a.i./ha  | n.a. Ongoing registration of product Scenic Gold (CZ is RMS); seed treated with 200 g a.s./100 kg. Converted app. Rate assuming seed density of 6 kg a.s./ha |
| 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 |
|-----------------------|---------------|----------------|----------------------------------|-------------|-------------|--------------------------------|------------|---------|
| Mustard seeds         | CZ, DE, AT    | F              | Phoma spp., Alternaria spp., Rhizoctonia spp., Hyaloperonospora brassicae | Seed treatment – general (see also comment field) | 200 g/L a.s. | 12 g a.i./ha | n.a. | Ongoing registration of product Scenic Gold (CZ is RMS); seed treated with 200 g a.s./100 kg. Converted app. Rate assuming seed density of 6 kg a.s./ha. |
| Hops                  | CZ, DE, AT    | F              | Pseudoperonospora humuli         | Foliar treatment – broadcast spraying | 44.4 g/kg | 100 g a.i./ha | n.a. | A more cGAP was assessed in EFSA, 2013b which has not been notified by any MS. |

MRL: maximum residue level; MS: Member State; a.i.: active ingredient; a.s.: active substance; WG: water-dispersible granule; SC: suspension concentrate; cGAP: critical GAP; GAP: Good Agricultural Practice.
(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.
### A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F G or F(e) | 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 application (min) | Water L/ha min–max | Rate and unit | |
| Table grapes          | ES            | F          | Mildew                            | WG          | 44.4 g/kg | Foliar treatment – general (see also comment field) | 3 | – | – | 130 g a.i./ha | 28 | Application time: before flowering to bunch closing. Do not apply more than 0,133 kg a.i./ha. Application method: Manual application or application with tractor |
| Wine grapes           | ES            | F          | Mildew                            | WG          | 44.4 g/kg | Foliar treatment – general (see also comment field) | 3 | – | – | 130 g a.i./ha | 28 | Application time: before flowering to bunch closing. Do not apply more than 0,133 kg a.i./ha. Application method: Manual application or application with tractor |
| Potatoes              | FR            | F          | Late blight Phytophthora infestans | SC          | 62.5 g/L | Foliar treatment – broadcast spraying | 20–95 | 4 | 7 | 100 g a.i./ha | 7 | – |
| Onions                | IT            | F          | Peronospora destructor            | SC          | 62.5 g/L | Foliar treatment – broadcast spraying | 12–49 | 1–3 | 7 | – | – | 100 g a.i./ha | 7 | – |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Range of growth stages & season | Number min-max | Interval between application (min) | PHI (days) | Remarks |
|-----------------------|--------------|------------------------------------|-------------|-------------|--------------------------------|----------------|----------------------------------|------------|---------|
| Cucumbers             | PT F         | Mildew                             | SC 62.5 g/L | Foliar treatment – broadcast spraying | 1-3             | 7                               | –         | –       | 100 g a.i./ha | 3 Mixture with propamocarb |
| Courgettes            | PT F         | Mildew                             | SC 62.5 g/L | Foliar treatment – broadcast spraying | 1-3             | 7                               | –         | –       | 100 g a.i./ha | 3 Mixture with propamocarb |
| Melons                | PT F         | Mildew                             | SC 62.5 g/L | Foliar treatment – broadcast spraying | 1-3             | 7                               | –         | –       | 100 g a.i./ha | 3 Mixture with propamocarb |
| Pumpkins              | IT F         | *Pseudoperonospora cubensis*      | SC 62.5 g/L | Foliar treatment – broadcast spraying | 21-89           | 1-3                             | 8         | –       | 100 g a.i./ha | 3 – |
| Watermelons           | PT F         | Mildew                             | SC 62.5 g/L | Foliar treatment – broadcast spraying | 1-3             | 7                               | –         | –       | 100 g a.i./ha | 3 Mixture with propamocarb |
| Broccoli              | ES F         | Mildew                             | SC 62.5 g/L | Foliar treatment – general (see also comment field) | 3               | 7                               | –         | –       | 100 g a.i./ha | 14 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Crop and/or situation | MS or country | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|----------------------|---------------|---------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| Cauliflowers         | EL            | F             | P. cubensis                       | SC          | 62.5 g/L    | Foliar treatment – broadcast spraying | 13–49 1–3 7 | – – 100 g a.i./ha 14 | Pseudoperonospora cubensis is mentioned on the certificate but may be not appropriate as this is relevant for cucurbits |
| Brussels sprouts     | ES            | F             | Mildew                            | SC          | 62.5 g/L    | Foliar treatment – general (see also comment field) | 13–49 1 | – – 100 g a.i./ha 14 | 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Head cabbages        | ES            | F             | Mildew                            | SC          | 62.5 g/L    | Foliar treatment – general (see also comment field) | 3 7 | – – 100 g a.i./ha 14 | 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Kohlrabies           | ES            | F             | Mildew                            | SC          | 62.5 g/L    | Foliar treatment – general (see also comment field) | 13–49 1 | – – 100 g a.i./ha 14 | 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Lamb’s lettuces      | ES            | F             | Mildew                            | SC          | 62.5 g/L    | Foliar treatment – general (see also comment field) | 2 7 | – – 100 g a.i./ha 14 | 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Crop and/or situation | MS or country | F or G | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|--------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Lettuces              | PT           | F      | mildew                            | SC          | Foliar treatment – broadcast spraying | 1–3 7 | – – | 100 g a.i./ha | 7 | Mixture with propamocarb |
| Escaroles             | ES           | F      | Mildew                            | SC          | Foliar treatment – general (see also comment field) | 2 7 | – – | 100 g a.i./ha | 14 | 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Cresses               | ES           | F      | Mildew                            | SC          | Foliar treatment – general (see also comment field) | 2 7 | – – | 100 g a.i./ha | 14 | 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Land cresses          | ES           | F      | Mildew                            | SC          | Foliar treatment – general (see also comment field) | 2 7 | – – | 100 g a.i./ha | 14 | 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Roman rocket          | ES           | F      | Mildew                            | SC          | Foliar treatment – general (see also comment field) | 2 7 | – – | 100 g a.i./ha | 14 | 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Crop and/or situation | MS or country | F | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|----------------------|--------------|---|----------------------------------|-------------|------------|--------------------------------|------------|---------|
| Red mustards         | ES           | F | Mildew                          | SC 62.5 g/L | Foliar treatment – general (see also comment field) | 2 – 7 | – – | 100 g a.i./ha | 14 | 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Baby leaf crops      | ES           | F | Mildew                          | SC 62.5 g/L | Foliar treatment – general (see also comment field) | 2 – 7 | – – | 100 g a.i./ha | 14 | 500–1,000 l/ha. Application method (OUTDOOR): Manual application or application with tractor |
| Spinaches            | IT           | F | Peronospora farinosa            | SC 62.5 g/L | Foliar treatment – broadcast spraying | 13–49 | 1–3 | 7 | – – | 100 g a.i./ha | 14 | – |
| Purslanes            | FR           | F | –                               | SC 62.5 g/L | Foliar treatment – broadcast spraying | 13–51 | 2 | 10 | – – | 100 g a.i./ha | 14 | EFSA Journal 2015;13(11):4260 |
| Chards               | FR           | F | mildew                          | SC 62.5 g/L | Foliar treatment – broadcast spraying | 13–51 | 2 | 10 | – – | 100 g a.i./ha | 14 | – |
| Chervil              | IT           | F | Bremia lactucae, Peronospora spp. | SC 62.5 g/L | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – – | 100 g a.i./ha | 7 | – |
| Crop and/or situation | MS or country | F or G or FG or F(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 application (min) | Water L/ha min–max | Rate and unit | |
| Chives                | IT            | F                    | Bremia lactucae, Peronospora spp. | SC | 62.5 g/L | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 7 | – |
| Celery leaves        | IT            | F                    | Bremia lactucae, Peronospora spp. | SC | 62.5 g/L | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 7 | – |
| Parsley              | IT            | F                    | Bremia lactucae, Peronospora spp. | SC | 62.5 g/L | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 7 | – |
| Sage                 | IT            | F                    | Bremia lactucae, Peronospora spp. | SC | 62.5 g/L | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 7 | – |
| Rosemary             | IT            | F                    | Bremia lactucae, Peronospora spp. | SC | 62.5 g/L | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 7 | – |
| Thyme                | IT            | F                    | Bremia lactucae, Peronospora spp. | SC | 62.5 g/L | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 7 | – |
| Basil                | IT            | F                    | Bremia lactucae, Peronospora spp. | SC | 62.5 g/L | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 7 | – |
| 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) (d) | Remarks |
|-----------------------|---------------|----------------|----------------------------------|-------------|-------------|---------------------------------|----------------|---------|
| Laurel                | IT            | F              | *Bremia lactucae, Peronospora spp.* | SC           | 62.5 g/L   | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 7 | – |
| Tarragon              | IT            | F              | *Bremia lactucae, Peronospora spp.* | SC           | 62.5 g/L   | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 7 | – |

MRL: maximum residue level; MS: Member State; a.i.: active ingredient; a.s.: active substance; WG: water-dispersible granule; SC: suspension concentrate.
(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.
# A.3. Authorised indoor uses in EU

| Crop and/or situation | MS or country | F G or I(1) | 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 application (min) | Water L/ha min-max | Rate and unit |                     |             |
| Blackberries DE I     |               |             | Downy mildew of cane fruit (Peronospora rubi) | WG        | 44.4 g/kg | Foliar treatment – ultra-low volume spraying | 60–85      | 2 10 | – – | 120 g a.i./ha | 14  | At beginning of infestation and/or when first symptoms become visible |
| Tomatoes CZ I          |               |             | Phytophthora infestans            | SC        | 62.5 g/L  | Foliar treatment – broadcast spraying | 3          | 7  – | – – | 100 g a.i./ha | 1   | –                     |
| Cucumbers CZ I         |               |             | Pseudoperonospora cubensis        | SC        | 62.5 g/L  | Foliar treatment – broadcast spraying | 3          | 7  – | – – | 100 g a.i./ha | 1   | –                     |
| Gherkins SK I          |               |             |                                   | SC        | 62.5 g/L  | Foliar treatment – general (see also comment field) | 20–89      | 1 3 | 7  – | 100 g a.i./ha | 1   | Max 300 g fluopicolide/36 months |
| Courgettes SK I        |               |             |                                   | SC        | 62.5 g/L  | Foliar treatment – general (see also comment field) | 20–89      | 1 3 | 7  – | 100 g a.i./ha | 1   | Max 300 g fluopicolide/36 months |
| Melons EL I            |               |             | P. cubensis                      | SC        | 62.5 g/L  | Foliar treatment – broadcast spraying | 21–86      | 1 3 | 7  – | 100 g a.i./ha | 3   | –                     |
| Crop and/or situation | MS or country | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|---------------|----------------------------------|-------------|-------------|-------------------------------|------------|---------|
|                        |               |               |                                  | Type(b)     | Conc. a.s.  | Range of growth stages & season(c) | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit | Remarks |
| Pumpkins               | IT            | I             | R. cubensis                      | SC          | 62.5 g/L   | 21–89 | 1–3 | 8 | – | – | 100 g a.i./ha | 3 | – |
| Watermelons            | EL            | I             | R. cubensis                      | SC          | 62.5 g/L   | 21–86 | 1–3 | 7 | – | – | 100 g a.i./ha | 3 | – |
| Broccoli               | UK            | I             | Downy mildew                    | SC          | 62.5 g/L   | 14    | 1   | – | – | – | 100 g a.i./ha | n.a. | 1 indoor application only. Applications should be made using conventional hydraulic spray equipment at a maximum application rate of 1.6 L product/ha in a minimum water volume of 200 L water/ha |
| Cauliflower            | BE            | I             | Mildew, rust                    | SC          | 68.5 g/L   | 41–49 | 1–3 | 10 | – | – | 100 g a.i./ha | 15 | Applications/culture. Max 0.4 kg fluopicolide/36 months |
| 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 |
|-----------------------|---------------|----------------|------------------------------------|-------------|-------------|--------------------------------|----------|---------|
| Brussels sprouts      | UK            | I              | Downy mildew                       | SC          | Foliar treatment – general (see also comment field) | 14 1 | – – | 100 g a.i./ha | n.a. | 1 indoor application only. Applications should be made using conventional hydraulic spray equipment at a maximum application rate of 1.6 L product/ha in a minimum water volume of 200 L water/ha |
| Head cabbages         | UK            | I              | Downy mildew                       | SC          | Foliar treatment – general (see also comment field) | 14 1 | – – | 100 g a.i./ha | n.a. | 1 indoor application only. Applications should be made using conventional hydraulic spray equipment at a maximum application rate of 1.6 L product/ha in a minimum water volume of 200 L water/ha |
| 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 |
|-----------------------|--------------|---------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Kales                 | UK           | I       | Downy mildew                      | SC          | 62.5 g/L   | Foliar treatment – general (see also comment field) | 14        | 1       | –       | 100 g a.i./ha | n.a. |
|                       |              |         |                                   |             |            |                               |           |         |         |               |     |
| Lamb's lettuces       | FR           | I       | mildew                            | SC          | 62.5 g/L   | Foliar treatment – broadcast spraying | 13-51     | 2       | 10      | –       | 100 g a.i./ha |
|                       |              |         |                                   |             |            |                               |           |         |         | 21      |       |
| Lettuces              | IT           | I       | Bremia lactucae, Peronospora spp. | SC          | 62.5 g/L   | Foliar treatment – broadcast spraying | 13-47     | 1-2     | 8       | –       | 100 g a.i./ha |
|                       |              |         |                                   |             |            |                               |           |         |         | 14      |       |
| Cresses               | FR           | I       | Mildew                            | SC          | 62.5 g/L   | Foliar treatment – broadcast spraying | 13-51     | 2       | 10      | –       | 100 g a.i./ha |
|                       |              |         |                                   |             |            |                               |           |         |         | 21      |       |
| Land cresses          | FR           | I       | Mildew                            | SC          | 62.5 g/L   | Foliar treatment – broadcast spraying | 13-51     | 2       | 10      | –       | 100 g a.i./ha |
|                       |              |         |                                   |             |            |                               |           |         |         | 21      |       |

1 indoor application only. Applications should be made using conventional hydraulic spray equipment at a maximum application rate of 1.6 L product/ha in a minimum water volume of 200 L water/ha.
| Crop and/or situation | MS or country | FG or I(α) | Pests or Group of pests controlled       | Preparation               | Application Method(β) | Type(a) | Conc. a.s. | Water L/ha min–max | Water L/ha max–min | PHI (days)  | Remarks                  |
|-----------------------|---------------|------------|------------------------------------------|---------------------------|-----------------------|---------|------------|-------------------|-------------------|-------------|--------------------------|
| Roman rocket          | EL I          |            | Plasmopara petroselini, Plasmopara nivea | SC 62.5 g/L               | Foliar treatment – broadcast spraying | 13–49   | 1–2        | 7                 | –                 | 14          | Minor uses               |
| Red mustards          | FR I          |            | Mildew                                   | SC 62.5 g/L               | Foliar treatment – broadcast spraying | 13–51   | 2          | 10                | –                 | 21          | –                        |
| Baby leaf crops       | FR I          |            | Mildew                                   | SC 62.5 g/L               | Foliar treatment – broadcast spraying | 13–51   | 2          | 10                | –                 | 21          | –                        |
| Spinaches             | FR, BE I      |            | Mildew                                   | SC 62.5 g/L               | Foliar treatment – broadcast spraying | 13–51   | 2          | 10                | –                 | 14          | EFSA Journal 2015;13 (11):4260 |
| Purslanes             | FR, BE I      |            | –                                        | SC 62.5 g/L               | Foliar treatment – broadcast spraying | 13–51   | 2          | 10                | –                 | 14          | EFSA Journal 2015;13 (11):4260 |
| Chards                | BE I          |            | Mildew                                   | SC 62.5 g/L               | Foliar treatment – broadcast spraying | 14–47   | 1–2        | –                 | –                 | 14          | EFSA Journal 2018;16 (1):5135 |
| Chervil               | IT I          |            | Bremia lactucae, Peronospora spp.        | SC 62.5 g/L               | Foliar treatment – broadcast spraying | 13–47   | 1–3        | 8                 | –                 | 14          | –                        |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| Chives IT I           | Bremia lactucae, Peronospora spp. SC 62.5 g/L Foliar treatment – broadcast spraying | Foliar treatment – broadcast spraying | 13–47 1–3 8 | – – 100 g a.i./ha | 14 | – |
| Celery leaves IT I    | Bremia lactucae, Peronospora spp. SC 62.5 g/L Foliar treatment – broadcast spraying | Foliar treatment – broadcast spraying | 13–47 1–3 8 | – – 100 g a.i./ha | 14 | – |
| Parsley IT I          | Bremia lactucae, Peronospora spp. SC 62.5 g/L Foliar treatment – broadcast spraying | Foliar treatment – broadcast spraying | 13–47 1–3 8 | – – 100 g a.i./ha | 14 | – |
| Sage IT I             | Bremia lactucae, Peronospora spp. SC 62.5 g/L Foliar treatment – broadcast spraying | Foliar treatment – broadcast spraying | 13–47 1–3 8 | – – 100 g a.i./ha | 14 | – |
| Rosemary IT I         | Bremia lactucae, Peronospora spp. SC 62.5 g/L Foliar treatment – broadcast spraying | Foliar treatment – broadcast spraying | 13–47 1–3 8 | – – 100 g a.i./ha | 14 | – |
| Thyme IT I            | Bremia lactucae, Peronospora spp. SC 62.5 g/L Foliar treatment – broadcast spraying | Foliar treatment – broadcast spraying | 13–47 1–3 8 | – – 100 g a.i./ha | 14 | – |
| Basil IT I            | Bremia lactucae, Peronospora spp. SC 62.5 g/L Foliar treatment – broadcast spraying | Foliar treatment – broadcast spraying | 13–47 1–3 8 | – – 100 g a.i./ha | 14 | – |
## Pests or Group of pests controlled

| 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 |
|----------------------|--------------|----------------|------------------------------------|-------------|-------------|---------------------------------|------------|---------|
| Laurel               | IT           | I              | *Bremia lactucae,* *Peronospora* spp. | SC 62.5 g/L | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 14 | – |
| Tarragon             | IT           | I              | *Bremia lactucae,* *Peronospora* spp. | SC 62.5 g/L | Foliar treatment – broadcast spraying | 13–47 | 1–3 | 8 | – | – | 100 g a.i./ha | 14 | – |

MRL: maximum residue level; MS: Member State; a.i.: active ingredient; a.s.: active substance; WG: water-dispersible granule; SC: suspension concentrate.

(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.
### A.4. Import tolerance

| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|--------------------------------|------------|---------|
|                        |               |                                    | Type(b)     | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit |           |
| Potatoes               | US F          | Phytophthora infestans             | SC          | Foliar treatment – spraying | n.a. | 3 | – – | 130 g a.i./ha | 7 | US import tolerance |
| Cassava roots          | US F          | Phytophthora infestans             | SC          | Foliar treatment – spraying | n.a. | 3 | – – | 130 g a.i./ha | 7 | US import tolerance |
| Sweet potatoes         | US F          | Phytophthora infestans             | SC          | Foliar treatment – spraying | n.a. | 3 | – – | 130 g a.i./ha | 7 | US import tolerance |
| Yams                   | US F          | Phytophthora infestans             | SC          | Foliar treatment – spraying | n.a. | 3 | – – | 130 g a.i./ha | 7 | US import tolerance |
| Arrowroots             | US F          | Phytophthora infestans             | SC          | Foliar treatment – spraying | n.a. | 3 | – – | 130 g a.i./ha | 7 | US import tolerance |
| Beetrootes             | US F          | Phytophthora infestans             | SC          | Foliar treatment – spraying | n.a. | 3 | – – | 130 g a.i./ha | 7 | US import tolerance |
| Carrots                | US F          | Phytophthora infestans             | SC          | Foliar treatment – spraying | n.a. | 3 | – – | 130 g a.i./ha | 7 | US import tolerance |
| Celeriacs              | US F          | Phytophthora infestans             | SC          | Foliar treatment – spraying | n.a. | 3 | – – | 130 g a.i./ha | 7 | US import tolerance |
| Horseradishes          | US F          | Phytophthora infestans             | SC          | Foliar treatment – spraying | n.a. | 3 | – – | 130 g a.i./ha | 7 | US import tolerance |
| Jerusalem artichokes   | US F          | Phytophthora infestans             | SC          | Foliar treatment – spraying | n.a. | 3 | – – | 130 g a.i./ha | 7 | US import tolerance |
| 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 | PH (days) (d) | Remarks |
|-----------------------|--------------|----------------|-----------------------------------|-------------|-------------|-------------------------------|--------------|---------|
|                       |              |                |                                   | Type(b)     | Conc. a.s.  | Method kind                   | a.s./HL min-max | Water L/ha min-max | Rate and unit |              |         |
| Parsnips              | US F         | Phytophthora infestans | SC 480 g/L | Foliar treatment – spraying | n.a. 3      | – 130 g a.i./ha | 7 | US import tolerance |
| Parsley roots         | US F         | Phytophthora infestans | SC 480 g/L | Foliar treatment – spraying | n.a. 3      | – 130 g a.i./ha | 7 | US import tolerance |
| Radishes              | US F         | Phytophthora infestans | SC 480 g/L | Foliar treatment – spraying | n.a. 3      | – 130 g a.i./ha | 7 | US import tolerance |
| Salsifies             | US F         | Phytophthora infestans | SC 480 g/L | Foliar treatment – spraying | n.a. 3      | – 130 g a.i./ha | 7 | US import tolerance |
| Swedes                | US F         | Phytophthora infestans | SC 480 g/L | Foliar treatment – spraying | n.a. 3      | – 130 g a.i./ha | 7 | US import tolerance |
| Turnips               | US F         | Phytophthora infestans | SC 480 g/L | Foliar treatment – spraying | n.a. 3      | – 130 g a.i./ha | 7 | US import tolerance |
| Sweet peppers         | US F         | Fungi (unspecified) | SC 480 g/L | Foliar treatment – spraying | 3           | – 140 g a.i./ha | 2 | US import tolerance |
| Sugar beets           | US F         | Phytophthora infestans | SC 480 g/L | Foliar treatment – spraying | n.a. 3      | – 130 g a.i./ha | 7 | US import tolerance |

MRL: maximum residue level; MS: Member State; a.i.: active ingredient; a.s.: active substance; WG: water-dispersible granule; SC: suspension concentrate.
(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.
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) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Grapes      | Foliar: 3 × 170 g a.s./ha 3 × 1,700 g a.s./ha | 21 DALA (28 DAT₂) | Phenyl and pyridinyl ring labelled (United Kingdom, 2006) |
| Root crops                        | Potatoes    | Foliar: 2 × 200 g a.s./ha 2 × 2,000 g a.s./ha | 20 DALA | Phenyl and pyridinyl ring labelled (United Kingdom, 2006) |
| Leafy crops                       | Lettuce     | Foliar: 2 × 200 g a.s./ha | 14 DALA | Phenyl and pyridinyl ring labelled (United Kingdom, 2006) |
| |                          | Soil drench: 1 × 200 g a.s./ha | 21, 35 | Phenyl labelled (United Kingdom, 2006) |
| Pulses/oilseeds                   | Rapeseed    | Seed treatment: 1 × 120 g a.s./ha (eq. to 20 g a.s./kg seeds) | 43 (forage) 160 (seeds) | Phenyl and pyridinyl ring labelled, assessed by Czech Republic (2017) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Radish      | Bare soil: 1 × 400 g a.s./ha | 29, 133, 365 | Phenyl and pyridinyl ring labelled (United Kingdom, 2006) |
| Leafy crops                         | Lettuce     | Bare soil: 1 × 400 g a.s./ha | 29, 133, 365 | Phenyl and pyridinyl ring labelled (United Kingdom, 2006) |
| Cereal (small grain)                | Wheat       | Bare soil: 1 × 400 g a.s./ha | 29, 133, 365 | Phenyl and pyridinyl ring labelled (United Kingdom, 2006) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Yes        | Study performed with pyridinyl ring labelled fluopicolide (United Kingdom, 2006) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | Study performed with pyridinyl ring labelled fluopicolide (United Kingdom, 2006) |
| Sterilisation (20 min, 120°C, pH 6)      | Yes        | Study performed with pyridinyl ring labelled fluopicolide (United Kingdom, 2006) |
Can a general residue definition be proposed for primary crops? | Yes | Similar results observed in 4 different crop groups and for 3 different types of applications
---|---|---
Rotational crop and primary crop metabolism similar? | Yes | Similar but more extensive metabolism in rotational crops. Significant metabolites identified in rotational crops (e.g. M-05, M-08 and M-09) but less toxic than parent compound (EFSA, 2009b)
Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes | Hydrolysis studies only available for parent compound (minor deficiency for metabolite M-01)

**Plant residue definition for monitoring (RD-Mo)**

**RD-Mo:** Fluopicolide

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

**RD-RA1:** Fluopicolide

**RD-RA2:** 2,6-dichlorobenzamide (metabolite M-01)

**Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)**

**Fluopicolide**

**Matrices with high water and high acid content:**
- HPLC–MS/MS, LOQ 0.01 mg/kg (cabbage and grapes), ILV available (Germany, 2010; EFSA, 2011)
- GC–MS/MS, LOQ 0.002 mg/kg, QuEChERS (EURLs, 2018)
- GC–MS, LOQ 0.02 mg/kg (potatoes) or 0.1 mg/kg (grapes), ILV available (EFSA, 2009b)

**Matrices with high oil content:**
- GC–MSD, LOQ 0.01 mg/kg, QuOil method BVL L 13.04-5:2003-08 (EURLs, 2018)
- HPLC–MS/MS, LOQ 0.01 mg/kg, QuEChERS (EFSA, 2015b)

**Dry matrices:**
- GC–MS/MS, LOQ 0.01 mg/kg, QuEChERS EN 15662:2008 (EURLs, 2018)
- GC–MS, LOQ 0.02 mg/kg (wheat grain), ILV available (EFSA, 2009b)

**Hops:**
- LC–MS/MS, LOQ 0.05 mg/kg, confirmatory method and ILV are missing (EFSA, 2013b)

*a.s.: active substance; DAT: days after treatment; DAT2: days after second treatment; PBI: plant-back interval; GC–MS/MS: gas chromatography with tandem mass spectrometry; GC–MS: gas chromatography with mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; MSD: Mass selective detector.*
## B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category   | Commodity | T (°C) | Stability period | Compounds covered                                      | Comment/Source       |
|-----------------------------------|------------|-----------|--------|------------------|--------------------------------------------------------|----------------------|
|                                   | High water content | Cabbage | 18     | 30 Months        | Fluopicolide                                           | United Kingdom (2006) |
|                                   |            |          | -18    |                  | 2,6-dichlorobenzamide (metabolite M-01)                | United Kingdom (2006) |
|                                   | High starch content | Wheat grain | 18     | 30 Months        | Fluopicolide                                           | United Kingdom (2006) |
|                                   | High starch content | Potatoes | 18     | 30 Months        | Fluopicolide                                           | United Kingdom (2006) |
|                                   | High starch content |           |        |                  | 2,6-dichlorobenzamide (metabolite M-01)                | United Kingdom (2006) |
|                                   | High acid content | Grapes   | 18     | 30 Months        | Fluopicolide                                           | United Kingdom (2006) |
|                                   | High oil content | Sunflower seed | 18     | 24 Months        | Fluopicolide                                           | Czech Republic (2017) |
|                                   | High oil content | Sunflower seed |        |                  | 2,6-dichlorobenzamide (metabolite M-01)                | Czech Republic (2017) |
|                                   | Others     | Wheat straw | 18     | 18 Months        | Fluopicolide                                           | United Kingdom (2006) |
|                                   |            |           |        |                  | 2,6-dichlorobenzamide (metabolite M-01)                | United Kingdom (2006) |
B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials – Primary crops (RD-RA1)

| Commodity | Region/Indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|-----------|---------------|---------------------------------------------------------------|-----------------|------------------------|--------------|----------------|
| RD-Mo and RD-RA1: fluopicolide | | | | | | |
| Table and wine grapes | NEU | 0.21; 0.24; 0.27; 0.33; 0.34; 0.41; 0.41; 0.52; 0.63 | Trials compliant with GAP for table and wine grapes (Hungary, 2018) MRL_OECD = 1.12 | 1.5 | 0.63 | 0.34 |
| | SEU | 0.11; 0.11; 0.15; 0.16; 0.2; 0.21; 0.21; 0.28; 0.32; 0.36; 0.39; 0.4; 0.46; 0.54; 0.65; 0.69; 0.97; 1.1; 1.2 | Residue trials compliant with GAP for table and wine grapes (EFSA, 2009b) MRL_OECD = 1.75 | 2 | 1.20 | 0.36 |
| Blackberries | NEU | 0.20; 0.25; 0.38; 0.49 | Trials compliant with GAP (EFSA, 2015b). MRL_OECD = 0.99 | 1 | 0.49 | 0.32 |
| | Indoor | 0.13; 0.43; 0.60; 1.10 | Trials compliant with GAP (EFSA, 2015b). MRL_OECD = 2.19 | 3 | 1.10 | 0.52 |
| Potatoes | NEU | 17 × < 0.01 | Trials performed with 4 applications instead of 5 deemed applicable considering that the first application has no impact on the final residue levels (EFSA, 2012a) | 0.01* | < 0.01 | < 0.01 |
| | SEU | 14 × < 0.01; 0.01; 0.01; 0.02 | Trials on potatoes compliant with GAP. An MRL of 0.03 mg/kg is proposed due to the HR of 0.02 mg/kg (see also EFSA 2012a) MRL_OECD = 0.02 | 0.03 | 0.02 | < 0.01 |
| Import (US) | | | | | | |
| Tropical root and tuber vegetables (Cassava roots/manioc, Sweet potatoes, Yams, Arrowroots) | NEU | 14 × < 0.01 | Trials on potatoes compliant with GAP (EFSA, 2013b) | 0.01* | < 0.01 | < 0.01 |
| | SEU | 19 × < 0.01 | Trials on potatoes compliant with GAP (EFSA, 2013b). Extrapolation to the whole group of tropical root and tuber vegetables is applicable | 0.01* | < 0.01 | < 0.01 |
| Commodity                                      | Region/Indoor(a)       | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|------------------------------------------------|------------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|----------------|
| Carrots                                       | Import (US)            | < 0.01, 2 × 0.01, 2 × 0.03, 0.04, 0.13                              | Trials on carrots, applicable to support uses on all ‘other root and tuber vegetables except sugar beet’ (EFSA, 2013b) MRL\_OECD = 0.21                                                                                       | 0.2                    | 0.13         | 0.03           |
| Beetroots                                     |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Celeriacs/turip rooted celeries               |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Horseradishes                                 |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Jerusalem artichokes                          |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Parsnips                                      |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Parsley roots/Hamburg roots parsley           |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Salsifies                                     |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Swedes/rutabagas                             |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Turnips                                       |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Radishes                                      | NEU                    | < 0.01; < 0.01; 0.02; 0.03                                      | Trials compliant with GAP (EFSA, 2012a) MRL\_OECD = 0.06                                                                                                                                                | 0.06                   | 0.03         | 0.02           |
| Import (US)                                   |                        | 3 × 0.02; 0.03; 0.05; 0.1                                       | Trials on radishes compliant with GAP (EFSA, 2013b) MRL\_OECD = 0.17                                                                                                                                     | 0.2                    | 0.10         | 0.03           |
| Onions                                         | NEU                    | < 0.01; < 0.01; 0.02; 0.03; 0.03; 0.03; 0.06; 0.06; 0.07; 0.21    | Trials on onions compliant with GAP (EFSA, 2012a). Extrapolation to garlic and shallots is applicable MRL\_OECD = 0.29                                                                                       | 0.3                    | 0.21         | 0.03           |
| Garlic                                         |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Shallots                                      |                        |                                                                  |                                                                                                                                                                                                             |                        |              |                |
| Spring onions/green onions and Welsh onions   | NEU                    | 0.03; 0.06; 0.08; 0.18; 0.31; 0.59; 0.63; 0.82                   | Trials performed on leek compliant with GAP on spring onions (EFSA, 2011). Extrapolation from leek to spring onions is applicable MRL\_OECD = 1.55                                                        | 1.5                    | 0.82         | 0.25           |
## Commodity Region/Indoor\(^{(a)}\) Residue levels observed in the supervised residue trials (mg/kg) Comments/Source Calculated MRL (mg/kg) HR\(^{(b)}\) (mg/kg) STMR\(^{(c)}\) (mg/kg)

| Commodity | Region/Indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) |
|-----------|-------------------------|---------------------------------------------------------------|----------------|------------------------|----------------------|----------------------|
| Tomatoes  | NEU                     | 0.015; 0.05; 0.07; 0.08; 0.14; 0.14; 0.22; 0.23               | Trials compliant with GAP: 4 trials (0.015; 0.14; 0.22; 0.23) from Germany (2010) considered for EFSA (2011) 4 trials (0.05; 0.07; 0.08; 0.14) from the Czech Republic (2018); considered on tentative basis since validity of analytical method and conditions under which samples stored not stated MRL\(_{OECD} = 0.43\) | 0.5 (tentative)\(^{(e)}\) | 0.23                  | 0.11                 |
|           | Indoor                  | 0.063; 0.08; 0.085; 0.093; 0.14; 0.18; 0.20; 0.21            | Trials compliant with GAP (with 25% tolerance on application rate) taken from Germany (2010); considered for EFSA (2011) MRL\(_{OECD} = 0.39\) | 0.4                    | 0.21                  | 0.12                 |
| Sweet peppers/bell peppers | Import (US)            | 0.043; 0.044; 0.076; 0.090; 0.126; 0.131; 0.149; 0.300; 0.516; 0.523 | Trials performed in the USA, compliant with GAP (EFSA, 2009a) MRL\(_{OECD} = 0.93\) | 1                      | 0.52                  | 0.13                 |
| Cucumbers Courgettes | NEU                     | Cucumbers: 0.02; 0.02; 0.03; 0.08               | Trials on cucumbers and courgettes compliant with GAP for all cucurbits with edible peel (Germany, 2010 considered for EFSA, 2011) NEU and SEU data sets similar (U-test, 5%), MRL derived from merged data for cucumbers and courgettes MRL\(_{OECD} = 0.15\) | 0.15 (tentative)\(^{(e)}\) | 0.08                  | 0.03                 |
|           | SEU                     | Courgettes: 0.01; 0.03; 0.03; 0.08               | Trials on cucumbers compliant with GAP for all cucurbits with edible peel (Germany, 2010 considered for EFSA, 2011) MRL\(_{OECD} = 0.15\) | 0.15                   | 0.09                  | 0.04                 |
|           | Indoor                  | Cucumbers: 0.02; 0.02; 0.03; 0.03; 0.04; 0.04; 0.08; 0.09 | Trials on cucumbers compliant with GAP for all cucurbits with edible peel (Germany, 2010 considered for EFSA, 2011) MRL\(_{OECD} = 0.15\) | 0.15                   | 0.09                  | 0.04                 |
| Gherkins  | NEU                     | Cucumbers: 0.02; 0.02; 0.03; 0.08               | Trials on cucumbers compliant with GAP for gherkins (Germany, 2010 considered for EFSA, 2011) MRL\(_{OECD} = 0.15\) | 0.15                   | 0.08                  | 0.03                 |
|           | Indoor                  | Cucumbers: 0.02; 0.02; 0.03; 0.03; 0.04; 0.04; 0.08; 0.09 | Trials on cucumbers compliant with GAP for gherkins (Germany, 2010 considered for EFSA, 2011) MRL\(_{OECD} = 0.15\) | 0.15                   | 0.09                  | 0.04                 |
| Commodity             | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                       | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|----------------------|------------------|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------|---------------|----------------|
| Melons, Pumpkins, Watermelons | SEU              | 0.02; 0.03; 0.03; 0.04; 0.07; 0.08; 0.10 | Trials on melons compliant with GAP on melons, pumpkins and water melons (Italy, 2018) MRL\_OECD = 0.17 | 0.2                    | 0.10          | 0.04           |
|                      | Indoor           | 0.01; 0.03; 0.04; 0.05; 0.08; 0.08; 0.08 | Trials on melons compliant with GAP on melons, pumpkins and water melons (Italy, 2018) MRL\_OECD = 0.16 | 0.2                    | 0.08          | 0.05           |
| Broccoli, Cauliflower | NEU              | Cauliflower: 4 × < 0.01; 0.01 Broccoli: 2 × < 0.01; 0.01; 0.02; 0.1 | Combined data set of GAP-compliant trials performed on cauliflower and broccoli; Germany (2010) considered for EFSA (2011) and Lithuania (2018) (2 NEU and 2 SEU trials). MRL proposal is derived from merged N/SEU data sets (similar with U-test) MRL\_OECD = 0.15 | 0.15                  | 0.11          | < 0.01         |
|                      | SEU              | Cauliflower: 3 × < 0.01; 0.01; 0.06 Broccoli: < 0.01; 0.04; 0.05; 0.06; 0.11 | Trials performed on cauliflower, compliant with GAP for cauliflower (Belgium, 2018). Tentative extrapolation to broccoli for which a less critical GAP is authorised. It is noted that 2 additional trials (not validated) were also available in the BE evaluation report (< 0.01; 0.0103) MRL\_OECD = 0.22 | 0.3 (tentative)(f)    | 0.10          | < 0.01         |
| Brussels sprouts     | NEU              | 0.01; 0.03; 0.03; 0.04; 0.05; 0.05; 0.13 | Trials performed on Brussels sprouts compliant with GAP (Germany, 2010 considered for EFSA, 2011) MRL\_OECD = 0.19 | 0.2                    | 0.13          | 0.04           |
|                      | SEU              | –                                                             | No SEU trials on Brussels sprouts are available                                                        | –                      | –             | –              |
|                      | Indoor           | –                                                             | No indoor trials on Brussels sprouts are available                                                       | –                      | –             | –              |
| Head cabbages        | NEU              | < 0.01; < 0.01; 0.01; 0.03; 0.03; 0.08; 0.18 | Trials on head cabbage compliant with GAP (EFSA, 2011) MRL\_OECD = 0.28 | 0.3                    | 0.18          | 0.02           |
|                      | SEU              | 0.01; 0.01; 0.02; 0.03 | Trials on head cabbage compliant with GAP (EFSA, 2011) MRL\_OECD = 0.06 | 0.07                    | 0.03          | 0.02           |
|                      | Indoor           | –                                                             | No indoor trials on head cabbages are available                                                          | –                      | –             | –              |
| Commodity | Region/Indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) |
|-----------|------------------------|---------------------------------------------------------------|-----------------|------------------------|----------------------|-----------------------|
| Kales     | NEU                    | 0.16; 0.69; 0.80; 0.84                                        | Trials performed on Kale compliant with GAP; extrapolation to Chinese cabbage is applicable (EFSA, 2012a, 2014) MRL\(_{OECD} = 1.88\) | 2                      | 0.84                 | 0.75                  |
|           | Indoor                 | –                                                             | No indoor trials on kales are available. No authorised uses for Chinese cabbages indoor | –                     | –                    | –                     |
| Kohlrabies | NEU                    | < 0.01; < 0.01; 0.01; 0.02                                     | Trials performed on Kohlrabies compliant with GAP (EFSA, 2011) MRL\(_{OECD} = 0.03\) | 0.03                  | 0.02                 | 0.01                  |
|           | SEU                    | –                                                             | No outdoor SEU trials on Kohlrabies are available | –                     | –                    | –                     |
| Lamb’s lettuces/corn salads, Cresses and other sprouts and shoots, Land cresses, Red mustards, Baby leaf crops (including brassica species) | NEU | Open leaf varieties: 0.10; 0.11 Other varieties: < 0.01; < 0.01; 0.05; 0.15; 0.21; 0.34 | Trials performed on lettuce with 3 applications instead of 2, sampled at PHI 13–14 days (Italy 2011 considered for EFSA, 2012b) Extrapolation to similar lettuce crops is applicable but tentative (only 2 trials performed on lettuce open-leaf varieties) MRL\(_{OECD} = 0.57\) | 0.6 (tentative)\(^{(f)}\) | 0.34                 | 0.11                  |
|           | SEU                    | Open leaf varieties: 0.06; 0.36; 0.30; 1.2 Other varieties: < 0.01; 0.01; 0.04; 0.14 | Trials performed on lettuce with 3 applications instead of 2, sampled at PHI 13–14 days (Italy 2011 considered for EFSA, 2012b) Extrapolation to similar lettuce crops is applicable MRL\(_{OECD} = 1.87\) | 2 (tentative)\(^{(f)}\) | 1.20                 | 0.10                  |
|           | Indoor                 | Open leaf varieties: 0.024; 0.16; 3.7 Other varieties: 0.12; 0.27; 0.53; 2.2; 4.3 | Trials performed on lettuce with 3 applications instead of 2, sampled at PHI 21 days (Italy 2011 considered for EFSA, 2012b) Extrapolation to similar lettuce crops is applicable noting that only 3 trials were performed on lettuce open-leaf varieties MRL\(_{OECD} = 8.41\) | 9 (tentative)\(^{(f)}\) | 4.30                 | 0.40                  |
| Commodity                      | Region/Indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR \(^{(b)}\) (mg/kg) | STMR \(^{(c)}\) (mg/kg) |
|-------------------------------|---------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|------------------------|------------------------|
| Lettuces                      | NEU           | Open leaf varieties: 0.36; 0.41; Other varieties: 0.07; 0.12; 0.31; 0.6; 0.74; 0.82 | Trials performed on lettuce and compliant with GAP for lettuce (EFSA, 2012b); only 2 trials performed on open-leaf varieties; MRL\(_{OECD}\) = 1.52 | 1.5 (tentative)\(^{(f)}\) | 0.82                   | 0.39                   |
|                               | SEU           | Open leaf varieties: 0.14; 0.91; 1.8; 3.4; Other varieties: 0.07; 0.41; 0.46; 1.0 | Trials performed on lettuce and compliant with GAP for lettuces (EFSA, 2012b); MRL\(_{OECD}\) = 5.47 | 6                      | 3.40                   | 0.69                   |
| Indoor                        |               | Open leaf varieties: 0.18; 0.21; 0.27; 0.30; 0.49; 1.1; 2.8; 3.1 | Trials performed on open leaf varieties of lettuce and compliant with GAP (EFSA, 2015b); MRL\(_{OECD}\) = 5.89 | 6                      | 3.10                   | 0.40                   |
| Roman rocket/rucola           | NEU           | Open leaf varieties: 0.36; 0.41; Other varieties: 0.07; 0.12; 0.31; 0.6; 0.74; 0.82 | Direct extrapolation from lettuces NEU, noting that trials performed on lettuces are overdosed (3 applications instead of 2) and that only 2 trials are performed on open-leaf varieties; MRL\(_{OECD}\) = 1.52 | 1.5 (tentative)\(^{(f)}\) | 0.82                   | 0.39                   |
|                               | SEU           | Open leaf varieties: 0.06; 0.36; 0.30; 1.2; Other varieties: < 0.01; 0.01; 0.04; 0.14 | Direct extrapolation from lamb’s lettuce SEU, noting that trials performed on lettuces are overdosed (3 applications instead of 2); MRL\(_{OECD}\) = 1.87 | 2 (tentative)\(^{(f)}\) | 1.20                   | 0.10                   |
| Indoor                        |               | Open leaf varieties: 0.18; 0.21; 0.27; 0.30; 0.49; 1.1; 2.8; 3.1 | Direct extrapolation from lettuces indoor (GAP-compliant trials); MRL\(_{OECD}\) = 5.89 | 6                      | 3.10                   | 0.40                   |
| Escaroles/broad-leaved endives | SEU           | Open leaf varieties: 0.06; 0.36; 0.30; 1.2; Other varieties: < 0.01; 0.01; 0.04; 0.14 | Direct extrapolation from lamb’s lettuce SEU, noting that trials performed on lettuces are overdosed (3 applications instead of 2); MRL\(_{OECD}\) = 1.87 | 2 (tentative)\(^{(f)}\) | 1.20                   | 0.10                   |
| Commodity                          | Region/ Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|-----------------------------------|-----------------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------------------|---------------------------|
| Spinaches, Purslanes, Chards/beet leaves | NEU                          | 0.05; 0.15; 0.30; 0.33                                          | Trials performed on spinaches compliant with GAP (EFSA, 2012b); extrapolation to spinach similar is applicable MRL<sub>OECD</sub> = 0.73 | 0.8                    | 0.33                     | 0.23                      |
| | SEU                          | 0.14; 0.17; 0.38; 1.7               | Trials performed on spinaches compliant with GAP with 3 applications (EFSA, 2012b); tentative extrapolation to purslane and chards (only 2 applications are authorised for these crops) MRL<sub>OECD</sub> = 3.57 | 4 (tentative for purslane and chards)<sup>(f)</sup> | 1.70                    | 0.28                      |
| Indoor                            |                             | Open leaf varieties: 0.18; 0.21; 0.27; 0.30; 0.49; 1.1; 2.8; 3.1 | Direct extrapolation from lettuces indoor (GAP-compliant trials) MRL<sub>OECD</sub> = 5.89 | 6                     | 3.10                     | 0.40                      |
| Fresh herbs                        | NEU                          | Open leaf varieties: 0.36; 0.41 Other varieties: 0.07; 0.12; 0.31; 0.6; 0.74; 0.82 | Direct extrapolation from lettuces NEU, noting that trials performed on lettuces are overdosed (3 applications instead of 2) and that only 2 trials are performed on open-leaf varieties MRL<sub>OECD</sub> = 1.52 | 1.5 (tentative)<sup>(g)</sup> | 0.82                     | 0.39                      |
|                                  | SEU                          | Open leaf varieties: 0.14; 0.91; 1.8; 3.4 Other varieties: 0.07; 0.41; 0.46; 1.0 | Direct extrapolation from lettuces SEU (GAP-compliant trials) MRL<sub>OECD</sub> = 5.47 | 6                     | 3.40                     | 0.69                      |
| Indoor                            |                             | Open leaf varieties: 2 × 0.4; 4.0 Other varieties: 0.63; 0.68; 1.5; 2.7; 4.9 | Trials performed on lettuce and compliant with GAP for fresh herbs (EFSA, 2012b). Extrapolation to fresh herbs is applicable, noting that only 3 trials were performed on open-leaf varieties MRL<sub>OECD</sub> = 8.96 | 9                     | 4.90                     | 1.09                      |
| Leeks                             | NEU                          | 0.03; 0.06; 0.08; 0.18; 0.31; 0.59; 0.63; 0.82          | Trials performed on leek compliant with GAP (EFSA, 2011) MRL<sub>OECD</sub> = 1.55 | 1.5                    | 0.82                     | 0.25                      |
| Rapeseeds/canola seeds, Mustard seeds | NEU                          | 6 × < 0.01                                      | Trials performed on rapeseeds compliant with GAP for rapeseeds and mustard seed (Czech Republic, 2017) | 0.01*                  | < 0.01                   | < 0.01                    |
| Hops                              | NEU                          | < 0.05; < 0.05; < 0.05; 0.078               | Trials performed on hops compliant with GAP (Germany, 2018) MRL<sub>OECD</sub> = 0.11 | 0.15 (tentative)<sup>(g)</sup> | 0.08                     | 0.05                      |
### Commodity Region/Indoor(a) Residue levels observed in the supervised residue trials (mg/kg) Comments/Source Calculated MRL (mg/kg) HR(b) (mg/kg) STMR(c) (mg/kg)

| Commodity       | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|-----------------|------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|---------------|----------------|
| Sugar beet roots| Import (US)      | < 0.01; 0.01; 0.01; 0.03; 0.04(d); 0.04; 0.04; 0.05; 0.05; 0.06 | Trials performed in USA on sugar beet and compliant with GAP (EFSA, 2013b) MRLOECD = 0.11 | 0.15                   | 0.06          | 0.04          |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; PHI: preharvest interval.

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

Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

(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. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): This value corresponds to a highest residue level observed at a longer PHI (compared to GAP) within a decline residue trial.

(e): MRL is tentative because of missing information regarding the validity of half of the data set (see clarification required to the Czech Republic).

(f): MRL is tentative because GAP-compliant residue trials are missing.

(g): MRL is tentative because of data gaps on the analytical method for enforcement.
### B.1.2.2. Summary of residues data from the supervised residue trials – Primary crops (RD-RA2)

| Commodity | Region/Indoor<sup>a</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL<sup>b</sup> (mg/kg) | HR<sup>c</sup> (mg/kg) | STMR<sup>d</sup> (mg/kg) |
|-----------|---------------------------|---------------------------------------------------------------|-----------------|-----------------------------------|-----------------------|-----------------------|
| RD-RA2: 2,6-dichlorobenzamide (metabolite M-01) |                          |                                                               |                 |                                   |                       |                       |
| Table and wine grapes | NEU | < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; 0.013 | Trials compliant with GAP (Hungary, 2018) | (0.02) | 0.01 | < 0.01 |
|                         | SEU | < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; 0.02; 0.02; 0.02; 0.02; 0.02; 0.03; 0.03; 0.04; 0.05 | Residue trials compliant with GAP (EFSA, 2009b) MRL<sub>OEC</sub> = 0.06 | (0.07) | 0.05 | 0.02 |
| Blackberries | NEU | 0.015; 0.018 | Trials compliant with GAP (EFSA, 2015b) | – | – | – |
| Indoor | 3 × < 0.01 | Trials compliant with GAP (EFSA, 2015b) | (0.01*) | (tentative)<sup>e</sup> | < 0.01 | < 0.01 |
| Potatoes | NEU | 17 × < 0.01 | Trials performed with 4 applications instead of 5 deemed applicable considering that the first application has no impact on the final residue levels (EFSA, 2012a) | (0.01*) | < 0.01 | < 0.01 |
| SEU | 17 × < 0.01 | Trials on potatoes compliant with GAP (EFSA, 2012a) | (0.01*) | < 0.01 | < 0.01 |
| Import (US) | 19 × < 0.01 | Trials on potatoes compliant with GAP (EFSA, 2013b). Extrapolation to the whole group of tropical root and tuber vegetables is applicable | (0.01*) | < 0.01 | < 0.01 |
| Tropical root and tuber vegetables (Cassava roots/manioc, Sweet potatoes, Yams, Arrowroots) | Import (US) | 19 × < 0.01 | Trials on potatoes compliant with GAP (EFSA, 2013b). Extrapolation to the whole group of tropical root and tuber vegetables is applicable | (0.01*) | < 0.01 | < 0.01 |
| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL<sup>(b)</sup> (mg/kg) | HR<sup>(c)</sup> (mg/kg) | STMR<sup>(d)</sup> (mg/kg) |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|-------------------------------------|-----------------|------------------|
| Carrots   | Indoor<sup>(a)</sup>         | 7 × < 0.01                                                    | Trials on carrots, applicable to support uses on all 'other root and tuber vegetables except sugar beet' (EFSA, 2013b) | (0.01*)          | < 0.01 | < 0.01 |
| Beetroots | Import (US)                 | 4 × < 0.01                                                    | Trials compliant with GAP (EFSA, 2012a) | (0.01*)          | < 0.01 | < 0.01 |
| Celeriacs/turnip rooted celeries | 6 × 0.01 | Trials on radishes compliant with GAP (EFSA, 2013b) | (0.02) | 0.01 | 0.01 |
| Horseradishes |                     | 7 × < 0.01; 0.03<sup>(f)</sup>; 0.05<sup>(f)</sup>; 0.05<sup>(f)</sup> | Trials on onions compliant with GAP (EFSA, 2012a). Extrapolation to garlic and shallots is applicable MRL<sub>OECD</sub> = 0.09 | (0.09) | 0.05 | < 0.01 |
| Jerusalem artichokes | | 8 × < 0.01 | Trials on onions compliant with GAP (Greece, 2011; considered for EFSA, 2012a). No authorised uses for garlic and shallots in SEU | (0.01*) | < 0.01 | < 0.01 |
| Parsnips | NEU                         | 8 × < 0.01                                                    | Trials performed on leek compliant with GAP on spring onions (EFSA, 2011). Extrapolation from leek to spring onions is applicable | (0.01*) | < 0.01 | < 0.01 |
| Parsley roots/Hamburg roots parsley | | 8 × < 0.01 | Trials compliant with GAP: 4 trials from Germany (2010) considered for EFSA (2011), 4 trials from CZ (2018); considered on tentative basis since validity of analytical method and conditions under which samples stored not stated | (0.01*) <sup>(tentative)</sup> | < 0.01 | < 0.01 |
| Salsifis | NEU                         | 8 × < 0.01                                                    | Trials compliant with GAP (with 25% tolerance on application rate) taken from Germany (2010); considered for EFSA (2011) | (0.01*) | < 0.01 | < 0.01 |
| Swedes/rutabagas | | 8 × < 0.01 | | | | |
| Commodity                  | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL(b) (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) |
|---------------------------|------------------|------------------------------------------------------------------|---------------------------------------------------------------------------------|---------------------------|--------------|---------------|
| Sweet peppers/ bell peppers | Import (US)      | 10 × < 0.01                                                      | Trials performed in the USA, compliant with GAP (EFSA, 2009a)                    | (0.01*)                   | < 0.01       | < 0.01        |
| Cucumbers Courgettes      | NEU              | Cucumbers: 4 × < 0.01                                            | Trials on cucumbers and courgettes compliant with GAP for all cucurbits with edible peel (Germany, 2010 considered for EFSA, 2011). NEU and SEU data sets similar (U-test, 5%), MRL derived from merged data for cucumbers and courgettes | (0.01*) (tentative)(e) | < 0.01       | < 0.01        |
|                           | SEU              | Courgettes: 4 × < 0.01                                           |                                                                                |                           |              |               |
|                           | Indoor           | Cucumbers: 8 × < 0.01                                            | Trials on cucumbers compliant with GAP for all cucurbits with edible peel (Germany, 2010 considered for EFSA, 2011) | (0.01*)                   | < 0.01       | < 0.01        |
| Gherkins                  | NEU              | Cucumbers: 4 × < 0.01                                            | Trials on cucumbers compliant with GAP for gherkins (Germany, 2010 considered for EFSA, 2011) | (0.01*)                   | < 0.01       | < 0.01        |
|                           | Indoor           | Cucumbers: 8 × < 0.01                                            | Trials on cucumbers compliant with GAP for gherkins (Germany, 2010 considered for EFSA, 2011) | (0.01*)                   | < 0.01       | < 0.01        |
| Melons         | SEU              | 8 × < 0.01                                                       | Trials on melons compliant with GAP on melons, pumpkins and water melons (Italy, 2018) | (0.01*)                   | < 0.01       | < 0.01        |
| Pumpkins       | Indoor           | 8 × < 0.01                                                       | Trials on melons compliant with GAP on melons, pumpkins and water melons (Italy, 2018) | (0.01*)                   | < 0.01       | < 0.01        |
| Watermelons    | NEU              | 10 × < 0.01                                                      | Combined data set of GAP-compliant trials performed on cauliflower (5 NEU/5 SEU) and broccoli (5 NEU/5 SEU); Germany (2010) considered for EFSA (2011) and Lithuania (2018) (4 trials). MRL proposal is derived from merged N/SEU data sets (similar with U-test). Additional residues expected from rotational crops | (0.01*)                   | < 0.01       | < 0.01        |
|                           | SEU              | 10 × < 0.01                                                      |                                                                                |                           |              |               |
|                           | Indoor           | 4 × < 0.01                                                       | Trials performed on cauliflower, compliant with GAP for cauliflower (Belgium, 2018). Extrapolation to broccoli for which a less critical is authorised (acceptable since residues < 0.01). It is noted that 2 additional trials (not validated) were also available in the BE evaluation report (2 × < 0.01) | (0.01*) (tentative)(e) | < 0.01       | < 0.01        |
| Commodity                  | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL<sup>(b)</sup> (mg/kg) | HR<sup>(c)</sup> (mg/kg) | STMR<sup>(d)</sup> (mg/kg) |
|----------------------------|-----------------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-------------------------|-------------------------|
| Brussels sprouts           | NEU                         | $8 \times < 0.01$                                              | Trials performed on Brussels sprouts compliant with GAP (Germany, 2010 considered for EFSA, 2011). Additional residues expected from rotational crops<br> HR<sup>(c)</sup> = 0.01*                               | (0.01*)                             | < 0.01                  | < 0.01                  |
|                            | SEU                         | —                                                               | No SEU trials on Brussels sprouts are available                                                                                                                                                    | –                                    | –                       | –                       |
|                            | Indoor                      | —                                                               | No indoor trials on Brussels sprouts are available                                                                                                                                                    | –                                    | –                       | –                       |
| Head cabbages              | NEU                         | $8 \times < 0.01$                                              | Trials on head cabbage compliant with GAP (EFSA, 2011). Additional residues expected from rotational crops<br> HR<sup>(c)</sup> = 0.01*                               | (0.01*)                             | < 0.01                  | < 0.01                  |
|                            | SEU                         | $4 \times < 0.01$                                              | Trials on head cabbage compliant with GAP (EFSA, 2011). Additional residues expected from rotational crops<br> HR<sup>(c)</sup> = 0.01*                               | (0.01*)                             | < 0.01                  | < 0.01                  |
|                            | Indoor                      | —                                                               | No indoor trials on head cabbages are available                                                                                                                                                    | –                                    | –                       | –                       |
| Kales Chinese cabbages/petsai | NEU                      | $< 0.01; < 0.01; 0.02; 0.02$                                     | Trials performed on Kale compliant with GAP; extrapolation to Chinese cabbage is applicable (EFSA, 2012a, 2014). Additional residues expected from rotational crops MRL<sub>OECD</sub> = 0.04<br> HR<sup>(c)</sup> = 0.05                     | (0.05)                              | 0.02                    | 0.02                    |
|                            | Indoor                      | —                                                               | No indoor trials on kales are available. No authorised uses for Chinese cabbages indoor                                                                                                              | –                                    | –                       | –                       |
| Kohlrabies                 | NEU                         | $4 \times < 0.01$                                              | Trials performed on Kohlrabi compliant with GAP (EFSA, 2011). Additional residues expected from rotational crops<br> HR<sup>(c)</sup> = 0.01*                               | (0.01*)                             | < 0.01                  | < 0.01                  |
|                            | SEU                         | —                                                               | No outdoor SEU trials on kohlrabies are available                                                                                                                                                    | –                                    | –                       | –                       |
| Commodity | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL(b) (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) |
|-----------|------------------|---------------------------------------------------------------|-----------------|---------------------------|------------|----------------|
| Lamb’s lettuces/corn salads Cresses and other sprouts and shoots Land cresses Red mustards Baby leaf crops (including brassica species) | NEU | Open leaf varieties: $< 0.01; 0.01$ Other varieties: $< 0.01; < 0.01; 0.01; 0.02; 0.02$ | Trials performed on lettuce with 3 applications instead of 2, sampled at PHI 13–14 days (Italy 2011 considered for EFSA, 2012b). Extrapolation to similar lettuce crops is applicable but tentative (only 2 trials performed on open-leaf varieties). Additional residues expected from rotational crops MRL_{OECD} = 0.03 | (0.04) (tentative)(e) | 0.02 | 0.01 |
| | SEU | Open leaf varieties: $< 0.01; < 0.01; 0.02; 0.03$ Other varieties: $< 0.01; < 0.01; < 0.01; 0.03$ | Trials performed on lettuce with 3 applications instead of 2, sampled at PHI 13–14 days (Italy 2011 considered for EFSA, 2012b). Extrapolation to similar lettuce crops is applicable. Additional residues expected from rotational crops MRL_{OECD} = 0.05 | (0.06) (tentative)(e) | 0.03 | 0.01 |
| Indoor | Open leaf varieties: $< 0.01; 0.013; 0.024$ Other varieties: $< 0.01; 0.011; 0.013; 0.015; 0.017$ | Trials performed on lettuce with 3 applications instead of 2, sampled at PHI 21 days (Italy 2011 considered for EFSA, 2012b). Extrapolation to similar lettuce crops is applicable noting that only 3 trials were performed on lettuce open-leaf varieties. Additional residues expected from rotational crops MRL_{OECD} = 0.04 | (0.04) (tentative)(e) | 0.02 | 0.01 |
| Lettuces | NEU | Open leaf varieties: $2 \times 0.01$ Other varieties: $< 0.01; < 0.01; 0.01; 0.01; 0.02^{(f)}; 0.03$ | Trials performed on lettuce and compliant with GAP for lettuces (EFSA, 2012b); only 2 trials performed on open-leaf varieties. Additional residues expected from rotational crops MRL_{OECD} = 0.04 | (0.05) (tentative)(e) | 0.03 | 0.01 |
| | SEU | Open leaf varieties: $< 0.01; 0.016; 0.02^{(f)}; 0.04$ Other varieties: $< 0.01; < 0.01; 0.01; 0.03$ | Trials performed on lettuce and compliant with GAP for lettuces (EFSA, 2012b). Additional residues expected from rotational crops MRL_{OECD} = 0.06 | (0.07) | 0.04 | 0.01 |
| Indoor | Open leaf varieties: $< 0.01; < 0.01; < 0.01; 0.01; 0.014; 0.018; 0.032$ | Trials performed on open leaf varieties of lettuce and compliant with GAP (EFSA, 2015b). Additional residues expected from rotational crops MRL_{OECD} = 0.05 | (0.05) | 0.03 | 0.01 |
| Commodity                  | Region/Indoor | Residue levels observed in the supervised residue trials (mg/kg)                                                                 | Comments/Source                                                                 | Calculated MRL\(^{(b)}\) (mg/kg) | HR\(^{(c)}\) (mg/kg) | STMR\(^{(d)}\) (mg/kg) |
|---------------------------|---------------|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|----------------------------------|----------------------|-----------------------|
| Roman rocket/ruccola      | NEU           | Open leaf varieties: 2 \(\times\) 0.01 Other varieties: < 0.01; < 0.01; 0.01; 0.02\(^{(f)}\); 0.03                                                                        | Direct extrapolation from lettuces NEU, noting that trials performed on lettuces are overdosed (3 applications instead of 2) and that only 2 trials are performed on open-leaf varieties MRL\(_{OECD}\) = 0.04 | (0.05) (tentative)\(^{(e)}\)   | 0.03                 | 0.01                  |
|                           | SEU           | Open leaf varieties: < 0.01; < 0.01; 0.02; 0.03 Other varieties: < 0.01; < 0.01; < 0.01; 0.03                                                                              | Direct extrapolation from lamb’s lettuce SEU, noting that trials performed on lettuces are overdosed (3 applications instead of 2) MRL\(_{OECD}\) = 0.05 | (0.06) (tentative)\(^{(e)}\)   | 0.03                 | 0.01                  |
|                           | Indoor        | Open leaf varieties: < 0.01; < 0.01; < 0.01; 0.01; 0.01; 0.014; 0.018; 0.032                                                                                      | Direct extrapolation from lettuces indoor (GAP-compliant trials) MRL\(_{OECD}\) = 0.05 | (0.05)                           | 0.03                 | 0.01                  |
| Escaroles/broad-leaved endives | SEU         | Open leaf varieties: < 0.01; < 0.01; 0.02; 0.03 Other varieties: < 0.01; < 0.01; < 0.01; 0.03                                                                              | Direct extrapolation from lamb’s lettuce SEU, noting that trials performed on lettuces are overdosed (3 applications instead of 2) MRL\(_{OECD}\) = 0.05 | (0.06) (tentative)\(^{(e)}\)   | 0.03                 | 0.01                  |
| Spinaches Purslanes Chards/beet leaves | NEU       | 0.02; 0.04; 0.04\(^{(f)}\); 0.08                                                                                                                            | Trials performed on spinaches compliant with GAP (EFSA, 2012b); extrapolation to spinach similar is applicable. Additional residues expected from rotational crops MRL\(_{OECD}\) = 0.15 | (0.2)                            | 0.08                 | 0.04                  |
|                           | SEU           | 0.03\(^{(f)}\); 0.05; 0.05; 0.06                                                                                                                            | Trials performed on spinaches compliant with GAP with 3 applications (EFSA, 2012b); tentative extrapolation to purslane and chards is proposed (only 2 applications authorised for these crops). Additional residues expected from rotational crops MRL\(_{OECD}\) = 0.14 | (0.15) (tentative for purslane and chards)\(^{(e)}\) | 0.06                 | 0.05                  |
|                           | Indoor        | Lettuce open leaf varieties: < 0.01; < 0.01; < 0.01; 0.01; 0.014; 0.018; 0.032                                                                                  | Direct extrapolation from lettuces indoor (GAP-compliant trials) MRL\(_{OECD}\) = 0.05 | (0.05)                           | 0.03                 | 0.01                  |
| Commodity                  | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL(b) (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) |
|---------------------------|------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------|----------------|
| Fresh herbs               | NEU              | Open leaf varieties: 2 × 0.01 Other varieties: < 0.01; < 0.01; 0.01; 0.02(f); 0.03 | Direct extrapolation from lettuces NEU, noting that trials performed on lettuces are overdosed (3 applications instead of 2) and that only 2 trials are performed on open-leaf varieties. Additional residues expected from rotational crops MRL\_OECD = 0.04 | (0.05) (tentative)(e) | 0.03         | 0.01           |
|                           | SEU              | Open leaf varieties: < 0.01; 0.016; 0.02(f); 0.04 Other varieties: < 0.01; < 0.01; 0.01; 0.03 | Direct extrapolation from SEU (GAP-compliant trials) Additional residues expected from rotational crops MRL\_OECD = 0.06 | (0.07) | 0.04         | 0.01           |
|                           | Indoor           | Open leaf varieties: < 0.01; 0.018; 0.024(f) Other varieties: 0.011; 0.017; 0.015(f); 0.017; 0.022 | Trials performed on lettuce and compliant with GAP for fresh herbs (EFSA, 2012b). Extrapolation to fresh herbs is applicable, noting that only 3 trials were performed on open-leaf varieties MRL\_OECD = 0.05 | (0.05) | 0.02         | 0.02           |
| Leeks                     | NEU              | 8 × < 0.01                                                      | Trials performed on leek compliant with GAP (EFSA, 2011)                                                                                                                                                | (0.01*)                  | < 0.01       | < 0.01         |
| Rapeseeds/canola seeds    | NEU              | 6 × < 0.01                                                      | Trials performed on rapeseeds compliant with GAP for rapeseeds and mustard seed (CZ, 2017)                                                                                                               | (0.01*)                  | < 0.01       | < 0.01         |
| Mustard seeds             |                  |                                                                |                                                                                                                                                                                                            |                          |              |                |
| Hops                      | NEU              | < 0.05; < 0.05; 0.07; 0.077                                     | Trials performed on hops compliant with GAP (Germany, 2018) MRL\_OECD = 0.12                                                                                                                         | (0.15)                   | 0.08         | 0.06           |
| Sugar beet roots          | Import (US)      | 8 × < 0.01; 2 × 0.01                                            | Trials performed in USA on sugar beet and compliant with GAP (EFSA, 2013b) MRL\_OECD = 0.01                                                                                                             | (0.02)                   | 0.01         | < 0.01         |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; PHI: preharvest interval.

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

Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

(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): Calculated MRL for 2,6-dichlorobenzamide is reported here (between brackets) for information only. Since 2,6-dichlorobenzamide is not relevant for enforcement, these MRLs are not proposed.

(c): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(e): MRL is tentative because GAP-compliant residue trials are missing.

(f): This value corresponds to a highest residue level observed at a longer PHI (compared to GAP) within a decline residue trial.

(g): MRL is tentative because of missing information regarding the validity of half of the data set (see clarification required to the Czech Republic).
B.1.2.3. Residues in rotational crops

(a) Overall summary

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Yes |
| --- | --- |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Yes |

Translocation of residues was observed in all crops at all plant-back intervals (PBIs). Highest TRR were observed at PBI 29 days, in wheat straw (up to 13.6 mg eq./kg), radish tops (up to 6.71 mg eq/kg), wheat grain (up to 2.6 mg eq/kg) and lettuce (up to 1.01 mg eq/kg). Although total radioactivity tends to decline over time, significant levels were also found at the PBI of 365 days (up to 2 mg eq./kg in radish tops, 1.0 mg eq./kg in wheat straw and 0.62 mg eq./kg in lettuce).

Residues in rotational and succeeding crops expected based on field rotational crop study:

Fluopicolide: Occurrence of fluopicolide in rotational crops is only expected in cereals straw (up to 0.12 mg/kg) and in valerian roots (up to 4.96 mg/kg dried root; see also EFSA, 2015a). MRL and risk assessment values for fluopicolide can be derived for these commodities (tentative for cereal straw as it is a feed item). No residue uptake is expected in cereals grain, pulses and leafy vegetables. For root crops, no conclusion on the potential uptake in rotational crops can be drawn.

2,6-dichlorobenzamide (metabolite M-01): Only indicative results based on field rotational crops studies where soil concentration of 2,6-dichlorobenzamide was not representative of the PEC soil total (resulting from the multiannual use of fluopicolide at the critical GAP ‘PEC plateau background’ + maximal seasonal application rate). Occurrence of 2,6-dichlorobenzamide in rotational crops is expected in cereals straw (up to 0.03 mg/kg), leafy vegetables (up to 0.04 mg/kg) and valerian roots (up to 2.48 mg/kg dried root; see also EFSA, 2015a). Tentative risk assessment values for 2,6-dichlorobenzamide can be derived for these commodities. No residue uptake is expected in cereals grain and pulses (tentative conclusion only).

TRR: total radioactive residue; MRL: maximum residue level; GAP: Good Agricultural Practice; PEC: predicted environmental concentration.
### (b) Summary of residues data from the rotational crops residue trials

| Commodity              | Region/Indoor(a) | PBI (days)(b) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) |
|------------------------|------------------|---------------|--------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|----------------|
| **RD-Mo and RD-RA1: fluopicolide** |                  |               |                                                                                                                                |                                                                                                                                                                                                          |                        |              |                |
| Dry beans              | NEU/SEU          | 57–227        | 8 × < 0.01                                                                                                                   | Combined data set of field rotational crops trials performed in SEU (2) and NEU (6). Trials performed on faba beans and sampled for dry seeds (United Kingdom, 2006). No residues uptake is expected in pulses and oilseeds for fluopicolide                      | n.n.                    | n.n.         | n.n.           |
| Head cabbage           | NEU/SEU          | 33–49         | 8 × < 0.01                                                                                                                   | Combined data set of field rotational crops trials performed in SEU (2) and NEU (6). Trials performed on cabbage (United Kingdom, 2006). No residues uptake is expected in leafy crops for fluopicolide                                                                 | n.n.                    | n.n.         | n.n.           |
| Winter wheat grain     | NEU/SEU          | 28–39         | 8 × < 0.01                                                                                                                   | Combined data set of field rotational crops trials performed in SEU (4) and NEU (12). Trials performed on winter and spring wheat (United Kingdom, 2006). No residues uptake is expected in cereals grain for fluopicolide                                                                 | n.n.                    | n.n.         | n.n.           |
| Spring wheat straw     | NEU/SEU          | 174–227       | 8 × < 0.01                                                                                                                   | Combined data set of field rotational crops trials performed in SEU (2) and NEU (6). Trials performed on winter wheat (United Kingdom, 2006). Risk assessment values are derived                                                                 | 0.20 (tentative(e))     | 0.09         | 0.06           |
| Winter wheat straw     | NEU/SEU          | 28–39         | 0.02; 0.03; 0.05; 0.06; 0.07; 0.08; 0.09                                                                                       | Combined data set of field rotational crops trials performed in SEU (2) and NEU (6). Trials performed on winter wheat (United Kingdom, 2006). Risk assessment values are derived                                                                 | 0.20 (tentative(e))     | 0.12         | 0.06           |
| Spring wheat straw     | NEU/SEU          | 174–227       | 0.01; 0.02; 0.04; 0.06; 0.07; 0.12                                                                                           | Combined data set of field rotational crops trials performed in SEU (2) and NEU (6). Trials performed on spring wheat (United Kingdom, 2006). Risk assessment values are derived                                                                 | 0.01; 0.02; 0.04; 0.06; 0.07; 0.12 | 0.12         | 0.06           |
| Valerian roots         | NEU              | 365–730       | 0.32; 0.32; 0.4; 0.64; 0.72; 0.80; 1.12; 1.44; 1.52; 3.04; 4.96                                                             | Field rotational crops trials performed with valerian (EFSA, 2015a). Residue levels determined in fresh roots were recalculated for dried roots using a factor from fresh to dried roots of 8. MRL and risk assessment values can be derived | 7                       | 4.96         | 0.8            |
| Commodity           | Region/Indoor | PBI (days) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>(c)</sup> (mg/kg) | STMR<sup>(d)</sup> (mg/kg) |
|---------------------|---------------|------------|------------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------------------|---------------------------|
| RD-RA2: 2,6-dichlorobenzamide (metabolite M-01) |               |            |                                                                  |                                                                                |                        |                          |                           |
| Dry beans           | NEU/SEU       | 57–227     | 8 × < 0.01                                                      | Combined data set of field rotational crops trials performed in SEU (2) and NEU (6). Trials performed on faba beans and sampled for dry seeds (United Kingdom, 2006). No residues uptake is expected in pulses and oilseeds for metabolite M-01 | n.r.                   | n.n.                     | n.n.                      |
| Head cabbage        | NEU/SEU       | 33–49      | 6 × < 0.01; 0.02; 0.04                                           | Combined data set of field rotational crops trials performed in SEU (2) and NEU (6). Trials performed on cabbage (United Kingdom, 2006). Tentative risk assessment values are derived, which can apply to all leafy crops | n.r.                   | 0.04                     | < 0.01                    |
| Winter wheat grain  | NEU/SEU       | 28–39      | 8 × < 0.01                                                      | Combined data set of field rotational crops trials performed in SEU (4) and NEU (12). Trials performed on winter and spring wheat (United Kingdom, 2006). No residues uptake is expected in cereals grain for metabolite M-01 | n.r.                   | n.n.                     | n.n.                      |
| Spring wheat grain  | NEU/SEU       | 174–227    | 8 × < 0.01                                                      |                                                                                   | n.r.                   | n.n.                     | n.n.                      |
| Winter wheat straw  | NEU/SEU       | 28–39      | 7 × < 0.01; 0.01                                               | Combined data set of field rotational crops trials performed in SEU (2) and NEU (6). Trials performed on winter wheat (United Kingdom, 2006). Tentative risk assessment values are derived | n.r.                   | 0.01                     | < 0.01                    |
| Spring wheat straw  | NEU/SEU       | 174–227    | 6 × < 0.01; 0.01; 0.03                                          | Combined data set of field rotational crops trials performed in SEU (2) and NEU (6). Trials performed on spring wheat (United Kingdom, 2006). Tentative risk assessment values are derived | n.r.                   | 0.03                     | < 0.01                    |
| Commodity   | Region/Indoor(a) | PBI (days)(b) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                                                                                                                                                                     | Calculated MRL (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) |
|-------------|------------------|---------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|----------------|
| Valerian roots | NEU              | 365–730       | 0.16; 0.16; 0.2; 0.32; 0.36; 0.40; 0.56; 0.72; 0.76; 1.52; 2.48 | Field rotational crops trials performed with valerian (EFSA, 2015a). No analysis was performed for metabolite M-01. However, residue levels for this compound were tentatively estimated based on fluopicolide residues multiplied by a factor of 0.5(f) (EFSA, 2015a) | n.r.                  | 2.48         | 0.40           |

MRL: maximum residue level; Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition; n.n.: not needed; n.r.: not relevant.

*: 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, Country code: if non-EU trials.

(b): Plant-back interval: The interval (days, months, years) between the final application of a pesticide product to a primary crop and the planting of a rotational crop.

(c): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(e): Tentative MRLs derived for feed items.

(f): The residues for metabolite M-01 were estimated considering that fluopicolide and 2,6-dichlorobenzamide were observed at similar levels in the confined rotational crops studies and considering the respective molecular weights of fluopicolide and 2,6-dichlorobenzamide. Overall, a factor of 0.5 was proposed by EFSA to derive the 2,6-dichlorobenzamide residue levels from the measured fluopicolide residue levels (EFSA, 2015a). Results for 2,6-dichlorobenzamide are therefore considered indicative.
### B.1.2.4. Processing factors

| Processed commodity | Number of valid studies (a) | Processing Factor (PF) | CF<sub>p</sub>(b) | Comment/Source |
|---------------------|-----------------------------|------------------------|-------------------|----------------|
|                     |                             | Individual values | Median |                  |
| **RD-Mo and RD-RA1: fluopicolide** |                             |                       |        |                  |
| Table grapes, raisins | 2                           | 2.2; 6.5               | 4.3    | n.a.            |
| Wine grapes, wine     | 6                           | 0.28; 0.31; 0.38; 0.40; 0.43; 0.61 | 0.39   | n.a.            |
|                      |                             |                        |        | No distinction was made between white, red and heated red wine although processes are different. It was agreed in this case that the type of process had very little influence on transfer factors (United Kingdom, 2006) |
| Wine grapes, must     | 6                           | 0.38; 0.38; 0.44; 0.48; 0.57; 0.65 | 0.46   | n.a.            |
| Tomatoes, juice       | 4                           | 0.16; 0.27; 0.29; 0.32 | 0.28   | n.a.            |
| Melons, peeled        | 16                          | < 0.10; < 0.13; < 0.13; < 0.13; < 0.13; < 0.13; < 0.14; < 0.20; < 0.25; < 0.25; < 0.33; < 0.33; < 0.33; < 0.33; < 0.33; < 0.33; < 0.50 | < 0.25 | n.a.          |
|                     |                             |                        |        | Based on 16 residue trials compliant with GAP where residues in melon pulp is < 0.01 mg/kg (Italy, 2018) |
| **RD-RA2: 2,6-dichlorobenzamide (metabolite M-01)** |                             |                       |        |                  |
| Table grapes, raisins | 2                           | 3.0; 3.0               | 3      | n.a.            |
| Wine grapes, wine     | 6                           | < 0.50; 0.50; < 1.0; < 1.0; 1.0; 1.0 | 1      | n.a.            |
|                      |                             |                        |        | No distinction was made between white, red and heated red wine although processes are different. It was agreed in this case that the type of process had very little influence on transfer factors (United Kingdom, 2006) |
| Wine grapes, must     | 6                           | 0.50; 1.0; 1.0; 1.3; 1.5; 1.5 | 1.15   | n.a.            |
| Tomatoes, juice       | 1                           | 0.50                   | 0.50   | n.a.            |
| Melons, peeled        | 16                          | Not relevant           | n.r.   | n.a.            |
|                     |                             |                        |        | In the available residue trials compliant with GAP, residues of metabolite M-01 (BAM) were < 0.01 mg/kg in whole fruits and in pulp (Italy, 2018). No PF can be derived |

GAP: Good Agricultural Practice; PF: Processing factor (Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); CF<sub>p</sub>: Conversion factor for risk assessment in processed commodity (Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo).

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Median of the individual conversion factors for each processing residues trial (not applicable here).
(c): A tentative PF is derived based on a limited data set.
### B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | Comments |
|----------------------------|-----------------------------|---------------------------|----------------------------|------------------------|----------|
|                            | mg/kg bw per day            | mg/kg DM                  |                            |                        |          |
|                            | Median | Maximum | Median | Maximum |                                    |          |
| **Risk assessment residue definition 1: fluopicolide** | | | | | | |
| Cattle (all)               | 0.0600 | 0.0723 | 1.79   | 2.31    | Cattle (dairy)              | Kale, leaves | Yes | – |
| Cattle (dairy only)        | 0.0600 | 0.0723 | 1.56   | 1.88    | Cattle (dairy)              | Kale, leaves | Yes | – |
| Sheep (all)                | 0.0419 | 0.0545 | 1.26   | 1.62    | Sheep (lamb)                | Kale, leaves | Yes | – |
| Sheep (ewe only)           | 0.0419 | 0.0539 | 1.26   | 1.62    | Sheep (ram/ewe)             | Kale, leaves | Yes | – |
| Swine (all)                | 0.0220 | 0.0326 | 0.95   | 1.41    | Swine (breeding)            | Kale, leaves | Yes | – |
| Poultry (all)              | 0.0082 | 0.0174 | 0.12   | 0.25    | Poultry (layer)             | Swede, roots | Yes | – |
| Poultry (layer only)       | 0.0070 | 0.0174 | 0.10   | 0.25    | Poultry (layer)             | Swede, roots | Yes | – |
| Fish                       | –     | –     | –     | –      | –                          | –          | –   | – |
| **Risk assessment residue definition 2: 2,6-dichlorobenzamide (metabolite M-01)** | | | | | | |
| Cattle (all)               | 0.0052 | 0.0067 | 0.14   | 0.18    | Cattle (dairy)              | Kale, leaves | Yes | – |
| Cattle (dairy only)        | 0.0052 | 0.0067 | 0.14   | 0.18    | Cattle (dairy)              | Kale, leaves | Yes | – |
| Sheep (all)                | 0.0050 | 0.0059 | 0.12   | 0.14    | Sheep (lamb)                | Kale, leaves | Yes | – |
| Sheep (ewe only)           | 0.0039 | 0.0046 | 0.12   | 0.14    | Sheep (ram/ewe)             | Kale, leaves | Yes | – |
| Swine (all)                | 0.0020 | 0.0024 | 0.09   | 0.11    | Swine (breeding)            | Kale, leaves | Yes | – |
| Poultry (all)              | 0.0011 | 0.0018 | 0.02   | 0.03    | Poultry (layer)             | Cabbage, heads, leaves | No  | – |
### Relevant groups (subgroups)

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup\(^{(a)}\) | Most critical commodity\(^{(b)}\) | Trigger exceeded (Y/N) | Comments |
|----------------------------|-----------------------------|-------------------------------|--------------------------------|------------------------|----------|
| Poultry (layer only)       | mg/kg bw per day            | Poultry (layer)               | Cabbage, heads, leaves        | No                     |          |
| Fish                       | mg/kg DM                    |                                |                                |                        |          |

bw: body weight; DM: dry matter.
\(^{(a)}\): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
\(^{(b)}\): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

### 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/d) | Duration (days) | Comment/Source                                                                 |
|-------------------------------|--------------|-------------------|-----------------|--------------------------------------------------------------------------------|
| Lactating cow                 |              |                   |                 | Study performed with phenyl and pyridinyl ring-labelled fluopicolide. Dose rate recalculated assuming body weight of 650 kg and feed intake of 25 kg per day (originally reported as 1 mg a.s./kg feed)/United Kingdom (2006) |
|                               |              | 0.038             | 7               | Study performed with phenyl and pyridinyl ring-labelled fluopicolide. Dose rate recalculated assuming body weight of 650 kg and feed intake of 25 kg per day (originally reported as 10 mg a.s./kg feed)/United Kingdom (2006) |
|                               |              | 0.385             | 7               | Study performed with phenyl and pyridinyl ring-labelled fluopicolide. Dose rate recalculated assuming body weight of 650 kg and feed intake of 25 kg per day (originally reported as 10 mg a.s./kg feed)/United Kingdom (2006) |
| Laying hen                    |              |                   |                 | Study performed with phenyl and pyridinyl ring-labelled fluopicolide. Dose rate recalculated assuming body weight of 1.9 kg and feed intake of 0.13 kg per day (originally reported as 1 mg a.s./kg feed)/United Kingdom (2006) |
|                               |              | 0.068             | 14              | Study performed with phenyl and pyridinyl ring-labelled fluopicolide. Dose rate recalculated assuming body weight of 1.9 kg and feed intake of 0.13 kg per day (originally reported as 10 mg a.s./kg feed)/United Kingdom (2006) |
|                               |              | 0.684             | 14              | Study performed with phenyl and pyridinyl ring-labelled fluopicolide. Dose rate recalculated assuming body weight of 1.9 kg and feed intake of 0.13 kg per day (originally reported as 10 mg a.s./kg feed)/United Kingdom (2006) |
### Time needed to reach a plateau concentration in milk and eggs (days)

|          | Milk | Eggs |
|----------|------|------|
|          | 4    | 8    |

### Metabolism in rat and ruminant similar

- Yes
- –

### Can a general residue definition be proposed for animals?

- Yes
- –

### Animal residue definition for monitoring (RD-Mo)

- **RD-Mo**: Fluopicolide

### Animal residue definition for risk assessment (RD-RA)

- **RD-RA1**: Fluopicolide
- **RD-RA2**: 2,6-dichlorobenzamide (metabolite M-01)

### Fat soluble residues

- No
- –

### Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)

- **Milk, muscle, fat, liver and kidney:**
  - HPLC–MS/MS, LOQ 0.01 mg/kg (milk), 0.02 mg/kg (muscle), 0.05 mg/kg (fat, liver, kidney); ILV missing (data gap)
  - Missing method for eggs (data gap)

- EURLs reported screening data for QuEChERS methods using HPLC–MS-QToF for milk and meat with screening detection levels (SDL) of 0.005 mg/kg and 0.01 mg/kg respectively (EURLs, 2018)

- It is noted that a multi-residues method (DFG method S19) was validated by JMPR with a LOQ of 0.01 mg/kg in milk, cream, meat, liver and eggs (FAO, 2009). However, not assessed in this review

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a.s.: active substance; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; LOQ: limit of quantification; ILV: independent laboratory validation; QToF: quadrupole time-of-flight.
## B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal   | Commodity | T (°C) | Stability period Value | Stability period Unit | Compounds covered                                      | Comment/Source                  |
|------------------------------------|----------|-----------|--------|------------------------|-----------------------|--------------------------------------------------------|--------------------------------|
|                                    | Bovine   | Muscle    | –18    | 4                      | Months               | Fluopicolide                                           | United Kingdom (2006)          |
|                                    | Bovine   | Fat       | –18    | 4                      | Months               | Fluopicolide                                           | United Kingdom (2006)          |
|                                    | Bovine   | Liver     | –18    | 9                      | Months               | Fluopicolide                                           | United Kingdom (2006)          |
|                                    | Bovine   | Kidney    | –18    | 9                      | Months               | Fluopicolide                                           | United Kingdom (2006)          |
|                                    | Bovine   | Milk      | –18    | 2                      | Months               | Fluopicolide                                           | United Kingdom (2006)          |
|                                    | Bovine   | Muscle    | –18    | 4                      | Months               | 2,6-dichlorobenzamide (metabolite M-01)                 | United Kingdom (2006)          |
|                                    | Bovine   | Fat       | –18    | 4                      | Months               | 2,6-dichlorobenzamide (metabolite M-01)                 | United Kingdom (2006)          |
|                                    | Bovine   | Liver     | –18    | 9                      | Months               | 2,6-dichlorobenzamide (metabolite M-01)                 | United Kingdom (2006)          |
|                                    | Bovine   | Kidney    | –18    | 9                      | Months               | 2,6-dichlorobenzamide (metabolite M-01)                 | United Kingdom (2006)          |
|                                    | Bovine   | Milk      | –18    | 2                      | Months               | 2,6-dichlorobenzamide (metabolite M-01)                 | United Kingdom (2006)          |
|                                    | Poultry  | Eggs      | –       | –                      | –                    | –                                                      | No study available (not required) |

*Animal products: Bovine (available studies)*
### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies: fluopicolide (RD-Mo and RD-RA1)

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) |
|------------------|---------------------------------------------|------------------------------------------|
|                  | Mean | Highest | STMR<sub>Mo</sub><sup>(a)</sup> (mg/kg) | HR<sub>Mo</sub><sup>(b)</sup> (mg/kg) |
| **Cattle (all)** | Closest feeding level (0.06 mg/kg bw; 1N rate)<sup>(c)</sup> | | |
| Muscle           | < 0.02 < 0.02 | < 0.02 | < 0.02 | 0.02* (tentative)<sup>(g)</sup> |
| Fat              | < 0.05 < 0.05 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| Liver            | < 0.05 < 0.05 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| Kidney           | < 0.05 < 0.05 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| **Cattle (dairy only)** | Closest feeding level (0.06 mg/kg bw; 1N rate)<sup>(c)</sup> | | |
| Milk<sup>(d)</sup> | < 0.01 n.a. | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(g)</sup> |
| **Sheep (all)** | Closest feeding level (0.06 mg/kg bw; 1.5N rate)<sup>(c)</sup> | | |
| Muscle           | < 0.02 < 0.02 | < 0.02 | < 0.02 | 0.02* (tentative)<sup>(g)</sup> |
| Fat              | < 0.05 < 0.05 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| Liver            | < 0.05 < 0.05 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| Kidney           | < 0.05 < 0.05 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| **Sheep (ewe only)** | Closest feeding level (0.06 mg/kg bw; 1.5N rate)<sup>(c)</sup> | | |
| Milk<sup>(d)</sup> | < 0.01 n.a. | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(g)</sup> |
| **Swine (all)** | Closest feeding level (0.02 mg/kg bw; 1N rate)<sup>(c)</sup> | | |
| Muscle           | < 0.02 < 0.02 | < 0.02 | < 0.02 | 0.02* (tentative)<sup>(g)</sup> |
| Fat              | < 0.05 < 0.05 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| Liver            | < 0.05 < 0.05 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| Kidney           | < 0.05 < 0.05 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| **Poultry (all)** | Metabolism study as surrogate of feeding study (0.68 mg/kg bw; 40N rate)<sup>(f)</sup> | | |
| Muscle           | n.a. | < 0.01 | < 0.02 | < 0.02 | 0.02* (tentative)<sup>(g)</sup> |
| Fat              | n.a. | < 0.01 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| Liver            | n.a. | < 0.01 | < 0.05 | < 0.05 | 0.05* (tentative)<sup>(g)</sup> |
| **Poultry (layer only)** | Metabolism study as surrogate of feeding study (0.68 mg/kg bw; 40N rate)<sup>(f)</sup> | | |
| Eggs             | n.a. | 0.02 | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(h)</sup> |

RD: residue definition; RA: risk assessment; Mo: monitoring; bw: body weight; n.a.: not applicable; n.r.: not reported.

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

(a): Median residues expressed according to the residue definition, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition, recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.

(d): For milk, mean was derived from samplings performed from day 4 to day 28.

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

(f): In the absence of feeding study performed with laying hens, results of the metabolism study were used to assess residue levels of fluopicolide in hen tissues and eggs.

(g): MRL is tentative because a ILV is required for the analytical method validated in milk, muscle, fat, liver and kidney.

(h): MRL is tentative because there is no analytical method validated in eggs. A default LOQ is proposed based on information reported by JMPR (FAO, 2009).
B.2.2.2. Summary of the residue data from livestock feeding studies: 2,6-dichlorobenzamide (RD-RA2)

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|-----------------------|----------------------|
|                  | Mean | Highest | STMR<sub>Mo</sub><sup>(a)</sup> (mg/kg) | HR<sub>Mo</sub><sup>(b)</sup> (mg/kg) |
| Cattle (all)     |      |         |                                    |                      |
| Muscle           | < 0.02 | < 0.02 | < 0.02 | < 0.02 | (0.02*)<sup>(g)</sup> |
| Fat              | < 0.05 | < 0.05 | < 0.05 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Liver            | < 0.05 | < 0.05 | < 0.05 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Kidney           | < 0.05 | < 0.05 | < 0.05 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Cattle (dairy only) |      |         |                                    |                      |
| Milk             | < 0.01 | n.a.    | < 0.01 | < 0.01 | (0.01*)<sup>(g)</sup> |
| Sheep (all)      |      |         |                                    |                      |
| Muscle           | < 0.02 | < 0.02 | < 0.02 | < 0.02 | (0.02*)<sup>(g)</sup> |
| Fat              | < 0.05 | < 0.05 | < 0.05 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Liver            | < 0.05 | < 0.05 | < 0.05 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Kidney           | < 0.05 | < 0.05 | < 0.05 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Sheep (ewe only) |      |         |                                    |                      |
| Milk             | < 0.01 | n.a.    | < 0.01 | < 0.01 | (0.01*)<sup>(g)</sup> |
| Swine (all)      |      |         |                                    |                      |
| Muscle           | < 0.02 | < 0.02 | < 0.02 | < 0.02 | (0.02*)<sup>(g)</sup> |
| Fat              | < 0.05 | < 0.05 | < 0.05 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Liver            | < 0.05 | < 0.05 | < 0.05 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Kidney           | < 0.05 | < 0.05 | < 0.05 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Poultry (all)    |      |         |                                    |                      |
| Muscle           | n.a. | < 0.01 | < 0.01 | < 0.02 | (0.02*)<sup>(g)</sup> |
| Fat              | n.a. | < 0.01 | < 0.01 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Liver            | n.a. | 0.36   | < 0.05 | < 0.05 | (0.05*)<sup>(g)</sup> |
| Poultry (layer only) |    |         |                                    |                      |
| Eggs             | n.a. | 0.02   | < 0.01 | < 0.01 | (0.01*)<sup>(g)</sup> |

RD: residue definition; RA: risk assessment; Mo: monitoring; bw: body weight; n.a.: not applicable; n.r.: not reported.

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

(a): Median residues expressed according to the residue definition, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition, recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.

(d): For milk, mean was derived from samplings performed from day 4 to day 28.

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

(f): In the absence of feeding study performed with laying hens, results of the metabolism study were used to assess residue levels of 2,6-dichlorobenzamide in hen tissues and eggs.

(g): MRLs are not needed for 2,6-dichlorobenzamide. However, the calculated values are reported here (between brackets) for information only. It is noted that the residue levels assessed for 2,6-dichlorobenzamide do not take into consideration the direct livestock exposure to this compound. However, considering that the residue transfer in livestock commodities extremely low and considering that the livestock exposure to 2,6-dichlorobenzamide is 10 times lower than the exposure to fluopicolide, this is deemed acceptable.
### B.3. Consumer risk assessment

#### B.3.1. Consumer risk assessment for fluopicolide without consideration of the existing CXLs

| ARfD | 0.18 mg/kg bw (EFSA, 2009a) |
|------|----------------------------|
| Highest IESTI, according to EFSA PRIMo (rev.2) | Scarole (broad-leaf endive): 58.3% of ARfD |
| NESTI (% ARfD) | Not assessed in this review |
| Assumptions made for the calculations | The calculation is based on the highest residue (HR) levels expected in raw agricultural commodities according to the GAPs reported in this review. For melons, pumpkins and watermelons the peeling processing factor derived in this review (< 0.25) was applied. For valerian roots, potential residue uptakes from rotational crops were considered using HR of the field rotational crops residue trials |

| ADI | 0.08 mg/kg bw per day (EFSA, 2009a) |
|------|----------------------------|
| TMDI according to EFSA PRIMo | Not assessed in this review |
| NTMDI, according to (to be specified) | Not assessed in this review |
| Highest IEDI, according to EFSA PRIMo (rev.2) | 2.4% ADI (WHO Cluster diet B) |
| NEDI (% ADI) | Not assessed in this review |
| Assumptions made for the calculations | The calculation is based on the median residue (STMR) levels derived for raw agricultural commodities according to the GAPs reported in this review. For melons, pumpkins and watermelons the peeling processing factor derived in this review (< 0.25) was applied. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation, except for valerian root for which residues from rotational crops were taken into account using the STMR derived from the field rotational crops residue trials |

ADfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; IESTI: international estimated short-term intake; GAP: Good Agricultural Practice.

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

| Metabolite(s) | Not assessed in this review |
|----------------|----------------------------|
| ADI (mg/kg bw per day) | Not assessed in this review |
| Intake of groundwater metabolites (% ADI) | Not assessed in this review |
B.3.2. Consumer risk assessment for fluopicolide with consideration of the existing CXLs

**ARfD**

Highest IESTI, according to EFSA PRIMo (rev.2)

| Scenario CX1: | Scarole (broad-leaf endive): 825.7% of ARfD  
Kale: 638.5% of ARfD  
Celery: 357.1% of ARfD  
Chinese cabbage: 350.7% of ARfD  
Lettuce: 254.1% of ARfD  
Spinach: 213.5% of ARfD  
Beet leaves (chard): 165.8% of ARfD  
Purslane: 142.7% of ARfD  
Head cabbage: 114.0% of ARfD |
| Scenario CX2: | Scarole (broad-leaf endive): 58.3% of ARfD |

**NESTI (% ARfD)**

Not assessed in this review

**Assumptions made for the calculations**

Scenario CX1:
For those commodities having a CXL higher than the EU MRL proposal, highest residue levels applied in the EU scenario were replaced by the highest residue levels derived by JMPR

Scenario CX2:
The CXLs for scarole (broad-leaf endive), kale, celery, Chinese cabbage, lettuce, spinach, beet leaves (chard), purslane and head cabbage were excluded from the calculation. All other input values remain unchanged

**ADI**

0.18 mg/kg bw (EFSA, 2009a)

**TMDI according to EFSA PRIMo**

Not assessed in this review

**NTMDI, according to (to be specified)**

Not assessed in this review

**Highest IEDI, according to EFSA PRIMo (rev.2)**

**NEDI (% ADI)**

Not assessed in this review

**Assumptions made for the calculations**

Scenario CX1:
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

Scenario CX2:
The CXLs for scarole (broad-leaf endive), kale, celery, Chinese cabbage, lettuce, spinach, beet leaves (chard), purslane and head cabbage were excluded from the calculation. All other input values remain unchanged

ARfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; IESTI: international estimated short-term intake; CXL: codex maximum residue limit; MRL: maximum residue level.

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; CXL: codex maximum residue limit; MRL: maximum residue level.
### B.3.3. Consumer risk assessment for 2,6-dichlorobenzamide

| ARfD | 0.3 mg/kg bw (EFSA, 2009a) |
|------|----------------------------|
| Highest IESTI, according to EFSA PRIMo (rev.2) | Scarole (broad-leaf endive): 2.0% of ARfD |
| NESTI (% ARfD) | Not assessed in this review |
| Assumptions made for the calculations | Input values are derived considering the residues of 2,6-dichlorobenzamide arising from the use of fluopicolide only. It is assumed that residues of 2,6-dichlorobenzamide from dichlobenil are not expected as this substance is not authorised in the EU. The calculation is based on the highest residue (HR) levels expected from primary and rotational crops (according to the GAPs reported in this review) and residues of M-01 which are associated with the CXLs of fluopicolide (assessed by JMPR (FAO, 2014)). Highest values between levels derived in this review and levels derived by JMPR were considered, noting that for scarole (broad-leaf endive), kale, celery, Chinese cabbage, lettuce, spinach, beet leaves (chard), purslane and head cabbage, the residue levels derived by JMPR were disregarded since already excluded in scenario CX2 (see Appendix B.3.2). |

ARfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; IESTI: international estimated short-term intake; GAP: Good Agricultural Practice; CXL: codex maximum residue limit.

| ADI | 0.05 mg/kg bw per day (EFSA, 2009a) |
|------|----------------------------|
| TMDI according to EFSA PRIMo | Not assessed in this review |
| NTMDI, according to (to be specified) | Not assessed in this review |
| Highest IEDI, according to EFSA PRIMo (rev.2) | 1.3% ADI (FR toddler) |
| NEDI (% ADI) | Not assessed in this review |
| Assumptions made for the calculations | Input values are derived considering the residues of 2,6-dichlorobenzamide arising from the use of fluopicolide only. It is assumed that residues of 2,6-dichlorobenzamide from dichlobenil are not expected as this substance is not authorised in the EU. The calculation is based on the median residue (STMR) levels expected from primary and rotational crops (according to the GAPs reported in this review) and residues which are associated with the CXLs of fluopicolide (assessed by JMPR (FAO, 2014)). Highest values between levels derived in this review and levels derived by JMPR were considered, noting that for scarole (broad-leaf endive), kale, celery, Chinese cabbage, lettuce, spinach, beet leaves (chard), purslane and head cabbage, the residue levels derive by JMPR were disregarded since already excluded in scenario CX2 (see appendix B.3.2). |

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; GAP: Good Agricultural Practice; CXL: codex maximum residue limit.
## B.4. Proposed MRLs

| Code number | Commodity                        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment  |
|-------------|----------------------------------|-------------------------|----------------------|-------------|----------|
| 151010      | Table grapes                     | 2                       | 2                    | 2           | Recommended (a) |
| 151020      | Wine grapes                      | 2                       | 2                    | 2           | Recommended (a) |
| 153010      | Blackberries                     | 3                       | –                    | 3           | Recommended (b) |
| 211000      | Potatoes                         | 0.03                    | –                    | 0.03        | Recommended (b) |
| 212010      | Cassava roots/maniaoc             | 0.01                    | –                    | 0.01*       | Recommended (b) |
| 212020      | Sweet potatoes                   | 0.01                    | –                    | 0.01*       | Recommended (b) |
| 212030      | Yams                             | 0.01                    | –                    | 0.01*       | Recommended (b) |
| 212040      | Arrowroots                       | 0.01                    | –                    | 0.01*       | Recommended (b) |
| 213010      | Beetroots                        | 0.15                    | –                    | 0.2         | Recommended (b) |
| 213020      | Carrots                          | 0.15                    | –                    | 0.2         | Recommended (b) |
| 213030      | Celeriacs/turnip rooted celeries | 0.15                    | –                    | 0.2         | Recommended (b) |
| 213040      | Horseradishes                    | 0.15                    | –                    | 0.2         | Recommended (b) |
| 213050      | Jerusalem artichokes             | 0.15                    | –                    | 0.2         | Recommended (b) |
| 213060      | Parsnips                         | 0.15                    | –                    | 0.2         | Recommended (b) |
| 213070      | Parsley roots/Hamburg roots parsley | 0.15                  | –                    | 0.2         | Recommended (b) |
| 213080      | Radishes                         | 0.15                    | –                    | 0.2         | Recommended (b) |
| 213090      | Salsifies                        | 0.15                    | –                    | 0.2         | Recommended (b) |
| 213100      | Swedes/rutabagas                 | 0.15                    | –                    | 0.2         | Recommended (b) |
| 213110      | Turnips                          | 0.15                    | –                    | 0.2         | Recommended (b) |
| 220010      | Garlic                           | 0.3                     | –                    | 0.3         | Recommended (b) |
| 220020      | Onions                           | 1                       | 1                    | 1           | Recommended (c) |
| 220030      | Shallots                          | 0.3                     | –                    | 0.3         | Recommended (b) |
| 220040      | Spring onions/green onions and Welsh onions | 10                        | 10                   | 10          | Recommended (c) |
| 231010      | Tomatoes                         | 1                       | 1                    | 1           | Recommended (d) |
| 231020      | Sweet peppers/bell peppers       | 1                       | 1                    | 1           | Recommended (a) |
| 231030      | Aubergines (egg plants)          | 1                       | 1                    | 1           | Recommended (e) |
| 231040      | Okra, lady’s fingers             | 1                       | 1                    | 1           | Recommended (e) |
| 232010      | Cucumbers                        | 0.5                     | 0.5                  | 0.5         | Recommended (c) |
| 232020      | Gherkins                         | 0.5                     | 0.5                  | 0.5         | Recommended (c) |
| 232030      | Courgettes                       | 0.5                     | 0.5                  | 0.5         | Recommended (c) |
| 233010      | Melons                           | 0.5                     | 0.5                  | 0.5         | Recommended (c) |
| 233020      | Pumpkins                         | 0.5                     | 0.5                  | 0.5         | Recommended (c) |
| 233030      | Watermelons                      | 0.5                     | 0.5                  | 0.5         | Recommended (c) |
| 241010      | Broccoli                         | 2                       | 2                    | 2           | Recommended (d) |
| 241020      | Cauliflowers                     | 2                       | 2                    | 2           | Recommended (d) |
| 242010      | Brussels sprouts                 | 0.2                     | 0.2                  | 0.2         | Recommended (a) |
| 242020      | Head cabbages                    | 0.2                     | 7                    | 0.3         | Recommended (f) |
| 243010      | Chinese cabbages/pe-tsai         | 2                       | 30                   | 2           | Recommended (f) |
| 243020      | Kales                            | 2                       | 30                   | 2           | Recommended (f) |
| 244000      | Kohlrabies                        | 0.03                    | –                    | 0.03        | Recommended (b) |

**Enforcement residue definition:** flupicolide
| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review |
|-------------|-----------|------------------------|----------------------|----------------------|
| 251010      | Lamb’s lettuces/corn salads | 9                      | 30                    | 30 Recommended\(^\text{(d)}\) |
| 251020      | Lettuces | 9                      | 30                    | 6 Recommended\(^\text{(f)}\) |
| 251030      | Escaroles/broad-leaved endives | 1.5                    | 30                    | 2 Further consideration needed\(^\text{(g)}\) |
| 251040      | Cresses and other sprouts and shoots | 9                      | 30                    | 30 Recommended\(^\text{(d)}\) |
| 251050      | Land cresses | 9                      | 30                    | 30 Recommended\(^\text{(d)}\) |
| 251060      | Roman rocket/rucoola | 9                      | 30                    | 30 Recommended\(^\text{(c)}\) |
| 251070      | Red mustards | 9                      | 30                    | 30 Recommended\(^\text{(d)}\) |
| 251080      | Baby leaf crops (including brassica species) | 9                      | 30                    | 30 Recommended\(^\text{(d)}\) |
| 252010      | Spinaches | 6                      | 30                    | 6 Recommended\(^\text{(f)}\) |
| 252020      | Purslanes | 6                      | 30                    | 6 Recommended\(^\text{(f)}\) |
| 252030      | Chards/beet leaves | 6                      | 30                    | 6 Recommended\(^\text{(f)}\) |
| 253000      | Vine leaves (grape leaves) | 0.01*                  | 30                    | 30 Recommended\(^\text{(e)}\) |
| 254000      | Water cress | 0.01*                  | 30                    | 30 Recommended\(^\text{(e)}\) |
| 256010      | Chervil | 9                      | 30                    | 30 Recommended\(^\text{(c)}\) |
| 256020      | Chives | 9                      | –                     | 9 Recommended\(^\text{(b)}\) |
| 256030      | Celery leaves | 9                      | –                     | 9 Recommended\(^\text{(b)}\) |
| 256040      | Parsley | 9                      | –                     | 9 Recommended\(^\text{(b)}\) |
| 256050      | Sage | 9                      | –                     | 9 Recommended\(^\text{(b)}\) |
| 256060      | Rosemary | 9                      | –                     | 9 Recommended\(^\text{(b)}\) |
| 256070      | Thyme | 9                      | –                     | 9 Recommended\(^\text{(b)}\) |
| 256080      | Basil and edible flowers | 9                      | –                     | 9 Recommended\(^\text{(b)}\) |
| 256090      | Laurel/bay leaf | 9                      | –                     | 9 Recommended\(^\text{(b)}\) |
| 256100      | Tarragon | 9                      | –                     | 9 Recommended\(^\text{(b)}\) |
| 270030      | Celery | 0.01*                  | 20                    | Further consideration needed\(^\text{(h)}\) |
| 270060      | Leeks | 1.5                    | –                     | 1.5 Recommended\(^\text{(b)}\) |
| 401060      | Rapseseds/canola seeds | 0.01*                  | –                     | 0.01* Recommended\(^\text{(b)}\) |
| 401080      | Mustard seeds | 0.01*                  | –                     | 0.01* Recommended\(^\text{(b)}\) |
| 633000      | Herbal infusions from roots | 7                      | –                     | 7 Recommended\(^\text{(i)}\) |
| 700000      | Hops | 0.7                    | –                     | 0.15 Further consideration needed\(^\text{(j)}\) |
| 900010      | Sugar beet roots | 0.15                   | –                     | 0.15 Recommended\(^\text{(b)}\) |
| 1011010     | Swine muscle | 0.01*                  | 0.01*                 | 0.02* Further consideration needed\(^\text{(k)}\) |
| 1011020     | Swine fat tissue | 0.01*                  | 0.01*                 | 0.05* Further consideration needed\(^\text{(k)}\) |
| 1011030     | Swine liver | 0.01*                  | 0.01*                 | 0.05* Further consideration needed\(^\text{(k)}\) |
| 1011040     | Swine kidney | 0.01*                  | 0.01*                 | 0.05* Further consideration needed\(^\text{(k)}\) |
| 1012010     | Bovine muscle | 0.01*                  | 0.01*                 | 0.02* Further consideration needed\(^\text{(k)}\) |
| 1012020     | Bovine fat tissue | 0.01*                  | 0.01*                 | 0.05* Further consideration needed\(^\text{(k)}\) |
| 1012030     | Bovine liver | 0.01*                  | 0.01*                 | 0.05* Further consideration needed\(^\text{(k)}\) |
| 1012040     | Bovine kidney | 0.01*                  | 0.01*                 | 0.05* Further consideration needed\(^\text{(k)}\) |
| 1013010     | Sheep muscle | 0.01*                  | 0.01*                 | 0.02* Further consideration needed\(^\text{(k)}\) |
| 1013020     | Sheep fat tissue | 0.01*                  | 0.01*                 | 0.05* Further consideration needed\(^\text{(k)}\) |
### Review of the existing MRLs for flupiculide

| Code number | Commodity             | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                                      |
|-------------|-----------------------|-------------------------|----------------------|-------------|----------------------------------------------|
| 1013030     | Sheep liver           | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed (k)            |
| 1013040     | Sheep kidney          | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed (k)            |
| 1014010     | Goat muscle           | 0.01*                   | 0.01*                | 0.02*       | Further consideration needed (k)            |
| 1014020     | Goat fat tissue       | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed (k)            |
| 1014030     | Goat liver            | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed (k)            |
| 1014040     | Goat kidney           | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed (k)            |
| 1015010     | Equine muscle         | 0.01*                   | 0.01*                | 0.02*       | Further consideration needed (k)            |
| 1015020     | Equine fat tissue     | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed (k)            |
| 1015030     | Equine liver          | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed (k)            |
| 1015040     | Equine kidney         | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed (k)            |
| 1016010     | Poultry muscle        | 0.01*                   | 0.01*                | 0.02*       | Further consideration needed (k)            |
| 1016020     | Poultry fat tissue    | 0.01*                   | –                    | 0.05*       | Further consideration needed (j)            |
| 1016030     | Poultry liver         | 0.01*                   | 0.01*                | 0.05*       | Further consideration needed (k)            |
| 1020010     | Cattle milk           | 0.02                    | 0.02                 | 0.02        | Further consideration needed (l)            |
| 1020020     | Sheep milk            | 0.02                    | 0.02                 | 0.02        | Further consideration needed (l)            |
| 1020030     | Goat milk             | 0.02                    | 0.02                 | 0.02        | Further consideration needed (l)            |
| 1020040     | Horse milk            | 0.02                    | 0.02                 | 0.02        | Further consideration needed (l)            |
| 1030000     | Birds eggs            | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed (k)            |
| –           | Other commodities of  | See Reg. 832/2018       | –                    | –           | Further consideration needed (m)            |
|             | plant and/or animal   |                         |                      |             |                                              |
|             | origin                |                         |                      |             |                                              |

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

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

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).

(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).

(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-V in Appendix E).

(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination F-VII in Appendix E).

(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).

(f): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination H-VI in Appendix E).

(g): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination F-V in Appendix E).

(h): There are no relevant authorisations or import tolerances reported at EU level; CXL is supported by data but a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-VI in Appendix E).

(i): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. However, MRL fully supported by data is derived to take into account the uptake in rotational crops (EFSA, 2015a); no risk to consumers is identified (equivalent to combination H-I in Appendix E).

(j): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination F-I in Appendix E).

(k): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination F-III in Appendix E).

(l): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination F-V in Appendix E).

(m): 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_fluopicolide (EU1)**

### Fluopicolide

| Status of the active substance: | LOQ (mg/kg bw): | Proposed LOQ: |
|--------------------------------|-----------------|---------------|
| Pesticide Residue Intake Model (PRIMo) | 0.08 | 0.18 |

| Toxicological end points | ADI (mg/kg bw per day): | ARfD (mg/kg bw): |
|--------------------------|-------------------------|------------------|
| Source of ADI: | EFSAs (2009a) | Source of ARfD: | EFSAs (2009a) |
| Year of evaluation: | | Year of evaluation: | |

- **Source of ADI:** EFSAs (2009a)
- **Source of ARfD:** EFSAs (2009a)

### Year of Evaluation

- 02

### No of diets exceeding ADI:

- ---

#### Highest calculated TMDI values in % of ADI

| Commodity/group of commodities | MS Diet | 2nd contributor to MS diet | 3rd contributor to MS diet | pTMRLs at LOQ |
|--------------------------------|---------|---------------------------|---------------------------|---------------|
| **Wine grapes** | WHO Cluster diet B | 0.8 | Lettuce | 0.3 | Lettuce |
| **Sugar beet (root)** | FR all population | 1.8 | Lettuce | 0.1 | Lettuce |
| **Sugar beet (root)** | UK Toddler | 1.1 | Lettuce | 0.3 | Milk and cream |
| **Milk and cream** | NL child | 0.4 | Table grapes | 0.3 | Table grapes |
| **Milk and cream** | IE adult | 0.6 | Table grapes | 0.2 | Other leafy brassica |
| **Spinach** | FR toddler | 0.5 | Tomato | 0.3 | Spinach |
| **Spinach** | PT General population | 1.1 | Tomato | 0.1 | Milk and cream |
| **Table grapes** | DE child | 0.6 | Tomato | 0.1 | Milk and cream |
| **Table grapes** | WHO cluster diet E | 0.7 | Tomato | 0.1 | Lettuce |
| **Table grapes** | UK Infant | 0.5 | Tomato | 0.1 | Milk and cream |
| **Table grapes** | WHO cluster diet D | 0.2 | Tomato | 0.1 | Milk and cream |
| **Table grapes** | WHO regional European diet | 0.3 | Tomato | 0.1 | Milk and cream |
| **Table grapes** | WHO Cluster diet F | 0.3 | Tomato | 0.1 | Milk and cream |
| **Table grapes** | ES adult | 0.5 | Tomato | 0.1 | Milk and cream |
| **Table grapes** | NL general | 0.3 | Tomato | 0.1 | Milk and cream |
| **Table grapes** | UK Adult | 0.5 | Tomato | 0.1 | Milk and cream |
| **Table grapes** | FR infant | 0.3 | Tomato | 0.1 | Milk and cream |
| **Milk and cream** | ES child | 0.4 | Tomato | 0.1 | Milk and cream |
| **Milk and cream** | UK vegetarian | 0.4 | Tomato | 0.1 | Milk and cream |
| **Wine grapes** | DK adult | 0.6 | Tomato | 0.1 | Milk and cream |
| **Wine grapes** | SE general population 90th percentile | 0.2 | Tomato | 0.1 | Milk and cream |
| **Wine grapes** | IT adult | 0.3 | Tomato | 0.1 | Milk and cream |
| **Wine grapes** | DK child | 0.2 | Tomato | 0.1 | Milk and cream |
| **Milk and cream** | IT kids/toddler | 0.2 | Tomato | 0.1 | Milk and cream |
| **Wine grapes** | PL general population | 0.1 | Tomato | 0.1 | Milk and cream |
| **Milk and cream** | FI adult | 0.1 | Tomato | 0.1 | Milk and cream |
| **Wine grapes** | LT adult | 0.1 | Tomato | 0.1 | Milk and cream |

### Conclusion:

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

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.
The acute risk assessment is based on the ARfD.
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS, with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

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

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

### Table: 

| No of commodities for which ARfD/ADI is exceeded (IESTI 1) | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|
| **Highest % of ARfD/ADI Commodities** | **pTMRL/Threshold MRL (mg/kg)** | **Highest % of ARfD/ADI Commodities** | **pTMRL/Threshold MRL (mg/kg)** | **Highest % of ARfD/ADI Commodities** | **pTMRL/Threshold MRL (mg/kg)** | **Highest % of ARfD/ADI Commodities** | **pTMRL/Threshold MRL (mg/kg)** |
|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|
| Unprocessed commodities | | | | | | | |
| 58.3 Scarole (broad-leaf) 1.2/- | 43.7 Table grapes 1.2/- | 21.2 Table grapes 1.2/- | 21.2 Table grapes 1.2/- |
| 50.8 Lettuce 3.4/- | 38.9 Spinach 3.1/- | 20.8 Lettuce 3.4/- | 16.7 Chinese cabbage 0.84/- |
| 43.7 Table grapes 1.2/- | 30.5 Lettuce 3.4/- | 17.8 Purslane 3.1/- | 16.2 Purslane 3.1/- |
| 38.9 Spinach 3.1/- | 22.9 Beet leaves 3.1/- | 16.7 Chinese cabbage 0.84/- | 15.8 Wine grapes 1.2/- |
| 31.5 Kale 0.84/- | | 15.8 Wine grapes 1.2/- | |

For processed commodities, no exceedance of the ARfD/ADI was identified.

### Table: 

| No of critical MRLs (IESTI 1) | No of critical MRLs (IESTI 2) |
|--------------------------------|--------------------------------|
| --- | --- |

### Table: 

| No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|------------------------------------------------|------------------------------------------------|
| **Highest % of ARfD/ADI Commodities** | **pTMRL/Processed commodities** (mg/kg) |
|------------------------------------------------|------------------------------------------------|
| Processed commodities | | |
| 21.9 Grape juice 1.2/- | 2.6 Wine 1.2/- |
| 3.1 Carrot, juice 0.13/- | 0.3 Raisins 1.2/- |
| 2.2 Tomato juice 0.23/- | 0.2 Tomato (preserved) 0.23/- |
| 1.0 Celery juice 0.13/- | 0.0 Bread/pizza 0.01/- |
| 0.3 Wine 1.2/- | 0.0 Potato urea (flakes) 0.02/- |

### Conclusion:

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

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

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**Review of the existing MRLs for fluopicolide**

- **PRIMo_fluopicolide (CX1)**

| Fluopicolide |
|--------------|
| **Status of the active substance:** | Code no.: |
| LOQ (mg/kg bw): | Proposed LOQ: |

| Toxicological endpoints |
|--------------------------|
| ADI (mg/kg bw per day): | ARfD (mg/kg bw): |
| Source of ADI: | Source of ARfD: |
| Year of evaluation: | Year of evaluation: |

| 0.08 | 0.18 |

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI minimum – maximum |
|--------------------------------|------------------------------------------|
|                                |                                          |

| Highest calculated TMDI values in % of ADI |
|------------------------------------------|
| MS Diet | Highest contributor to MS diet (in % of ADI) |
|         | Commodity/group of commodities                |
|---------|-----------------------------------------------|
| NL adult| 4.0 Spinach                                   |
| FR toddler | 7.6 Spinach                              |
| WHO Cluster diet B | 3.9 Lettuce                  |
| IT adult | 4.1 Lettuce                                   |
| ES adult | 5.8 Lettuce                                   |
| IT kids/toddler | 3.1 Lettuce                           |
| ES child | 4.5 Lettuce                                   |
| WHO regional European diet | 4.0 Lettuce                  |
| IE adult | 2.2 Other leafy brassica                     |
| NL general | 1.5 Spinach                                 |
| WHO cluster diet O | 2.0 Chinese cabbage |
| FR infant | 4.8 Spinach                                    |
| FR all population | 2.0 Other lettuce and other salad plants |
| WHO Cluster diet F | 3.2 Lettuce                                |
| DE child | 2.2 Spinach                                   |
| WHO cluster diet E | 1.0 Lettuce                                |
| UK vegetarian | 1.5 Lettuce                               |
| UK Toddler | 1.1 Sugar beet (root)                        |
| UK Adult | 1.3 Lettuce                                   |
| DK child | 1.5 Lettuce                                   |
| UK Infant | 1.0 Milk and cream                           |
| FL adult | 0.8 Lettuce                                   |
| LT adult | 0.7 Lettuce                                   |
| PT General population | 1.1 Wine grapes |
| PL general population | 0.5 Head cabbage |
| DK adult | 0.6 Wine grapes                               |

| 2nd contributor to MS diet (in % of ADI) |
|-----------------------------------------|
| Commodity/group of commodities                |
| 2.2 Scarlet (broad-leaf endive)            |
| 1.0 Milk and cream                         |
| 0.9 Chinese cabbage                        |
| 0.9 Best leaves (chard)                    |
| 0.9 Other lettuce and other salad plants   |
| 0.9 Spinach                                |
| 0.5 Head cabbage                           |
| 1.3 Spinach                                |
| 1.0 Spinach                                |
| 0.7 Lettuce                                |
| 0.7 Chinese cabbage                        |
| 0.7 Wine grapes                            |
| 0.7 Sugar beet (root)                      |
| 0.4 Spinach                                |
| 0.5 Milk and cream                         |
| 0.5 Wine grapes                            |
| 0.5 Sugar beet (root)                      |
| 0.2 Cucumbers                              |
| 0.2 Other lettuce and other salad plants   |
| 0.2 Milk and cream                         |
| 0.2 Sugar beet (root)                      |
| 0.2 Head cabbage                           |
| 0.1 Milk and cream                         |
| 0.1 Other lettuce and other salad plants   |
| 0.1 Table grapes                           |
| 0.1 Chinese cabbage                        |
| 0.1 Sugar beet (root)                      |

| 3rd contributor to MS diet (in % of ADI) |
|-----------------------------------------|
| Commodity/group of commodities                |
| 1.0 Kale                                    |
| 0.6 Scarlet (broad-leaf endive)            |
| 0.9 Spinach                                 |
| 0.8 Spinach                                 |
| 0.6 Best leaves (chard)                     |
| 0.6 Best leaves (chard)                     |
| 0.4 Scarlet (broad-leaf endive)            |
| 0.9 Lettuce                                 |
| 1.2 Scarlet (broad-leaf endive)            |
| 1.0 Kale                                    |
| 0.1 Kale                                    |
| 0.1 Broccoli                                |
| 1.0 Lettuce                                 |
| 0.4 Head cabbage                            |
| 0.6 Table grapes                            |
| 0.7 Spinach                                 |
| 0.7 Spinach                                 |
| 0.1 Milk and cream                          |
| 0.1 Milk and cream                          |
| 0.1 Table grapes                            |
| 0.1 Chinese cabbage                         |

| pTMRLs at LOQ (mg/kg ADI) |
|---------------------------|
| 1.7                        |
| 0.6                        |
| 0.9                        |
| 0.8                        |
| 0.6                        |
| 0.4                        |
| 0.9                        |
| 0.9                        |
| 0.4                        |
| 0.9                        |
| 0.4                        |
| 0.9                        |
| 0.9                        |
| 0.4                        |
| 0.9                        |
| 0.4                        |
| 0.9                        |
| 1.2                        |
| 1.0                        |
| 0.1                        |
| 1.0                        |
| 0.4                        |
| 0.4                        |
| 0.1                        |
| 0.1                        |
| 0.1                        |
| 0.1                        |

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

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

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

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

### No of critical MRLs (ESTI 1)

| Commodity | pTMRL (mg/kg) | ARfD/ADI |
|-----------|---------------|----------|
| Scarole (broad-leaf) | 17/2.05 | 825.7 |
| Kale | 17/2.05 | 638.5 |
| Celery | 17/2.05 | 357.1 |
| Chinese cabbage | 17/2.05 | 350.7 |
| Lettuce | 17/2.05 | 254.1 |
| Spinach | 17/2.05 | 213.5 |
| Beet leaves (chard) | 17/2.05 | 165.8 |
| Purslane | 17/2.05 | 142.7 |
| Head cabbage | 3.9/3.42 | 114.0 |

No of critical MRLs (ESTI 1): 9

### No of critical MRLs (ESTI 2)

| Commodity | pTMRL (mg/kg) | ARfD/ADI |
|-----------|---------------|----------|
| Grape juice | 1.2- | 21.9 |
| Tomato juice | 0.58- | 5.6 |
| Carrot juice | 0.13- | 3.1 |
| Celery juice | 0.13- | 1.0 |
| Wine | 1.2- | 0.3 |
| Wine (processed) | 1.2- | 0.3 |

No of critical MRLs (ESTI 2): 8

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

| Commodity | pTMRL (mg/kg) |
|-----------|---------------|
| Scarole (broad-leaf) | 17/2.05 |
| Kale | 17/2.05 |
| Celery | 17/2.05 |
| Chinese cabbage | 17/2.05 |
| Lettuce | 17/2.05 |
| Spinach | 17/2.05 |
| Beet leaves (chard) | 17/2.05 |
| Purslane | 17/2.05 |
| Head cabbage | 3.9/3.42 |

No of commodities for which ARfD/ADI is exceeded: 9

### No of commodities for which ARfD/ADI is exceeded (ESTI 2)

| Commodity | pTMRL (mg/kg) |
|-----------|---------------|
| Grape juice | 1.2- |
| Tomato juice | 0.58- |
| Carrot juice | 0.13- |
| Celery juice | 0.13- |
| Wine | 1.2- |

No of commodities for which ARfD/ADI is exceeded: 4

### Processed commodities

| Commodity | pTMRL (mg/kg) |
|-----------|---------------|
| Wine | 1.2- |

No of commodities for which ARfD/ADI is exceeded: 3

### Conclusion:

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

The estimated short term intake (ESTI 1) exceeded the ARfD/ADI for 9 commodities.

Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 8 commodities.

For processed commodities, no exceedance of the ARfD/ADI was identified.
### Fluopicolide

**Status of the active substance:** Code no.

| LOQ (mg/kg bw): | proposed LOQ: |
|-----------------|--------------|
| ADI (mg/kg bw/day): | 0.08 |
| ARfD (mg/kg bw): | 0.18 |
| Source of ADI: | EFSA (2009a) |
| Year of evaluation: | 03 |

**Source of ARfD:** EFSA (2009a)

**Year of evaluation:** 03

**No of diets exceeding ADI:** ---

#### Highest calculated TMDI values in % of ADI

| MS Diet                  | Commodity/group of commodities | TMDI (range) in % of ADI |
|--------------------------|--------------------------------|-------------------------|
| 3.3 WHO Cluster diet B   | Wine grapes                    | 0.8 – 0.5 |
| 2.6 IE adult             | Milk                           | 0.6 – 0.5 |
| 2.5 DE child             | Table grapes                   | 0.6 – 0.5 |
| 2.5 FR toddler           | Milk and cream                 | 1.0 – 0.3 |
| 2.5 NL child             | Milk and cream                 | 0.7 – 0.3 |
| 2.4 FR all population    | Wine grapes                    | 1.8 – 0.1 |
| 2.3 WHO cluster diet D   | Herbs                          | 0.7 – 0.2 |
| 2.2 UK Toddler           | Sugar beet (root)              | 1.1 – 0.6 |
| 2.0 WHO cluster diet E   | Milk and cream                 | 0.7 – 0.3 |
| 1.8 UK Infant            | Herbs                          | 1.9 – 0.3 |
| 1.8 WHO regional European diet | Milk and cream | 0.4 – 0.2 |
| 1.6 PT General population | Wine grapes                    | 1.1 – 0.2 |
| 1.5 FR infant            | Milk and cream                 | 0.6 – 0.2 |
| 1.5 SE general population 90th percentile | Milk and cream | 0.3 – 0.2 |
| 1.4 NL general           | Wine grapes                    | 0.3 – 0.2 |
| 1.3 UK vegetarian        | Wine grapes                    | 0.4 – 0.2 |
| 1.3 WHO Cluster diet F   | Wine grapes                    | 0.3 – 0.2 |
| 1.2 ES adult             | Lettuce                        | 0.5 – 0.1 |
| 1.2 ES child             | Lettuce                        | 0.4 – 0.1 |
| 1.2 IT adult             | Lettuce                        | 0.3 – 0.1 |
| 1.2 UK Adult             | Wine grapes                    | 0.5 – 0.1 |
| 1.1 DK adult             | Milk and cream                 | 0.6 – 0.1 |
| 1.1 IT kids/toddler      | Tomatoes                       | 0.3 – 0.1 |
| 1.0 DK child             | Milk and cream                 | 0.3 – 0.1 |
| 0.7 PL general population | Tomatoes                       | 0.2 – 0.1 |
| 0.6 FI adult             | Milk and cream                 | 0.1 – 0.1 |
| 0.4 LT adult             | Tomatoes                       | 0.1 – 0.1 |

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

### Toxicological end points

- **ADI (mg/kg bw):** 0.08
- **ARfD (mg/kg bw):** 0.18
- **Source of ADI:** EFSA (2009a)
- **Year of evaluation:** 03
- **LOQ (mg/kg bw):** proposed LOQ:

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI |
|--------------------------------|-------------------------|
| Wine grapes                    | 0.5 – 0.2 |
| Milk                           | 0.5 – 0.4 |
| Table grapes                   | 0.5 – 0.4 |
| Milk and cream                 | 0.3 – 0.2 |
| Milk and cream                 | 0.2 – 0.1 |
| Herbs                          | 0.2 – 0.1 |
| Sugar beet (root)              | 0.2 – 0.1 |
| Milk and cream                 | 0.1 – 0.1 |
| Milk and cream                 | 0.1 – 0.1 |
| Chinese cabbage                | 0.2 – 0.1 |
| Milk and cream                 | 0.1 – 0.1 |
| Lettuce                        | 0.1 – 0.1 |
| Milk and cream                 | 0.1 – 0.1 |
| Lettuce                        | 0.1 – 0.1 |
| Milk and cream                 | 0.1 – 0.1 |
| Milk and cream                 | 0.1 – 0.1 |
| Lettuce                        | 0.1 – 0.1 |
| Milk and cream                 | 0.1 – 0.1 |
| Milk and cream                 | 0.1 – 0.1 |

### The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL).

The pTMRLs have been submitted to EFSA in September 2006.
### Acute risk assessment/children – refined calculations

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

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

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

#### Highest % of ARfD/ADI Commodities

| ARfD/ADI exceeded (IESTI 1) | --- | ARfD/ADI exceeded (IESTI 2) | --- | ARfD/ADI is exceeded (IESTI 1) | --- | ARfD/ADI is exceeded (IESTI 2) | --- |
|-----------------------------|------|-----------------------------|------|--------------------------------|------|--------------------------------|------|

#### Highest % of ARfD/ADI Commodities

| ARfD/ADI exceeded (IESTI 1) | --- | ARfD/ADI exceeded (IESTI 2) | --- | ARfD/ADI is exceeded (IESTI 1) | --- | ARfD/ADI is exceeded (IESTI 2) | --- |
|-----------------------------|------|-----------------------------|------|--------------------------------|------|--------------------------------|------|

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

- **IESTI 1:** 58.3 Scarcicle (broad-leaf) 1.2/-
- **IESTI 2:** 43.7 Table grapes 1.2/-
- **IESTI 1:** 50.8 Lettuce 3.4/-
- **IESTI 2:** 35.0 Scarcicle (broad-leaf) 1.2/-
- **IESTI 1:** 38.9 Spinach 1.5/-
- **IESTI 2:** 29.2 Rocket, Rucola 17/-
- **IESTI 1:** 31.5 Kale 0.84/-
- **IESTI 2:** 15.8 Wine grapes 1.2/-

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

- **IESTI 1:** 21.9 Grape juice 1.2/-
- **IESTI 2:** 0.6 Wine 1.2/-
- **IESTI 1:** 3.1 Carrot, juice 0.13/-
- **IESTI 2:** 0.3 Raisins 1.2/-
- **IESTI 1:** 1.0 Celeriac juice 0.13/-
- **IESTI 2:** 0.0 Potato, onion (fakes) 0.02/-
- **IESTI 1:** 0.3 Wine 1.2/-
- **IESTI 2:** 0.0 Fried potatoes 0.02/-

#### Conclusion:

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

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

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**pTMRL:** provisional temporary MRL

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

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

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**pTMRL:** provisional temporary MRL.
### 2,6-Dichlorobenzamide

**Status of the active substance:** Code no.

**LOQ (mg/kg bw):** Proposed LOQ

**Toxicological end points**

| ADI (mg/kg bw per day): | 0.05 | ARfD (mg/kg bw): | 0.3 |
|-------------------------|------|------------------|-----|
| Source of ADI:          | EFSA | Source of ARfD:  | EFSA |
| Year of evaluation:     | 2009 | Year of evaluation: | 2009 |

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

#### Chronic risk assessment – refined calculations

| Highest calculated TMDI values in % of ADI | MS Diet | Highest contributor to MS diet in % of ADI | Commodity/ group of commodities | 2nd contributor to MS diet in % of ADI | Commodity/ group of commodities | 3rd contributor to MS diet in % of ADI | Commodity/ group of commodities | pTMRLs at LOQ in % of ADI |
|-------------------------------------------|---------|-------------------------------------------|---------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|---------------------------------|---------------------------|
| 1.3 FR toddler                            | 0.8     | Milk and cream                            | 0.1 Potatoes                    | 0.1 Spinach                          | 0.1 Potatoes                      | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 1.2 UK Infant                             | 0.8     | Milk and cream                            | 0.1 Potatoes                    | 0.1 Spinach                          | 0.1 Potatoes                      | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 1.2 NL child                              | 0.6     | Milk and cream                            | 0.1 Potatoes                    | 0.1 Spinach                          | 0.1 Potatoes                      | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 1.1 UK Toddler                            | 0.5     | Sugar beet (root)                         | 0.1 Milk and cream             | 0.1 Tomatoes                         | 0.1 Tomatoes                      | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.9 WHO Cluster diet B                    | 0.2     | Wheat                                     | 0.1 Milk and cream             | 0.1 Tomatoes                         | 0.1 Tomatoes                      | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.8 FR infant                             | 0.5     | Milk and cream                            | 0.1 Beef                       | 0.1 Wheat                           | 0.1 Wheat                         | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.7 DE child                              | 0.3     | Milk and cream                            | 0.1 Wheat                      | 0.1 Wheat                           | 0.1 Wheat                         | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.7 ES child                              | 0.3     | Milk and cream                            | 0.1 Wheat                      | 0.1 Wheat                           | 0.1 Wheat                         | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.6 DK child                              | 0.3     | Milk and cream                            | 0.1 Wheat                      | 0.1 Wheat                           | 0.1 Wheat                         | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.6 IE adult                              | 0.1     | Sweet potatoes                            | 0.1 Milk and cream             | 0.1 Tomatoes                         | 0.1 Tomatoes                      | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.6 WHO cluster diet D                    | 0.1     | Wheat                                     | 0.1 Milk and cream             | 0.1 Tomatoes                         | 0.1 Tomatoes                      | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.6 WHO cluster diet E                    | 0.1     | Wheat                                     | 0.1 Milk and cream             | 0.1 Tomatoes                         | 0.1 Tomatoes                      | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.6 SE general population 90th percentile | 0.2     | Milk and cream                            | 0.1 Potatoes                    | 0.1 Wheat                           | 0.1 Wheat                         | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.6 WHO regional European diet            | 0.1     | Wheat                                     | 0.1 Milk and cream             | 0.1 Tomatoes                         | 0.1 Tomatoes                      | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.5 WHO Cluster diet F                    | 0.1     | Milk and cream                            | 0.1 Wheat                      | 0.1 Wheat                           | 0.1 Wheat                         | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.5 NL general                            | 0.1     | Milk and cream                            | 0.1 Potatoes                    | 0.1 Wheat                           | 0.1 Wheat                         | 0.1 Wheat                           | 0.1 Wheat                      | 0.1 Wheat                  |
| 0.4 ES adult                              | 0.1     | Milk and cream                            | 0.0 Wheat                      | 0.0 Bovine: Meat                     | 0.0 Bovine: Meat                  | 0.0 Milk and cream                  | 0.0 Milk and cream             | 0.0 Milk and cream          |
| 0.4 FR all population                     | 0.1     | Wine grapes                               | 0.1 Wheat                      | 0.1 Wheat                           | 0.1 Wheat                         | 0.1 Wine grapes                     | 0.1 Wine grapes               | 0.1 Wine grapes            |
| 0.4 PT General population                 | 0.1     | Potatoes                                  | 0.1 Wheat                      | 0.1 Wheat                           | 0.1 Wheat                         | 0.1 Wine grapes                     | 0.1 Wine grapes               | 0.1 Wine grapes            |
| 0.3 LT adult                              | 0.1     | Milk and cream                            | 0.1 Potatoes                    | 0.1 Wheat                           | 0.1 Wheat                         | 0.1 Water                           | 0.1 Water                      | 0.1 Water                  |
| 0.3 UK vegetarian                        | 0.1     | Sugar beet (root)                         | 0.1 Milk and cream             | 0.1 Tomatoes                         | 0.1 Tomatoes                      | 0.1 Water                           | 0.1 Water                      | 0.1 Water                  |
| 0.3 DK adult                              | 0.1     | Milk and cream                            | 0.0 Wine grapes                 | 0.0 Wheat                           | 0.0 Wheat                         | 0.0 Tomatoes                        | 0.0 Tomatoes                   | 0.0 Tomatoes               |
| 0.3 UK adult                              | 0.1     | Sugar beet (root)                         | 0.1 Milk and cream             | 0.1 Tomatoes                         | 0.1 Tomatoes                      | 0.1 Water                           | 0.1 Water                      | 0.1 Water                  |
| 0.3 IT kids/toddler                      | 0.1     | Wheat                                     | 0.0 Other cereal               | 0.0 Tomatoes                         | 0.0 Tomatoes                      | 0.0 Water                           | 0.0 Water                      | 0.0 Water                  |
| 0.2 FI adult                              | 0.1     | Milk and cream                            | 0.0 Potatoes                   | 0.0 Lettuce                          | 0.0 Lettuce                       | 0.0 Tomatoes                        | 0.0 Tomatoes                   | 0.0 Tomatoes               |
| 0.2 IT adult                              | 0.1     | Wheat                                     | 0.0 Potatoes                   | 0.0 Lettuce                          | 0.0 Lettuce                       | 0.0 Tomatoes                        | 0.0 Tomatoes                   | 0.0 Tomatoes               |
| 0.1 PL general population                 | 0.1     | Potatoes                                  | 0.0 Tomatoes                   | 0.0 Head cabbage                     | 0.0 Head cabbage                  | 0.0 Other cereal                    | 0.0 Other cereal              | 0.0 Other cereal           |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of 2,6-dichlorobenzamide is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

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

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002) for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a 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

| ARfD/ADI is exceeded (ESTI 1) | ARfD/ADI is exceeded (ESTI 2) | ARfD/ADI is exceeded (ESTI 1) | ARfD/ADI is exceeded (ESTI 2) |
|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| **Highest % of ARfD/ADI**     | **pTMRL/ threshold MRL**     | **Highest % of ARfD/ADI**     | **pTMRL/ threshold MRL**     |
| Commodities                   | (mg/kg)                       | Commodities                   | (mg/kg)                       |
| Scarole (broad-leaf)          | 2.0                           | Chinese cabbage               | 0.7                           |
| Kale                          | 1.4                           | Cauliflower                  | 0.5                           |
| Cauliflower                   | 1.1                           | Table grapes                 | 0.5                           |
| Table grapes                  | 1.1                           | Kale                         | 0.5                           |
| Leek                          | 1.0                           | Spinach                      | 0.4                           |

### Processed commodities

| ARfD/ADI is exceeded:        | ARfD/ADI is exceeded:        |
|-------------------------------|-------------------------------|
| **Highest % of ARfD/ADI**     | **pTMRL/ threshold MRL**     |
| Commodities                   | (mg/kg)                       |
| Grape juice                   | 0.0                           |
| Carrot juice                  | 0.0                           |
| Tomato juice                  | 0.0                           |
| Potato puree (flakes)         | 0.0                           |
| Celery juice                  | 0.0                           |

**Conclusion:**

For 2,6-dichlorobenzamide, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.
## Appendix D – Input values for the exposure calculations

### D.1. Livestock dietary burden calculations

| Feed commodity          | Median dietary burden | Maximum dietary burden | Comment                          |
|-------------------------|-----------------------|-------------------------|----------------------------------|
|                         | Input value (mg/kg)   | Comment                 | Input value (mg/kg)   |
| **Risk assessment residue definition 1: flupicolid** |                       |                         |                                |
| Potato, culls           | 0.01*                 | STMR primary crops      | 0.02                 |
| Potato, process waste   | 0.20                  | STMR primary crops × default PF (20)  |
| Potato, dried pulp      | 0.38                  | STMR primary crops × default PF (38)  |
| Cassava/tapioca, roots  | 0.01*                 | STMR primary crops      | 0.01*                |
| Carrot, culls           | 0.03                  | STMR primary crops      | 0.13                 |
| Swede, roots            | 0.03                  | STMR primary crops      | 0.13                 |
| Turnip, roots           | 0.03                  | STMR primary crops      | 0.13                 |
| Cabbage, heads, leaves  | 0.02                  | STMR primary crops      | 0.18                 |
| Kale                    | 0.75                  | STMR primary crops      | 0.84                 |
| Canola (Rape seed), meal| 0.01*                 | STMR primary crops (default PF not applied)  |
| Rape seed, meal         | 0.01*                 | STMR primary crops (default PF not applied)  |
| Beet, sugar, dried pulp | 0.72                  | STMR primary crops × default PF (18)  |
| Beet, sugar, ensiled pulp| 0.12                 | STMR primary crops × default PF (3)  |
| Beet, sugar, molasses   | 1.12                  | STMR primary crops × default PF (28)  |
| Cereals, straw          | 0.06                  | STMR rotational crops   | 0.12                 |
| **Risk assessment residue definition 2: 2,6-dichlorobenzamide (metabolite M-01)** |                       |                         |                                |
| Potato, culls           | 0.01*                 | STMR primary crops      | 0.01*                |
| Potato, process waste   | 0.01*                 | STMR primary crops (default PF not applied)  |
| Potato, dried pulp      | 0.01*                 | STMR primary crops (default PF not applied)  |
| Cassava/tapioca, roots  | 0.01*                 | STMR primary crops      | 0.01*                |
| Carrot, culls           | 0.01*                 | STMR primary crops      | 0.01*                |
| Swede, roots            | 0.01*                 | STMR primary crops      | 0.01*                |
| Turnip, roots           | 0.01*                 | STMR primary crops      | 0.01*                |
| Cabbage, heads, leaves  | 0.02                  | STMR primary crops + STMR rotational crops (0.01)  |
| Kale                    | 0.03                  | STMR primary crops + STMR rotational crops (0.01)  |
| Canola (Rape seed), meal| 0.01*                 | STMR primary crops (default PF not applied)  |
| Rape seed, meal         | 0.01*                 | STMR primary crops (default PF not applied)  |
| Beet, sugar, dried pulp | 0.18                  | STMR primary crops × default PF (18)  |
### Median dietary burden

| Feed commodity | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
|----------------|--------------------|---------|--------------------|---------|
| Beet, sugar, ensiled pulp | 0.03 | STMR primary crops × default PF (3) | 0.03 | STMR primary crops × default PF (3) |
| Beet, sugar, molasses | 0.28 | STMR primary crops × default PF (28) | 0.28 | STMR primary crops × default PF (28) |
| Cereals, straw | 0.01 | STMR rotational crops⁹⁶ | 0.03 | HR rotational crops⁹⁶ |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): In the absence of processing factors supported by data, default the processing factor of was included in the calculation to consider the potential concentration of residues in these commodities.

(b): For rape seed and canola meals no default processing factor was applied because fluopicolide is applied as a seed treatment and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

(c): No GAP is authorised for this crop but possible intake from rotational crops is expected. STMR and HR were derived based on the rotational crop field trials.

(d): For 2,6-dichlorobenzamide, no default processing factor was applied for processed commodities of potatoes because levels of 2,6-dichlorobenzamide are below the LOQ. Concentration of residues in these commodities is therefore not expected.

(e): For cabbage and kale, cumulated intake from primary and rotational crops was considered. Therefore, STMR and HR derived from the rotational crop field trials performed with cabbage were added to STMR and HR derived for primary crops.

### Consumer risk assessment without consideration of the existing CXLs: fluopicolide

| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|-----------------------|
|            | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition: fluopicolide |
| Table grapes | 0.36 | STMR | 1.20 | HR |
| Wine grapes | 0.36 | STMR | 1.20 | HR |
| Blackberries | 0.52 | STMR | 1.10 | HR |
| Potatoes | 0.01* | STMR | 0.02 | HR |
| Cassava roots/manioc | 0.01* | STMR | 0.01* | HR |
| Sweet potatoes | 0.01* | STMR | 0.01* | HR |
| Yams | 0.01* | STMR | 0.01* | HR |
| Arrowroots | 0.01* | STMR | 0.01* | HR |
| Beetroots | 0.03 | STMR | 0.13 | HR |
| Carrots | 0.03 | STMR | 0.13 | HR |
| Celeriacs/turnip rooted celeries | 0.03 | STMR | 0.13 | HR |
| Horseradishes | 0.03 | STMR | 0.13 | HR |
| Jerusalem artichokes | 0.03 | STMR | 0.13 | HR |
| Parsnips | 0.03 | STMR | 0.13 | HR |
| Parsley roots/Hamburg roots parsley | 0.03 | STMR | 0.13 | HR |
| Radishes | 0.03 | STMR | 0.10 | HR |
| Salsifies | 0.03 | STMR | 0.13 | HR |
| Swedes/rutabagas | 0.03 | STMR | 0.13 | HR |
| Tumips | 0.03 | STMR | 0.13 | HR |
| Garlic | 0.03 | STMR | 0.21 | HR |
| Onions | 0.03 | STMR | 0.21 | HR |
| Shallots | 0.03 | STMR | 0.21 | HR |
| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------|------------------------|-----------------------|
| Spring onions/green onions and Welsh onions   | 0.25 STMR              | 0.82 HR               |
| Tomatoes                                      | 0.12 STMR (tentative)  | 0.23 HR (tentative)   |
| Sweet peppers/bell peppers                    | 0.13 STMR              | 0.52 HR               |
| Cucumbers                                     | 0.04 STMR              | 0.09 HR               |
| Gherkins                                      | 0.04 STMR              | 0.09 HR               |
| Courgettes                                    | 0.04 STMR              | 0.09 HR               |
| Melons                                         | 0.01 STMR x PF         | 0.03 HR x PF          |
| Pumpkins                                       | 0.01 STMR x PF         | 0.03 HR x PF          |
| Watermelons                                    | 0.01 STMR x PF         | 0.03 HR x PF          |
| Broccoli                                       | 0.01* STMR (tentative) | 0.11 HR (tentative)   |
| Cauliflowers                                   | 0.01* STMR (tentative) | 0.11 HR (tentative)   |
| Brussels sprouts                               | 0.04 STMR              | 0.13 HR               |
| Head cabbages                                  | 0.02 STMR              | 0.18 HR               |
| Chinese cabbages/pe-tsai                       | 0.75 STMR              | 0.84 HR               |
| Kales                                          | 0.75 STMR              | 0.84 HR               |
| Kohlrabies                                     | 0.01 STMR              | 0.02 HR               |
| Lamb’s lettuces/corn salads                    | 0.40 STMR (tentative)  | 4.30 HR (tentative)   |
| Lettuces                                       | 0.69 STMR              | 3.40 HR               |
| Escaroles/broad-leaved endives                 | 0.10 STMR (tentative)  | 1.20 HR (tentative)   |
| Cresses and other sprouts and shoots           | 0.40 STMR (tentative)  | 4.30 HR (tentative)   |
| Land cresses                                   | 0.40 STMR (tentative)  | 4.30 HR (tentative)   |
| Roman rocket/rucola                            | 0.40 STMR              | 3.10 HR               |
| Red mustards                                   | 0.40 STMR (tentative)  | 4.30 HR (tentative)   |
| Baby leaf crops (including brassica species)   | 0.40 STMR (tentative)  | 4.30 HR (tentative)   |
| Spinaches                                      | 0.40 STMR              | 3.10 HR               |
| Purslanes                                      | 0.40 STMR              | 3.10 HR               |
| Chards/beet leaves                             | 0.40 STMR              | 3.10 HR               |
| Chervil                                        | 1.09 STMR              | 4.90 HR               |
| Chives                                         | 1.09 STMR              | 4.90 HR               |
| Celery leaves                                  | 1.09 STMR              | 4.90 HR               |
| Parsley                                        | 1.09 STMR              | 4.90 HR               |
| Sage                                           | 1.09 STMR              | 4.90 HR               |
| Rosemary                                       | 1.09 STMR              | 4.90 HR               |
| Thyme                                          | 1.09 STMR              | 4.90 HR               |
| Basil and edible flowers                       | 1.09 STMR              | 4.90 HR               |
| Laurel/bay leave                               | 1.09 STMR              | 4.90 HR               |
| Tarragon                                       | 1.09 STMR              | 4.90 HR               |
| Leeks                                          | 0.25 STMR              | 0.82 HR               |
| Rapeseeds/canola seeds                         | 0.01* STMR             | 0.01* HR              |
| Mustard seeds                                  | 0.01* STMR             | 0.01* HR              |
| Herbal infusions from roots                    | 0.80 STMR (rotational crops) (a) | 4.96 HR (rotational crops) (a) |
| Hops                                           | 0.05 STMR (tentative)  | 0.08 HR (tentative)   |
### Chronic risk assessment

| Commodity                | Input value (mg/kg) | Comment       | Input value (mg/kg) | Comment       |
|--------------------------|---------------------|---------------|---------------------|---------------|
| Sugar beet roots         | 0.04                | STMR          | 0.06                | HR            |
| Swine meat               | 0.02*               | STMR muscle (tentative) | 0.02*          | HR muscle (tentative) |
| Swine fat tissue         | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Swine liver              | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Swine kidney             | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Bovine meat              | 0.02*               | STMR muscle (tentative) | 0.02*          | HR muscle (tentative) |
| Bovine fat tissue        | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Bovine liver             | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Bovine kidney            | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Sheep meat               | 0.02*               | STMR muscle (tentative) | 0.02*          | HR muscle (tentative) |
| Sheep fat tissue         | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Sheep liver              | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Sheep kidney             | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Goat meat                | 0.02*               | STMR muscle (tentative) | 0.02*          | HR muscle (tentative) |
| Goat fat tissue          | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Goat liver               | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Equine kidney            | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Equine meat              | 0.02*               | STMR muscle (tentative) | 0.02*          | HR muscle (tentative) |
| Equine fat tissue        | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Equine liver             | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Equine kidney            | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Poultry meat             | 0.02*               | STMR muscle (tentative) | 0.02*          | HR muscle (tentative) |
| Poultry fat tissue       | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Poultry liver            | 0.05*               | STMR (tentative) | 0.05*              | HR (tentative) |
| Cattle milk              | 0.01*               | STMR (tentative) | 0.01*              | HR (tentative) |
| Sheep milk               | 0.01*               | STMR (tentative) | 0.01*              | HR (tentative) |
| Goat milk                | 0.01*               | STMR (tentative) | 0.01*              | HR (tentative) |
| Horse milk               | 0.01*               | STMR (tentative) | 0.01*              | HR (tentative) |
| Birds eggs               | 0.01*               | STMR (tentative) | 0.01*              | HR (tentative) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

* Indicates that the input value is proposed at the limit of quantification.
(a): No GAP is authorised for this crop but possible intake from rotational crops is expected in valerian roots. STMR and HR were derived based on the rotational crop field trials.

### D.3. Consumer risk assessment with consideration of the existing CXLs: fluopicolide

| Commodity                | Input value (mg/kg) | Comment       | Input value (mg/kg) | Comment       |
|--------------------------|---------------------|---------------|---------------------|---------------|
| Table grapes             | 0.36                | STMR          | 1.20                | HR            |
| Wine grapes              | 0.36                | STMR          | 1.20                | HR            |
| Blackberries            | 0.52                | STMR          | 1.10                | HR            |
| Potatoes                 | 0.01*               | STMR          | 0.02                | HR            |
| Cassava roots/manioc     | 0.01*               | STMR          | 0.01*               | HR            |
| Sweet potatoes           | 0.01*               | STMR          | 0.01*               | HR            |
| Yams                     | 0.01*               | STMR          | 0.01*               | HR            |

Risk assessment residue definition: fluopicolide
| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------|-------------------------|-----------------------|
| Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Arrowroots                  | 0.01* STMR             | 0.01* HR              |
| Beetroots                   | 0.03 STMR              | 0.13 HR               |
| Carrots                     | 0.03 STMR              | 0.13 HR               |
| Celeriacs/turnip rooted celeries | 0.03 STMR             | 0.13 HR               |
| Horseradishes               | 0.03 STMR              | 0.13 HR               |
| Jerusalem artichokes        | 0.03 STMR              | 0.13 HR               |
| Parsnips                    | 0.03 STMR              | 0.13 HR               |
| Parsley roots/Hamburg roots parsley | 0.03 STMR             | 0.13 HR               |
| Radishes                    | 0.03 STMR              | 0.10 HR               |
| Salsifies                   | 0.03 STMR              | 0.13 HR               |
| Swedes/rutabagas            | 0.03 STMR              | 0.13 HR               |
| Turnips                     | 0.03 STMR              | 0.13 HR               |
| Garlic                      | 0.03 STMR              | 0.21 HR               |
| Onions                      | 0.07 STMR (CXL)        | 0.58 HR (CXL)         |
| Shallots                    | 0.03 STMR              | 0.21 HR               |
| Spring onions/green onions and Welsh onions | 2.10 STMR (CXL)    | 4.50 HR (CXL)         |
| Tomatoes                    | 0.16 STMR (CXL)        | 0.58 HR (CXL)         |
| Sweet peppers/bell peppers  | 0.13 STMR              | 0.52 HR               |
| Aubergines (egg plants)     | 0.16 STMR (CXL)        | 0.58 HR (CXL)         |
| Okra, lady’s fingers        | 0.16 STMR (CXL)        | 0.58 HR (CXL)         |
| Cucumbers                   | 0.07 STMR (CXL)        | 0.30 HR (CXL)         |
| Gherkins                    | 0.07 STMR (CXL)        | 0.30 HR (CXL)         |
| Courgettes                  | 0.07 STMR (CXL)        | 0.30 HR (CXL)         |
| Melons                      | 0.01 STMR × PF (CXL)   | 0.04 HR × PF (CXL)    |
| Pumpkins                    | 0.01 STMR × PF (CXL)   | 0.04 HR × PF (CXL)    |
| Watermelonoids              | 0.01 STMR × PF (CXL)   | 0.04 HR × PF (CXL)    |
| Broccoli                    | 0.39 STMR (CXL)        | 0.69 HR (CXL)         |
| Cauliflower                 | 0.39 STMR (CXL)        | 0.69 HR (CXL)         |
| Brussels sprouts            | 0.04 STMR              | 0.13 HR               |
| Head cabbages               | 1.20 Scenario CX1: STMR (CXL) | 3.90 Scenario CX1: HR (CXL) |
| Chinese cabbages/pe-tsai    | 0.02 Scenario CX2: STMR(a) | 0.18 Scenario CX2: HR(a) |
| Kales                       | 8.60 Scenario CX1: STMR (CXL) | 17.00 Scenario CX1: HR (CXL) |
| Kohlrabies                  | 0.01 STMR              | 0.02 HR               |
| Lamb’s lettuces/corn salads | 0.01 STMR              | 0.02 HR               |
| Lettuces                    | 0.69 Scenario CX1: STMR (CXL) | 3.40 Scenario CX1: HR (CXL) |
| Escaroles/broad-leaved endives | 8.60 Scenario CX1: STMR (CXL) | 17.00 Scenario CX1: HR (CXL) |
| Cresses and other sprouts and shoots | 8.60 Scenario CX1: STMR (CXL) | 17.00 Scenario CX1: HR (CXL) |
| Commodity                          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------|-----------------------|
|                                   | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Land cresses                      | 8.60                    | STMR (CXL)            | 17.00               | HR (CXL)              |
| Roman rocket/rucola              | 8.60                    | STMR (CXL)            | 17.00               | HR (CXL)              |
| Red mustards                      | 8.60                    | STMR (CXL)            | 17.00               | HR (CXL)              |
| Baby leaf crops                  | 8.60                    | STMR (CXL)            | 17.00               | HR (CXL)              |
| (including brassica              |                         |                       |                     |                       |
| species)                          |                         |                       |                     |                       |
| Spinaches                         | 8.60                    | Scenario CX1: STMR (CXL) | 17.00           | Scenario CX1: HR (CXL) |
| Purslanes                         | 8.60                    | Scenario CX1: STMR (CXL) | 17.00           | Scenario CX1: HR (CXL) |
| Chards/beet leaves                | 8.60                    | Scenario CX2: STMR (a) | 3.10              | Scenario CX2: HR (a)  |
| Vine leaves (grape                | 8.60                    | Scenario CX1: STMR (CXL) | 17.00           | Scenario CX1: HR (CXL) |
| leaves)                           |                         |                       |                     |                       |
| Water cress                       | 8.60                    | STMR (CXL)            | 17.00               | HR (CXL)              |
| Chervil                           | 8.60                    | STMR (CXL)            | 17.00               | HR (CXL)              |
| Chives                            | 1.09                    | STMR                  | 4.90                | HR                    |
| Celery leaves                     | 1.09                    | STMR                  | 4.90                | HR                    |
| Parsley                           | 1.09                    | STMR                  | 4.90                | HR                    |
| Sage                              | 1.09                    | STMR                  | 4.90                | HR                    |
| Rosemary                          | 1.09                    | STMR                  | 4.90                | HR                    |
| Thyme                             | 1.09                    | STMR                  | 4.90                | HR                    |
| Basil and edible flowers          | 1.09                    | STMR                  | 4.90                | HR                    |
| Laurel/bay leave                  | 1.09                    | STMR                  | 4.90                | HR                    |
| Tarragon                          | 1.09                    | STMR                  | 4.90                | HR                    |
| Celery                            | 1.40                    | STMR (CXL)            | 14.00               | HR (CXL)              |
| Leeks                             | 0.25                    | STMR                  | 0.82                | HR                    |
| Rapeseeds/canola seeds            | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Mustard seeds                     | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Herbal infusions from roots       | 0.80                    | STMR (rotational crops)(c) | 4.96        | HR (rotational crops)(c) |
| Hops                              | 0.05                    | STMR (tentative)      | 0.08                | HR (tentative)        |
| Sugar beet roots                  | 0.04                    | STMR                  | 0.06                | HR                    |
| Swine muscle                      | 0.02*                   | STMR (tentative)      | 0.02*               | HR (tentative)        |
| Swine fat tissue                  | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Swine liver                       | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Swine kidney                      | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Bovine muscle                     | 0.02*                   | STMR (tentative)      | 0.02*               | HR (tentative)        |
| Bovine fat tissue                 | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Bovine liver                      | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Bovine kidney                     | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Sheep muscle                      | 0.02*                   | STMR (tentative)      | 0.02*               | HR (tentative)        |
| Sheep fat tissue                  | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Sheep liver                       | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Sheep kidney                      | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Goat muscle                       | 0.02*                   | STMR (tentative)      | 0.02*               | HR (tentative)        |
| Goat fat tissue                   | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
### D.4. Consumer risk assessment for metabolite 2,6-dichlorobenzamide (Metabolite M-01)

| Commodity               | Chronic risk assessment | Acute risk assessment |
|-------------------------|-------------------------|-----------------------|
|                         | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Table grapes            | 0.015                   | STMR                  | 0.05                | HR      |
| Wine grapes             | 0.015                   | STMR                  | 0.05                | HR      |
| Blackberries           | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative) |
| Potatoes                | 0.01*                   | STMR                  | 0.01*               | HR      |
| Cassava roots/manioc    | 0.01*                   | STMR                  | 0.01*               | HR      |
| Sweet potatoes          | 0.01*                   | STMR                  | 0.01*               | HR      |
| Yams                    | 0.01*                   | STMR                  | 0.01*               | HR      |
| Arrowroots              | 0.01*                   | STMR                  | 0.01*               | HR      |
| Beetroots               | 0.01*                   | STMR                  | 0.01*               | HR      |
| Carrots                 | 0.01*                   | STMR                  | 0.01*               | HR      |
| Celeriacs/turnip rooted celeries | 0.01* | STMR | 0.01* | HR |
| Horseradishes           | 0.01*                   | STMR                  | 0.01*               | HR      |
| Jerusalem artichokes    | 0.01*                   | STMR                  | 0.01*               | HR      |
| Parsnips                | 0.01*                   | STMR                  | 0.01*               | HR      |

**Risk assessment residue definition:** 2,6-dichlorobenzamide (metabolite M-01)
| Commodity                                      | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
|-----------------------------------------------|---------------------|---------|---------------------|---------|
| Parsley roots/Hamburg roots parsley           | 0.01*               | STMR    | 0.01*               | HR      |
| Radishes                                      | 0.01                | STMR    | 0.01                | HR      |
| Salsifies                                     | 0.01*               | STMR    | 0.01*               | HR      |
| Swedes/rutabagas                              | 0.01*               | STMR    | 0.01*               | HR      |
| Turnips                                       | 0.01*               | STMR    | 0.01*               | HR      |
| Garlic                                        | 0.01*               | STMR    | 0.05                | HR      |
| Onions                                        | 0.01*               | STMR    | 0.05                | HR      |
| Shallots                                      | 0.01*               | STMR    | 0.05                | HR      |
| Spring onions/green onions and Welsh onions   | 0.01*               | STMR (CXL) | 0.01*               | HR (CXL) |
| Tomatoes                                      | 0.01*               | STMR    | 0.01*               | HR      |
| Sweet peppers/bell peppers                    | 0.01*               | STMR    | 0.01*               | HR      |
| Aubergines (egg plants)                       | 0.01*               | STMR (CXL) | 0.01*               | HR (CXL) |
| Okra, lady’s fingers                          | 0.01*               | STMR (CXL) | 0.01*               | HR (CXL) |
| Cucumbers                                     | 0.01*               | STMR    | 0.01*               | HR      |
| Gherkins                                      | 0.01*               | STMR    | 0.01*               | HR      |
| Courgettes                                    | 0.01*               | STMR    | 0.01*               | HR      |
| Melons                                        | 0.01*               | STMR    | 0.01*               | HR      |
| Pumpkins                                      | 0.01*               | STMR    | 0.01*               | HR      |
| Watermelons                                   | 0.01*               | STMR    | 0.01*               | HR      |
| Broccoli                                      | 0.02                | STMR primary crops (0.01) + STMR rotational crops (0.01) (tentative) | 0.05 | HR primary crops (0.01) + HR rotational crops (0.04) (tentative)(a) |
| Cauliflower                                   | 0.02                | STMR primary crops (0.01) + STMR rotational crops (0.01) (tentative) | 0.05 | HR primary crops (0.01) + HR rotational crops (0.04) (tentative)(a) |
| Brussels sprouts                              | 0.02                | STMR primary crops (0.01) + STMR rotational crops (0.01) (tentative) | 0.05 | HR primary crops (0.01) + HR rotational crops (0.04) (tentative)(a) |
| Head cabbages                                 | 0.02                | STMR primary crops (0.01) + STMR rotational crops (0.01) (tentative) | 0.05 | HR primary crops (0.01) + HR rotational crops (0.04) (tentative)(a) |
| Chinese cabbages/pe-tsai                      | 0.03                | STMR primary crops (0.01) + STMR rotational crops (0.01) (tentative) | 0.06 | HR primary crops (0.02) + HR rotational crops (0.04) (tentative)(a),(c) |
| Kales                                         | 0.03                | STMR primary crops (0.02) + STMR rotational crops (0.01) (tentative) | 0.06 | HR primary crops (0.02) + HR rotational crops (0.04) (tentative)(a),(c) |
| Kohlrabies                                     | 0.02                | STMR primary crops (0.01) + STMR rotational crops (0.01) (tentative) | 0.05 | HR primary crops (0.01) + HR rotational crops (0.04) (tentative)(a) |
| Lamb’s lettuces/corn salads                   | 0.07                | STMR (CXL) | 0.19                | HR (CXL) |
| Lettuces                                      | 0.02                | STMR primary crops (0.01) + STMR rotational crops (0.01) (tentative) | 0.08 | HR primary crops (0.04) + HR rotational crops (0.04) (tentative)(a),(c) |
| Commodity                                      | Chronic risk assessment                                                                 | Acute risk assessment                                                                 |
|-----------------------------------------------|-----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
|                                               | Comment                                                                                 | Comment                                                                                |
|                                               | Input value (mg/kg)                                                                     | Input value (mg/kg)                                                                     |
| Escaroles/broad-leaved endives                | STMR primary crops (0.01) + STMR rotational crops (0.01) (tentative)(a),(c)             | HR primary crops (0.03) + HR rotational crops (0.04) (tentative)(a),(c)                |
|                                               |                                           0.02                                                                                     | 0.07                                                                                   |
| Cresses and other sprouts and shoots          | STMR (CXL)                                                                              | HR (CXL)                                                                               |
|                                               |                                           0.07                                                                                     | 0.19                                                                                   |
| Land cresses                                  | STMR (CXL)                                                                              | HR (CXL)                                                                               |
|                                               |                                           0.07                                                                                     | 0.19                                                                                   |
| Red mustards                                  | STMR (CXL)                                                                              | HR (CXL)                                                                               |
|                                               |                                           0.07                                                                                     | 0.19                                                                                   |
| Baby leaf crops (including brassica species)  | STMR (CXL)                                                                              | HR (CXL)                                                                               |
|                                               |                                           0.07                                                                                     | 0.19                                                                                   |
| Spinaches                                     | STMR primary crops (0.05) + STMR rotational crops (0.01) (tentative)(a),(c)             | HR primary crops (0.08) + HR rotational crops (0.04) (tentative)(a),(c)                |
|                                               |                                           0.06                                                                                     | 0.12                                                                                   |
| Purslanes                                     | STMR primary crops (0.05) + STMR rotational crops (0.01) (tentative)(a),(c)             | HR primary crops (0.08) + HR rotational crops (0.04) (tentative)(a),(c)                |
|                                               |                                           0.06                                                                                     | 0.12                                                                                   |
| Chards/beet leaves                            | STMR primary crops (0.05) + STMR rotational crops (0.01) (tentative)(a),(c)             | HR primary crops (0.08) + HR rotational crops (0.04) (tentative)(a),(c)                |
|                                               |                                           0.06                                                                                     | 0.12                                                                                   |
| Vine leaves (grape leaves)                    | STMR (CXL)                                                                              | HR (CXL)                                                                               |
|                                               |                                           0.07                                                                                     | 0.19                                                                                   |
| Water cress                                   | STMR (CXL)                                                                              | HR (CXL)                                                                               |
|                                               |                                           0.07                                                                                     | 0.19                                                                                   |
| Chervil                                       | STMR (CXL)                                                                              | HR (CXL)                                                                               |
|                                               |                                           0.07                                                                                     | 0.19                                                                                   |
| Chives                                        | STMR primary crops (0.02) + STMR rotational crops (0.01) (tentative)(a)                 | HR primary crops (0.04) + HR rotational crops (0.04) (tentative)(a)                    |
|                                               |                                           0.03                                                                                     | 0.08                                                                                   |
| Celery leaves                                 | STMR primary crops (0.02) + STMR rotational crops (0.01) (tentative)(a)                 | HR primary crops (0.04) + HR rotational crops (0.04) (tentative)(a)                    |
|                                               |                                           0.03                                                                                     | 0.08                                                                                   |
| Parsley leaves                                | STMR primary crops (0.02) + STMR rotational crops (0.01) (tentative)(a)                 | HR primary crops (0.04) + HR rotational crops (0.04) (tentative)(a)                    |
|                                               |                                           0.03                                                                                     | 0.08                                                                                   |
| Sage                                          | STMR primary crops (0.02) + STMR rotational crops (0.01) (tentative)(a)                 | HR primary crops (0.04) + HR rotational crops (0.04) (tentative)(a)                    |
|                                               |                                           0.03                                                                                     | 0.08                                                                                   |
| Rosemary                                      | STMR primary crops (0.02) + STMR rotational crops (0.01) (tentative)(a)                 | HR primary crops (0.04) + HR rotational crops (0.04) (tentative)(a)                    |
|                                               |                                           0.03                                                                                     | 0.08                                                                                   |
| Thyme                                         | STMR primary crops (0.02) + STMR rotational crops (0.01) (tentative)(a)                 | HR primary crops (0.04) + HR rotational crops (0.04) (tentative)(a)                    |
|                                               |                                           0.03                                                                                     | 0.08                                                                                   |
| Basil and edible flowers                      | STMR primary crops (0.02) + STMR rotational crops (0.01) (tentative)(a)                 | HR primary crops (0.04) + HR rotational crops (0.04) (tentative)(a)                    |
|                                               |                                           0.03                                                                                     | 0.08                                                                                   |
| Laurel/bay leaves                             | STMR primary crops (0.02) + STMR rotational crops (0.01) (tentative)(a)                 | HR primary crops (0.04) + HR rotational crops (0.04) (tentative)(a)                    |
|                                               |                                           0.03                                                                                     | 0.08                                                                                   |
| Tarragon                                      | STMR primary crops (0.02) + STMR rotational crops (0.01) (tentative)(a)                 | HR primary crops (0.04) + HR rotational crops (0.04) (tentative)(a)                    |
|                                               |                                           0.03                                                                                     | 0.08                                                                                   |
| Asparagus                                     | STMR rotational crops (tentative)(b)                                                    | HR rotational crops (tentative)(b)                                                     |
|                                               |                                           0.01                                                                                     | 0.04                                                                                   |
| Cardoons                                      | STMR rotational crops (tentative)(b)                                                    | HR rotational crops (tentative)(b)                                                     |
|                                               |                                           0.01                                                                                     | 0.04                                                                                   |
| Celery                                        | STMR rotational crops (tentative)(b),(c)                                                | HR rotational crops (tentative)(b),(c)                                                |
|                                               |                                           0.01                                                                                     | 0.04                                                                                   |
| Florence fennels                              | STMR rotational crops (tentative)(b)                                                    | HR rotational crops (tentative)(b)                                                     |
|                                               |                                           0.01                                                                                     | 0.04                                                                                   |
| Globe artichokes                              | STMR rotational crops (tentative)(b)                                                    | HR rotational crops (tentative)(b)                                                     |
|                                               |                                           0.01                                                                                     | 0.04                                                                                   |
| Leeks                                         | STMR primary crops (0.01) + STMR rotational crops (0.01) (tentative)(a)                 | HR primary crops (0.01) + HR rotational crops (0.04) (tentative)(a)                    |
|                                               |                                           0.02                                                                                     | 0.05                                                                                   |

Review of the existing MRLs for fluopicolide

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| Commodity                          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------|-----------------------|
|                                   | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Rhubarbs                          | 0.01* STMR rotational crops (tentative)
(b)           | 0.04 HR rotational crops (tentative)
(b)           |
| Beans (dry)                       | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Lentils (dry)                     | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Peas (dry)                        | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Lupins (dry)                      | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Rapeseeds/canola seeds            | 0.01* STMR              | 0.01* HR              |
| Soya bean                         | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Mustard seeds                     | 0.01* STMR              | 0.01* HR              |
| Barley grains                     | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Buckwheat grain                   | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Maize grain                       | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Millet grain                      | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Oat grains                        | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Rice grain                        | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Rye grains                        | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Sorghum grain                     | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Wheat grains                      | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Herbal infusions from flowers     | 0.01* STMR rotational crops (tentative)
(b)           | 0.04 HR rotational crops (tentative)
(b)           |
| Herbal infusions from leaves and herbs | 0.01* STMR rotational crops (tentative)
(b)           | 0.04 HR rotational crops (tentative)
(b)           |
| Herbal infusions from roots       | 0.40 STMR rotational crops (tentative)
(b)           | 2.48 STMR rotational crops (tentative)
(b)           |
| Hops                              | 0.07 STMR primary crops (0.06) + STMR rotational crops (0.01) (tentative)
(a) | 0.12 HR primary crops (0.08) + HR rotational crops (0.04) (tentative)
(a) |
| Bark spices                       | 0.01* STMR rotational crops (tentative)
(b)           | 0.04 HR rotational crops (tentative)
(b)           |
| Bud spices                        | 0.01* STMR rotational crops (tentative)
(b)           | 0.04 HR rotational crops (tentative)
(b)           |
| Flower pistil spices              | 0.01* STMR rotational crops (tentative)
(b)           | 0.04 HR rotational crops (tentative)
(b)           |
| Sugar beet roots                  | 0.01* STMR              | 0.01 HR              |
| Swine muscle                      | 0.02* STMR (tentative)  | 0.02* HR (tentative)  |
| Swine fat tissue                  | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Swine liver                       | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Swine kidney                      | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Bovine muscle                     | 0.02* STMR (tentative)  | 0.02* HR (tentative)  |
| Bovine fat tissue                 | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Bovine liver                      | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Bovine kidney                     | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Sheep muscle                      | 0.02* STMR (tentative)  | 0.02* HR (tentative)  |
| Sheep fat tissue                  | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Sheep liver                       | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Sheep kidney                      | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Goat muscle                       | 0.02* STMR (tentative)  | 0.02* HR (tentative)  |
| Goat fat tissue                   | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Goat liver                        | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
| Goat kidney                       | 0.05* STMR (tentative)  | 0.05* HR (tentative)  |
### Commodity

| Commodity         | Chronic risk assessment | Acute risk assessment |
|-------------------|-------------------------|-----------------------|
|                   | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Equine muscle     | 0.02*                  | STMR (tentative)      | 0.02*                  | HR (tentative)        |
| Equine fat tissue | 0.05*                  | STMR (tentative)      | 0.05*                  | HR (tentative)        |
| Equine liver      | 0.05*                  | STMR (tentative)      | 0.05*                  | HR (tentative)        |
| Equine kidney     | 0.05*                  | STMR (tentative)      | 0.05*                  | HR (tentative)        |
| Poultry muscle    | 0.02*                  | STMR (CXL) (tentative)| 0.02                  | HR (CXL) (tentative)  |
| Poultry fat tissue| 0.05*                  | STMR (tentative)      | 0.05*                  | HR (tentative)        |
| Poultry liver     | 0.05*                  | STMR (CXL) (tentative)| 0.08                  | HR (CXL) (tentative)  |
| Cattle milk       | 0.01*                  | STMR (tentative)      | 0.01*                  | HR (tentative)        |
| Sheep milk        | 0.01*                  | STMR (tentative)      | 0.01*                  | HR (tentative)        |
| Goat milk         | 0.01*                  | STMR (tentative)      | 0.01*                  | HR (tentative)        |
| Horse milk        | 0.01*                  | STMR (CXL) (tentative)| 0.01*                 | HR (CXL) (tentative)  |
| Birds eggs        | 0.01*                  | STMR (CXL) (tentative)| 0.02                  | HR (CXL) (tentative)  |

**STMR**: supervised trials median residue; **HR**: highest residue; **CXL**: codex maximum residue limit.

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

(a): Cumulated residues from primary and rotational crops were considered for this commodity. Therefore, STMR and HR derived from the rotational crop field trials performed with cabbage (extrapolated to leafy crops) were added to STMR and HR derived for primary crops.

(b): No GAP is authorised for this crop but possible intake from rotational crops is expected in leafy crops and valerian roots. STMR and HR derived from the rotational crop field trials on cabbage are extrapolated to all leafy crops (including stem vegetable). For herbal infusions from roots, STMR and HR are derived from the rotational crop field trials performed on valerian roots.

(c): Residue levels of 2,6-dichlorobenzamide associated with the CXL assessed by JMPR are higher for this commodity. However, considering that the CXLs of fluopicolide for this commodity leads to acute concerns, the risk assessment values for 2,6-dichlorobenzamide which are associated to this CXL are not considered in the consumer exposure.
Appendix E – Decision tree for deriving MRL recommendations
Comparison of the EU recommendation with the existing CXL

CXL available?

Yes

RD comparable?

Yes

CXL higher?

Yes

No

Consumer risk assessment with consideration of the existing CXL

CXL supported by data?

Yes

No

Risk identified?

Yes

No

Input values for the RA remain unchanged.

CXL is included in the RA.

Codex median/ highest residues are included in the RA.

Input values for the RA remain unchanged.

CXL is included in the RA.

Input values for the RA remain unchanged.

CXL is included in the RA.

Risk identified?

Yes

No

Recommendations with consideration of the existing CXL

(VI) Maintain EU recommendation; higher CXL is not safe for consumer.

(VII) CXL is recommended; EU recommendation is covered as well.

(V) Maintain EU recommendation; higher CXL is not safe for consumer.

(IV) Maintain EU recommendation; CXL is not safe for consumer.

(III) Maintain EU recommendation indicating that CXL is not covered.

(II) Maintain EU recommendation indicating that no CXL is available.

Risk identified?

Yes

No

Input values for the RA remain unchanged.

CXL is included in the RA.

Input values for the RA remain unchanged.

CXL is included in the RA.

Input values for the RA remain unchanged.

CXL is included in the RA.

No

Yes
### Appendix F – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| flupicoline          | 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide | ![Flupicoline structure](image) |
|                      | Clc1ccc(C)c1C(O)=CNc1ncc(cc1Cl)C(F)(F)F | GBOYJIHYACSLGN-UHFFFAOYSA-N |
| Dichlobenil          | 2,6-dichlorobenzonitrile                | ![Dichlobenil structure](image) |
|                      | N#Cc1c(C)ccc1Cl                          | YOYAIZYFCNQIRF-UHFFFAOYSA-N |
| Chlorthiamide        | 2,6-dichlorothiobenzamide               | ![Chlorthiamide structure](image) |
|                      | S=C(N)c1c(Cl)ccc1Cl                      | KGKSIUWJCAFPX-UHFFFAOYSA-N |
| M-01(also referred to as BAM) | 2,6-dichlorobenzamide                             | ![M-01 structure](image) |
|                      | O=C(N)c1c(Cl)ccc1Cl                      | JHSPCUHPSIUQRB-UHFFFAOYSA-N |
| M-02                 | 3-chloro-5-(trifluoromethyl)pyridine-2-carboxylic acid | ![M-02 structure](image) |
|                      | Clc1cc(cnc1O)=OC(F)(F)F                  | HXRM CZBDTCCOP-UHFFFAOYSA-N |
| M-04                 | 2,6-dichloro-3-hydroxybenzamide          | ![M-04 structure](image) |
|                      | Clc1ccc(O)c(Cl)c1C(N)=O                  | WCSKGUMNEYMMBE-UHFFFAOYSA-N |
| M-05                 | 3-(methylsulfonyl)-5-(trifluoromethyl)pyridine-2-carboxylic acid | ![M-05 structure](image) |
|                      | OC(=O)c1ncc(cc1S(C)=O)C(F)(F)F           | RQFCURAIFZONFT-UHFFFAOYSA-N |
| M-06                 | 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]methyl-3-hydroxybenzamide | ![M-06 structure](image) |
|                      | Clc1ccc(O)c(Cl)c1C(O)=NCc1ncc(cc1Cl)C(F)(F)F | SGEPQYDBDSDVEH-UHFFFAOYSA-N |
| M-07                 | 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]methyl-4-hydroxybenzamide | ![M-07 structure](image) |
|                      | Clc1cc(O)c(Cl)c1C(O)=NCc1ncc(cc1Cl)C(F)(F)F | SNQRBDGDHQIZDP-UHFFFAOYSA-N |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|------------------------------------------|-----------------|
| M-08                          | 3-chloro-5-(trifluoromethyl)pyridine-2-carboxamide Clc1cc(nc1C(-O)N)c(F)(F)F DVUFZZZAYXFTB-UHFFFAOYSA-N | ![Structural formula of M-08](image1) |
| M-09                          | 3-chloro-5-(trifluoromethyl)pyridin-2-ol Clc1cc(nc1O)c(F)(F)F AJPOOWWMZOPUCG-UHFFFAOYSA-N | ![Structural formula of M-09](image2) |

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

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

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

<sup>(c)</sup> ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).
## Appendix G – Overview of the residue levels of 2,6-dichlorobenzamide (from primary and rotational crops) assessed in the present review and by JMPR

| Code number | Commodity             | EU assessment | Codex assessment | Comment                                                                                                                                 |
|-------------|-----------------------|---------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------|
| 151010      | Table grapes          | 0.07          | Not relevant    | 0.05 Residues from the GAP assessed in this review (primary crops) are expected to be significant (and higher than the existing CXL)       |
| 151020      | Wine grapes           | 0.07          | Not relevant    | 0.05 Residues from the GAP assessed in this review (primary crops) are expected to be significant (and higher than the existing CXL)       |
| 153010      | Blackberries         | 0.01*         | Not relevant    | 0.2 Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. Higher residue levels are expected from CXL but should, however, not be considered because derived from a GAP on dichlobenil (FAO, 2014) |
| 153020      | Dewberries            | no GAP        | Not relevant    | (0.2) No EU GAPs authorised. Furthermore, residue levels expected from CXL should not be considered because derived from a GAP on dichlobenil (FAO, 2014) |
| 153030      | Raspberries           | no GAP        | Not relevant    | (0.2) No EU GAPs authorised. Furthermore, residue levels expected from CXL should not be considered because derived from a GAP on dichlobenil (FAO, 2014) |
| 211000      | Potatoes              | 0.01*         | No data         | No CXL Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available                  |
| 212010      | Cassava roots/       | 0.01*         | No data         | No CXL Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available                  |
| 212020      | Sweet potatoes        | 0.01*         | No data         | No CXL Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available                  |
| 212030      | Yams                  | 0.01*         | No data         | No CXL Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available                  |
| 212040      | Arrowroots            | 0.01*         | No data         | No CXL Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available                  |
| 213010      | Beetroots             | 0.01*         | No data         | No CXL Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available                  |
| 213020      | Carrots               | 0.01*         | No data         | No CXL Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available                  |
| 213030      | Celeriacs/turnip      | 0.01*         | No data         | No CXL Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available                  |

Review of the existing MRLs for fluopicolide
## Review of the existing MRLs for fluopicolide

| Code number | Commodity                                         | EU assessment MRL derived from GAP primary crops | HR in rotational crops (if relevant) | Codex assessment CXL | Comment                                                                 |
|-------------|--------------------------------------------------|-------------------------------------------------|-------------------------------------|----------------------|-------------------------------------------------------------------------|
| 213040      | Horseradishes                                    | 0.01*                                            | No data                            | No CXL               | Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available |
| 213050      | Jerusalem artichokes                             | 0.01*                                            | No data                            | No CXL               | Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available |
| 213060      | Parsnips                                         | 0.01*                                            | No data                            | No CXL               | Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available |
| 213070      | Parsley roots/Hamburg roots parsley              | 0.01*                                            | No data                            | No CXL               | Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available |
| 213080      | Radishes                                         | 0.02                                             | No data                            | No CXL               | Residues from the GAP assessed in this review (primary crops) are expected to be significant. No CXL available |
| 213090      | Salsifies                                        | 0.01*                                            | No data                            | No CXL               | Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available |
| 213100      | Swedes/rutabagas                                 | 0.01*                                            | No data                            | No CXL               | Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available |
| 213110      | Turnips                                          | 0.01*                                            | No data                            | No CXL               | Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available |
| 220010      | Garlic                                           | 0.09                                             | No data                            | No CXL               | Residues from the GAP assessed in this review (primary crops) are expected to be significant. No CXL available |
| 220020      | Onions                                           | 0.09                                             | No data                            | 0.01*                | Residues from the GAP assessed in this review (primary crops) are expected to be significant (and higher than the existing CXL) |
| 220030      | Shallots                                         | 0.09                                             | No data                            | No CXL               | Residues from the GAP assessed in this review (primary crops) are expected to be significant. No CXL available |
| 220040      | Spring onions/green onions and Welsh onions      | 0.01*                                            | No data                            | 0.02                 | Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. However, higher residue levels are expected from CXL (FAO, 2014) |
| 231010      | Tomatoes                                         | 0.01*                                            | No data                            | 0.01*                | Residues from the GAP assessed in this review (primary crops) and from CXL are expected to remain below LOQ |
| 231020      | Sweet peppers/bell peppers                       | 0.01*                                            | No data                            | 0.01*                | Residues from the GAP assessed in this review (primary crops) and from CXL are expected to remain below LOQ |
| Code number | Commodity                        | EU assessment | Codex assessment | Comment                                                                 |
|-------------|----------------------------------|---------------|-----------------|--------------------------------------------------------------------------|
| 231030      | Aubergines (egg plants)          | No GAP        | No data         | 0.01* No EU GAPs authorised. Residue levels from CXL are expected to be below LOQ (FAO, 2014) |
| 231040      | Okra, lady’s fingers             | No GAP        | No data         | 0.01* No EU GAPs authorised. Residue levels from CXL are expected to be below LOQ (FAO, 2014) |
| 232010      | Cucumbers                        | 0.01*         | No data         | 0.01* Residues from the GAP assessed in this review (primary crops) and from CXL are expected to remain below LOQ |
| 232020      | Gherkins                         | 0.01*         | No data         | 0.01* Residues from the GAP assessed in this review (primary crops) and from CXL are expected to remain below LOQ |
| 232030      | Courgettes                       | 0.01*         | No data         | 0.01* Residues from the GAP assessed in this review (primary crops) and from CXL are expected to remain below LOQ |
| 233010      | Melons                           | 0.01*         | No data         | 0.01* Residues from the GAP assessed in this review (primary crops) and from CXL are expected to remain below LOQ |
| 233020      | Pumpkins                         | 0.01*         | No data         | 0.01* Residues from the GAP assessed in this review (primary crops) and from CXL are expected to remain below LOQ |
| 233030      | Watermelons                      | 0.01*         | No data         | 0.01* Residues from the GAP assessed in this review (primary crops) and from CXL are expected to remain below LOQ |
| 241010      | Broccoli                         | 0.01*         | 0.04            | 0.05 Residue levels from primary crops assessed in this review are not expected to exceed LOQ. However, residues from rotational crops are expected to be significant. Residues from existing CXL are expected to be in the same range |
| 241020      | Cauliflowers                     | 0.01*         | 0.04            | 0.05 Residue levels from primary crops assessed in this review are not expected to exceed LOQ. However, residues from rotational crops are expected to be significant. Residues from existing CXL are expected to be in the same range |
| 242010      | Brussels sprouts                 | 0.01*         | 0.04            | 0.05 Residue levels from primary crops assessed in this review are not expected to exceed LOQ. However, residues from rotational crops are expected to be significant. Residues from existing CXL are expected to be in the same range |
| 242020      | Head cabbages                    | 0.01*         | 0.04            | 0.05 Residue levels from primary crops assessed in this review are not expected to exceed LOQ. However, residues from rotational crops are expected to be significant. Residues from existing CXL are expected to be in the same range |
| Code number | Commodity                          | EU assessment | Codex assessment | Comment                                                                                                                                                                                                 |
|-------------|-----------------------------------|---------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 243010      | Chinese cabbages/pe-tsai          | 0.05          | 0.04            | (0.3) Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. Higher residue levels are expected from CXL (FAO, 2014) but should, however, not be considered because are linked to non-safe CXLs for fluopicolide (see scenario CX2) |
| 243020      | Kales                             | 0.05          | 0.04            | (0.3) Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. Higher residue levels are expected from CXL (FAO, 2014) but should, however, not be considered because are linked to non-safe CXLs for fluopicolide (see scenario CX2) |
| 244000      | Kohlrabies                        | 0.01*         | 0.04            | 0.05 Residue levels from primary crops assessed in this review are not expected to exceed LOQ. However, residues from rotational crops are expected to be significant. Residues from existing CXL are expected to be in the same range |
| 251010      | Lamb’s lettuces/corn salads       | 0.06          | 0.04            | 0.3 Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. However, higher residues are expected based on the existing CXL |
| 251020      | Lettuces                          | 0.07          | 0.04            | (0.3) Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. Higher residue levels are expected from CXL (FAO, 2014) but should, however, not be considered because are linked to non-safe CXLs for fluopicolide (see scenario CX2) |
| 251030      | Escaroles/broad-leaved endives    | 0.06          | 0.04            | (0.3) Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. Higher residue levels are expected from CXL (FAO, 2014) but should, however, not be considered because are linked to non-safe CXLs for fluopicolide (see scenario CX2) |
| 251040      | Cresses and other sprouts and shoots | 0.06      | 0.04            | 0.3 Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. However, higher residues are expected based on the existing CXL |
| 251050      | Land cresses                      | 0.06          | 0.04            | 0.3 Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. However, higher residues are expected based on the existing CXL |
| 251060      | Roman rocket/rucola               | 0.06          | 0.04            | 0.3 Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. However, higher residues are expected based on the existing CXL |
### Review of the existing MRLs for fluopicolide

| Code number | Commodity                  | EU assessment | Codex assessment | Comment |
|-------------|-----------------------------|---------------|------------------|---------|
| 251070      | Red mustards                | 0.06          | 0.3              | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. However, higher residues are expected based on the existing CXL. |
| 251080      | Baby leaf crops (including brassica species) | 0.06          | 0.3              | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. However, higher residues are expected based on the existing CXL. |
| 252010      | Spinaches                   | 0.2           | (0.3)            | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. Higher residue levels are expected from CXL (FAO, 2014) but should, however, not be considered because are linked to non-safe CXLs for fluopicolide (see scenario CX2). |
| 252020      | Purslanes                   | 0.2           | (0.3)            | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. Higher residue levels are expected from CXL (FAO, 2014) but should, however, not be considered because are linked to non-safe CXLs for fluopicolide (see scenario CX2). |
| 252030      | Chards/beet leaves          | 0.2           | (0.3)            | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. Higher residue levels are expected from CXL (FAO, 2014) but should, however, not be considered because are linked to non-safe CXLs for fluopicolide (see scenario CX2). |
| 253000      | Vine leaves (grape leaves)  | No GAP        | 0.3              | Residue levels assessed in this review (rotational leafy crops) are expected to be significant. However, higher residues are expected based on the existing CXL. |
| 254000      | Water cress                 | No GAP        | 0.3              | Residue levels assessed in this review (rotational leafy crops) are expected to be significant. However, higher residues are expected based on the existing CXL. |
| 256010      | Chervil                     | 0.07          | 0.3              | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. However, higher residues are expected based on the existing CXL. |
| 256020      | Chives                      | 0.07          | No CXL           | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. No CXL available. |
| 256030      | Celery leaves               | 0.07          | No CXL           | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. No CXL available. |
| 256040      | Parsley                     | 0.07          | No CXL           | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. No CXL available. |
| Code number | Commodity                      | EU assessment | Codex assessment | Comment                                                                 |
|------------|--------------------------------|---------------|-----------------|--------------------------------------------------------------------------|
| 256050     | Sage                           | 0.07          | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. No CXL available |
| 256060     | Rosemary                       | 0.07          | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. No CXL available |
| 256070     | Thyme                          | 0.07          | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. No CXL available |
| 256080     | Basil and edible flowers       | 0.07          | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. No CXL available |
| 256090     | Laurel/bay leave               | 0.07          | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. No CXL available |
| 256100     | Tarragon                       | 0.07          | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. No CXL available |
| 270010     | Asparagus                      | No GAP        | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 270020     | Cardoons                       | No GAP        | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 270030     | Celery                         | No GAP        | 0.04            | (0.07)                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (rotational leafy crops) are expected to be significant. Higher residue levels are expected from CXL (FAO, 2014) but should, however, not be considered because are linked to non-safe CXLs for fluopicolide (see scenario CX2) |
| 270040     | Florence fennels               | No GAP        | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 270050     | Globe artichokes               | No GAP        | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 270060     | Leeks                          | 0.01*         | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels from primary crops assessed in this review are not expected to exceed LOQ. However, residues from rotational crops are expected to be significant. No CXL available |
| 270070     | Rhubarbs                       | no GAP        | 0.04            | No CXL                                                                   |
|            |                                | HR in rotational crops (if relevant) | CXL            | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 300010     | Beans (dry)                    | No GAP        | < 0.01          | 0.01*                                                                    |
|            |                                | HR in rotational crops (if relevant) | CXL            | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ |
| Code number | Commodity        | EU assessment (MRL derived from GAP primary crops) | HR in rotational crops (if relevant) | Codex assessment (CXL) | Comment |
|------------|------------------|--------------------------------------------------|-------------------------------------|------------------------|---------|
| 300020     | Lentils (dry)    | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 300030     | Peas (dry)       | no GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 300040     | Lupins (dry)     | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 401060     | Rapesed/canola seeds | 0.01*                                         | Not expected                        | No CXL                | Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available. |
| 401070     | Soya bean        | No GAP                                           | Not expected                        | 0.01*                  | No EU GAPs authorised. Residue levels from CXL are expected to be below LOQ (FAO, 2014). |
| 401080     | Mustard seeds    | 0.01*                                            | Not expected                        | No CXL                | Residues from the GAP assessed in this review (primary crops) are expected to remain below LOQ. No CXL available. |
| 500010     | Barley grains    | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 500020     | Buckwheat grain  | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 500030     | Maize grain      | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 500040     | Millet grain     | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 500050     | Oat grains       | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 500060     | Rice grain       | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 500070     | Rye grains       | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 500080     | Sorghum grain    | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| 500090     | Wheat grains     | No GAP                                           | < 0.01                              | 0.01*                  | No EU GAPs are authorised. Furthermore, residues from rotational crops assessed in this review and by FAO (2014) are expected to remain below LOQ. |
| Code number | Commodity | EU assessment | HR in rotational crops (if relevant) | Codex assessment | Comment |
|-------------|-----------|---------------|-------------------------------------|-----------------|---------|
| 631000      | Herbal infusions from flowers | No GAP | 0.04 | No CXL | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 632000      | Herbal infusions from leaves and herbs | No GAP | 0.04 | No CXL | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 633000      | Herbal infusions from roots | No GAP | 2.48 | No CXL | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 700000      | Hops | 0.15 | 0.04 | No CXL | Residue levels assessed in this review (primary crops + rotational leafy crops) are expected to be significant. No CXL available |
| 830000      | Bark spices | No GAP | 0.04 | No CXL | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 850000      | Bud spices | No GAP | 0.04 | No CXL | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 860000      | Flower pistil spices | No GAP | 0.04 | No CXL | Residue levels assessed in this review (based on rotational crops) are expected to be significant. No CXL available |
| 900010      | Sugar beet roots | 0.02 | no data | No CXL | Residues from the GAP assessed in this review (primary crops) are expected to be significant. No CXL available |
| 1011010     | Swine muscle | 0.02* | Not relevant | 0.01* | MRL derived from this review is at the LOQ but covers the CXL |
| 1011020     | Swine fat tissue | 0.05* | Not relevant | 0.01* | MRL derived from this review is at the LOQ but covers the CXL |
| 1011030     | Swine liver | 0.05* | Not relevant | 0.04 | MRL derived from this review is at the LOQ but covers the CXL |
| 1011040     | Swine kidney | 0.05* | Not relevant | 0.04 | MRL derived from this review is at the LOQ but covers the CXL |
| 1012010     | Bovine muscle | 0.02* | Not relevant | 0.01* | MRL derived from this review is at the LOQ but covers the CXL |
| 1012020     | Bovine fat tissue | 0.05* | Not relevant | 0.01* | MRL derived from this review is at the LOQ but covers the CXL |
| 1012030     | Bovine liver | 0.05* | Not relevant | 0.04 | MRL derived from this review is at the LOQ but covers the CXL |
| 1012040     | Bovine kidney | 0.05* | Not relevant | 0.04 | MRL derived from this review is at the LOQ but covers the CXL |
| 1013010     | Sheep muscle | 0.02* | Not relevant | 0.01* | MRL derived from this review is at the LOQ but covers the CXL |
| 1013020     | Sheep fat tissue | 0.05* | Not relevant | 0.01* | MRL derived from this review is at the LOQ but covers the CXL |
| 1013030     | Sheep liver | 0.05* | Not relevant | 0.04 | MRL derived from this review is at the LOQ but covers the CXL |
| 1013040     | Sheep kidney | 0.05* | Not relevant | 0.04 | MRL derived from this review is at the LOQ but covers the CXL |
| 1014010     | Goat muscle | 0.02* | Not relevant | 0.01* | MRL derived from this review is at the LOQ but covers the CXL |
| Code number | Commodity     | EU assessment | Codex assessment | Comment                                      |
|-------------|---------------|---------------|-----------------|----------------------------------------------|
| 1014020     | Goat fat tissue | 0.05*         | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1014030     | Goat liver    | 0.05*         | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1014040     | Goat kidney   | 0.05*         | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1015010     | Equine muscle | 0.02*         | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1015020     | Equine fat tissue | 0.05*      | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1015030     | Equine liver  | 0.05*         | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1016010     | Poultry muscle | 0.02*         | Not relevant    | MRL derived from this review is at the LOQ. Higher residues are expected based on the existing CXL |
| 1016020     | Poultry fat tissue | 0.05*        | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1016030     | Poultry liver | 0.05*         | Not relevant    | MRL derived from this review is at the LOQ. Higher residues are expected based on the existing CXL |
| 1020010     | Cattle milk   | 0.01*         | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1020020     | Sheep milk    | 0.01*         | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1020030     | Goat milk     | 0.01*         | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1020040     | Horse milk    | 0.01*         | Not relevant    | MRL derived from this review is at the LOQ but covers the CXL |
| 1030000     | Birds eggs    | 0.01*         | Not relevant    | MRL derived from this review is at the LOQ. Higher residues are expected based on the existing CXL |

MRL: maximum residue level; GAP: Good Agricultural Practice; HR: highest residue; CXL: codex maximum residue limit; LOQ: limit of quantification.

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