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Review of the existing maximum residue levels for imidacloprid 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 imidacloprid. To assess the occurrence of imidacloprid 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/or 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 chronic/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.

Keywords: imidacloprid, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, neonicotinoid/nitroguanidine group, insecticide

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Summary

Imidacloprid was included in Annex I to Directive 91/414/EEC on 1 August 2009 by Commission Directive 2008/116/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Germany, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 2 May 2016 and finalised on 2 July 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 26 August 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS and Member States, EFSA prepared in October 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 14 November 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

Based on the recent EFSA conclusions on the peer review of the updated pesticide risk assessment for bees, the conditions of approval for imidacloprid were recently restricted to uses in permanent greenhouses or for the treatment of seeds intended to be used only in permanent greenhouses, with crops staying within a permanent greenhouse during its entire life cycle. Member States were required to amend or withdraw their authorisations by 19 September 2018, with a maximum period of grace expiring on the 19 of December, 2018.

As the good agricultural practices (GAPs) and the supporting residue data considered in this MRL review were collected before the new conditions of approval entering into force, the data assessed in the present reasoned opinion are reflecting not only the uses compliant with the new conditions of approval, but also the (former) authorised European Union (EU) outdoor uses. In particular, in order to support risk managers in the decision making process, EFSA considered in this assessment:

- Residue data reflecting the EU indoor GAPs and the uses authorised in third countries (import tolerances) only, in line with the new conditions of approval for imidacloprid. This data was used to derive the MRL recommendations for plant and animal commodities as reported in the summary table and in Appendix B.4. These MRLs are also expected to cover the possible carry-over from the (former) authorised EU outdoor uses.
- Residue data reflecting all uses, including the EU outdoor GAPs. This data was used to derive a list of alternative MRLs possibly safe for consumers that could be considered by risk managers to support emergency authorisations. The list of alternative MRLs derived considering all uses and the results of the related risk assessment are reported, respectively, in Appendices G and B.3.2 to this reasoned opinion. Moreover, residue trials supporting the outdoor EU uses were also considered to assess the possible carry-over of imidacloprid in plant and animal commodities after the entry into force of the new conditions of approval.

The metabolism of imidacloprid was investigated in primary (fruit, root and leafy crops, cereals and pulses and oilseeds) and in rotational crops (root and leafy crops, cereals). Based on the results of the metabolism in primary and rotational crops, the residue definition for enforcement in plant commodities is proposed as imidacloprid only. For risk assessment, the residue definition is confirmed as the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid. The same residue definitions apply to rotational crops and processed commodities.

It is noted that results from the available residue trials suggest that imidacloprid only could not be a sufficient marker in pulses and oilseeds. Nevertheless, the limited residue data available does not allow concluding if a different residue definition for enforcement is required for these crops. Therefore, it is underlined that based on the results of the additional trials on dry beans, peanuts, beans and peas without pods required to support the existing import tolerances, the residue definition for enforcement in pulses and oilseeds may need to be reconsidered.

A sufficiently validated analytical method is available for the enforcement of the proposed residue definition in high water content, high acid content and dry commodities at the limit of quantification (LOQ) of 0.01 mg/kg, in high oil content at the LOQ of 0.02 mg/kg and in hops at 0.2 mg/kg. There are indications that imidacloprid can be enforced in coffee beans with an LOQ of 0.01 mg/kg, however a confirmatory method and an independent laboratory validation (ILV) are still missing. According to the EURLs, during routine analyses an LOQ of 0.01 mg/kg is achievable in the four main matrices.

Regarding the magnitude of residues expected in primary crops from the uses compliant with the new conditions of approval (indoor uses and import tolerances only), the available data were sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for currants, gooseberries, rose hips, mulberries, azaroles, elderberries, granate apples, lettuce and other salad plants where the available data were insufficient to derive even tentative MRLs.

As imidacloprid is a persistent active substance expected to accumulate in soil following multiannual applications and the available studies demonstrated that it can be taken up from the soil by the plant, in the assessment of the magnitude of residues in rotational crops, EFSA considered not only the uses compliant with the new conditions of approval, but also the possible carry-over from the (former) authorised EU outdoor uses.

When considering only the uses compliant with the new conditions of approval, it is concluded that specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures (e.g. use only on sweet peppers grown with soil-less growing systems) in order to avoid significant residues to occur in rotational crops.

When considering the possible carry-over of residues in plant commodities due to (former) authorised EU outdoor uses, it is concluded that specific temporary MRLs for plant commodities are not required to cover the possible carry-over from (former) outdoor EU uses. On other hand, as significant residues of parent and metabolites can be expected in cereals straw, their impact on the residues in livestock was considered further.

Imidacloprid is authorised for use on several crops (dry pulses, citrus fruits and peanuts) that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock according to OECD guidance. As EU outdoor GAPs are expected to be withdrawn according to the new conditions of approval, only indoor uses and import tolerances were considered for the calculation of the livestock exposure. Moreover in order to cover the carry-over in cereals due to the (former) authorised EU outdoor uses, the results from the available outdoor trials on wheat and barley (grain and straw) were also considered for the calculation of the livestock exposure. Since, the dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM), the behaviour of residues was assessed in all commodities of animal origin.

Metabolism studies in lactating goats and laying hens were submitted and evaluated during the peer review. According to the results of these studies, it is clear that parent compound is almost completely degraded in the liver and kidney of ruminants and in poultry tissues and eggs, with glucuronide conjugates of hydroxy-metabolites, imidacloprid olefine metabolite (M06) and a glycine-conjugate of 6-chloropyridine-3-carboxylic acid, representing the main identified compounds. Nevertheless, on the basis of livestock exposure resulting from the uses assessed in this review, no significant residues are expected in animal commodities. Hence, the residue definition for enforcement in all animal commodities is proposed as parent compound only (by default) and MRLs and risk assessment values for the relevant commodities in ruminants and poultry can be established at the LOQ level. These MRLs are expected to cover the possible carry-over in cereal due to the (former) authorised outdoor EU uses. For risk assessment, it is still proposed to keep the following residue definition as agreed during the peer review: sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid. It is underlined that, if additional uses leading to significant increase in livestock exposure will be granted in the future, the residue definition for animal commodities should be reconsidered.

Analytical methods for the enforcement of the proposed residue definition were evaluated during the peer review and showed that imidacloprid can be enforced in milk at the LOQ of 0.01 mg/kg and in animal tissues and in eggs at an LOQ of 0.03 mg/kg. According to the EURLs, based on the general experience with this compound, although only a screening method is available for animal commodities (except for honey validated down to 0.002 mg/kg), it is expected that imidacloprid residues can be enforced with an LOQ of 0.01 mg/kg in all commodities of animal origin.

Chronic and acute exposure calculations resulting from the authorised **indoor uses** and **import tolerances** (in line with the new conditions of approval) reported in the framework of this review

were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This calculation is also expected to cover the possible carry-over in cereals from the former authorised outdoor EU uses. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. According to the RMS, MRLs in the EU legislation are currently established for the parent compound only, but are actually based on data according to the so-called 'total residue' which is expected to cover the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety. Therefore, when considering the existing EU MRL, no conversion factor from enforcement to risk assessment was applied. Based on these calculations, a potential risk to consumers was identified for the use of imidacloprid on escaroles and no further refinements of the risk assessment were possible. For the remaining commodities, although uncertainties remain due to the data gaps identified in the assessment, the indicative exposure calculation did not indicate a risk to consumers.

Chronic and acute exposure calculations for **all uses** (including the former authorised outdoor EU uses) reported in the framework of this review were also performed using revision 2 of the EFSA PRIMo (EFSA, 2007). For those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. For the same reasons reported above, when considering the existing MRL, no conversion factor from enforcement to risk assessment was applied. Based on these calculations, a potential risk to consumers was identified for the southern outdoor GAPs on escaroles, sweet peppers and kale. For these commodities, fall-back GAPs were identified in order to reduce the exposure of consumers. For the remaining commodities, although uncertainties remain due to the data gaps identified in the assessment, the indicative exposure calculation did not indicate a risk to consumers.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for imidacloprid. Nevertheless, as the residue definition for enforcement of the CXLs is not compatible with the residue definition for enforcement proposed in the framework of this review, for information purposes, an indicative risk assessment was performed considering the existing CXLs only. These calculations indicate a potential risk to consumers for the existing CXLs on celery and kales. For the remaining CXLs, the indicative exposure calculation did not indicate a risk to consumers. However, considering that CXLs are currently expressed according to a residue definition for enforcement not compatible with the one proposed by EFSA, they are not recommended for inclusion in the EU legislation.

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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. As imidacloprid was included in Annex I to Council Directive 91/414/EEC on 1 August 2009 by means of Commission Directive 2008/116/EC[3], and has been deemed to be approved under Regulation (EC) No 1107/2009[4], in accordance with Commission Implementing Regulation (EU) No 540/2011[5], as amended by Commission Implementing Regulation (EU) No 541/2011[6], EFSA initiated the review of all existing MRLs for that active substance.

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

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

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

Germany, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for imidacloprid and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report (Germany, 2015) were submitted to EFSA on 11 June 2015 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 2 May 2016 and finalised on 2 July 2016. Additional evaluation reports were submitted by Belgium, the Czech Republic, France, Germany, Greece, Hungary, Italy, the Netherlands, Portugal, Spain and the European Union Reference Laboratories for Pesticide Residues (EURLs) (Belgium, 2016; Chech Republic, 2016a,b; France, 2016; Germany, 2016; Greece, 2016; Hungary, 2016; Italy, 2016a,b; Netherlands, 2016; Portugal, 2016; Spain, 2016; EURLs, 2016) and, after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 26 August 2016. Further clarifications were sought from Member States via a written procedure in August-October 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission (codex maximum residue limit (CXL)) and the additional information provided by the Member States, EFSA prepared in October 2018 a draft

[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 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include aclonifen, imidacloprid and metazachlor as active substances. OJ No L 337, 15.12.2008, p. 86–91.

[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.

reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 14 November 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation reports submitted by the RMS (Germany, 2015, 2016) and the evaluation reports submitted by Member States the Czech Republic, France, Germany, Greece, Hungary, Italy, the Netherlands, Portugal, Spain and EURLs (Chech Republic, 2016a,b; France, 2016; Germany, 2016; Greece, 2016; Hungary, 2016; Italy, 2016a,b; Netherlands, 2016; Portugal, 2016; Spain, 2016; EURLs, 2016) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2016) and the Member States consultation report (EFSA, 2018b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, screenshots of the Report sheet of PRIMo (Indoor EU and IT), PRIMo(All uses) and PRIMo(CXL) are presented in Appendix C.

Considering the importance of the completeness check and consultation report, also these documents are considered as background documents to this reasoned opinion and, thus, are made publicly available.

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

Imidacloprid is the ISO common name for *(E)*-1-(-(6-chloro-3-pyridylmethyl)-*N*-nitroimidazolidin-2-ylideneamine (IUPAC).

Imidacloprid belongs to the group of neonicotinoid/nitroguanidine compounds which are used as insecticides. It is a systemic substance with translaminar activity and with contact and stomach action. It is readily taken up by the plant and further distributed acropetally, with good root-systemic action. It acts as an antagonist by binding to postsynaptic nicotinic receptors in the insects' central nervous system. It has broad uses, mainly against aphids, in all crops. In addition, different modes of application are registered for imidacloprid, including foliar sprays from sowing until harvest, granular application in furrow or seedbed, seed dressing and preplanting or post-harvest dipping of plants.

The chemical structure of the active substance and its main metabolites are reported in Appendix F.

Imidacloprid was evaluated in the framework of Directive 91/414/EEC with Germany designated as rapporteur Member State (RMS). The representative uses supported for the peer review process were seed treatment for sugar beet and foliar application on apples and tomatoes. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2008/116/EC, which entered into force on 1 August 2009. According to Regulation (EU) No 540/2011, imidacloprid is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as insecticide only.

Following a peer review of the pesticides risk assessment for bees the conditions of approval were amended by means of Commission Directive (EU) No 485/2013[7]. Due to risks for bees from treated seeds the use and the placing on the market of seeds treated with plant protection products containing imidacloprid was prohibited for seeds of crops attractive to bees and for seeds of cereals except for winter cereals and seeds used in greenhouses.

[7] Regulation (EU) 485/2013 amending Regulation (EU) 540/2011, as regards the conditions of approval of certain active substances, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances. OJ L 139, 25.5.2013, p. 12–26.

Commission Implementing Regulation (EU) No 485/2013 also required the applicants to submit confirmatory data by 31 December 2014, covering all uses that could still be authorised (including certain seed, soil and foliar treatments). Furthermore, on 13 November 2015, EFSA was mandated to provide conclusions concerning an updated risk assessment for bees as regards the uses of imidacloprid applied as seed treatment or granules by organising a peer review and taking into account the data collected in the framework of the specific open call for data and any other new data from studies, research and monitoring activities relevant to the uses under consideration. EFSA conclusions on the confirmatory data and on the peer review of the updated pesticide risk assessment for bees considering the uses as seed treatment and granules were published, respectively, on 11 October 2016 and on 28 February 2018. Taking into account these conclusions, the Standing Committee on Plants, Animals, Food and Feed concluded that the restrictions laid down in Regulation (EU) No 485/2013 needed further modification. Consequently, the conditions of approval were further restricted to uses as insecticide, in permanent greenhouses or for the treatment of seeds intended to be used only in permanent greenhouses, with crops staying within a permanent greenhouse during its entire life cycle (European Commission, 2018). Member States were required to amend or withdraw their authorisations by 19 September 2018, with a maximum period of grace expiring on the 19 December 2018 by means of Commission Implementing Regulation (EU) 2018/783[8].

The EU MRLs for imidacloprid are established in Annex IIIA of Regulation (EC) No 396/2005 and CXLs for active substance were also established by the Codex Alimentarius Commission (CAC). An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided Table 1.

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure	Legal implementation	Remarks
Implementation of CAC 2009	Commission Regulation (EU) No 459/2010(a)	CXLs for imidacloprid
MRL application	Commission Regulation (EU) No 893/2010(b)	Modification of the existing MRLs for imidacloprid in rice
Implementation of CAC 2013	Commission Regulation (EU) No 491/2014(c)	CXLs for imidacloprid

MRL: maximum residue level; CXL: codex maximum residue limit; CAC: Codex Alimentarius Commission.

(a): Commission Regulation (EU) No 459/2010 of 27 May 2010 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products. OJ L 129, 28.5.2010, p. 3–49.

(b): Commission Regulation (EU) No 893/2010 of 8 October 2010 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 acequinocyl, bentazone, carbendazim, cyfluthrin, fenamidone, fenazaquin, flonicamid, flutriafol, imidacloprid, ioxynil, metconazole, prothioconazole, tebufenozide and thiophanate-methyl in or on certain products. OJ L 260, 9.10.2010, p. 10–38.

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

For the purpose of this MRL review, the critical uses of imidacloprid authorised within the EU, as well as uses authorised in third countries that might have a significant impact on international trade, have been collected by the RMS and reported in the PROFile. The additional Good Agricultural Practices (GAPs) reported by Member States during the completeness check were also considered. The details of GAPs for imidacloprid received in the framework of this review are given in Appendix A.

It is underlined that, as the GAPs and the supporting residue data considered in this MRL review were collected before the new conditions of approval entering into force, the overall data assessed in the present reasoned opinion is reflecting not only the uses compliant with the new conditions of approval, but also the (former) authorised EU outdoor uses. In particular, in order to support risk managers in the decision making process, EFSA considered in this assessment:

- Residue data reflecting the EU indoor GAPs and the uses authorised in third countries (import tolerances) only, in line with the new conditions of approval for imidacloprid. This data was used to derive the MRL recommendations for plant and animal as reported in the summary table and in Appendix B.4. These MRLs are also expected to cover the possible carry-over from the (former) authorised EU outdoor uses.

[8] Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid. OJ L 132, 30.5.2013, p. 31–34.

- Residue data reflecting all uses, including the EU outdoor GAPs. This data was used to derive a list of alternative MRLs possibly safe for consumers that could be considered by risk managers to support emergency authorisations. The list of alternative MRLs derived considering all uses and the results of the related risk assessment are reported, respectively, in Appendices G and B.3.2 to this reasoned opinion. Moreover, residue trials supporting the outdoor EU uses were also considered to assess the possible carry-over of imidacloprid in plant and animal commodities after the entry into force of the new conditions of approval.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Germany, 2015), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Germany, 2005, 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance imidacloprid (EFSA, 2008a), the peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance imidacloprid (EFSA, 2008b), the technical report on the Evaluation of the data on clothianidin, imidacloprid and thiamethoxam for the updated risk assessment to bees for seed treatments and granules in the EU (EFSA, 2018a), the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2008, 2015), the previous reasoned opinion on imidacloprid (EFSA, 2010) as well as the evaluation reports submitted during the completeness check (Belgium, 2016; Chech Republic, 2016a,b; France, 2016; Germany, 2016; Greece, 2016; Hungary, 2016; Italy, 2016a,b; Netherlands, 2016; Portugal, 2016; Spain, 2016; EURLs, 2016). 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[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

Under the peer review of Directive 91/414/EEC, the metabolism of imidacloprid residues in plants was investigated in fruit crops, root crops, leafy crops, cereals, pulses and oilseeds following foliar application (apples, tomatoes, potatoes and tobacco), seed treatment (maize, cotton and rice) and soil granular application (eggplants, potatoes, rice). All available metabolism studies were performed using pyridinyl-^{14}C-methylene labelled imidacloprid (Germany, 2005).

After the foliar application, the metabolic pattern in aerial parts of the plants was dominated by the parent compound which represents 70–95% of the extractable residues. Most of the radioactivity remained on the surface of fruits and leaves and could be washed off with methanol. In potato tubers, the total radioactivity was very low (characterisation was not possible) showing that transport from sprayed leaves to tubers was negligible.

Metabolism after soil granular application and seed treatment show active uptake and translocation of the radioactivity to aerial plant parts. Qualitatively, the metabolic routes of degradation suggested by these studies are the same as after foliar treatment, but the residue pattern found after seed and soil treatments reflects a more extensive degradation. In particular, following soil treatment, although parent compound was still present (ranging from 10% total radioactive residue (TRR) in eggplants foliage to 48% TRR in potatoes tubers) the following metabolites were identified above the 10% TRR: imidacloprid-desnitro (M09, accounting for up to 34% TRR, corresponding to 0.97 mg/kg in eggplants leaves); imidacloprid-6-CNA (M14, accounting for up to 13% TRR corresponding to 0.004 mg/kg in eggplants); imidacloprid-CHMP-glucoside (M29, accounting for up to 13% TRR corresponding to 0.007 mg/kg in eggplants).

[9] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

Similarly, following seed treatment, parent compound accounted from 8% TRR (rice straw) to 65% TRR (immature corn) and imidacloprid-desnitro represented the main metabolite, accounting for up to 36% TRR (0.48 mg/kg) in rice straw. It is noted that in cotton seeds following seed treatment, imidacloprid was not detected and the only measured compound was imidacloprid-CHMP (M28), accounting for 23% TRR but present at low absolute amounts (0.001 mg eq/kg).

All studies indicate that translocation of the substance in plants occurs by acropetal transport mainly from roots to leaves. In general, it was concluded that metabolism in plants proceeds according to three routes that were observed in almost all plants: (a) hydroxylation of imidazoline ring by forming the mono- and dihydroxylated compounds; (b) reduction of nitro group; and (c) oxidative cleavage of the methylene bridge.

1.1.2. Nature of residues in rotational crops

Imidacloprid is authorised on several crops that can be grown in crop rotation. In the framework of the peer review under Directive 91/411/EEC, the rate of degradation of imidacloprid in soil was investigated in field and laboratory studies (Germany, 2005). Since reported field DT_{90} values largely exceed 100 days (up to 956 days), a special consideration should be given to imidacloprid residues in rotational crops following annual and multiannual applications according to the most critical authorised uses. The metabolism of imidacloprid in rotational crops was investigated in a confined study following the application of pyridinyl-^{14}C-methylene-imidacloprid (Germany, 2005). The study was performed by applying imidacloprid on a bare soil at an application rate of 0.454 kg a.s./ha with Swiss chard, red beet and wheat sown or planted 30, 120 and 271 days after treatment (DAT). The nature of metabolites in rotational crops was observed to be the same as in crops from primary plant metabolism studies. The parent compound (ranging from 0.4% TRR in wheat grain to 47% TRR in wheat forage) was metabolised into several compounds containing 6-chloropyridinyl moiety, the most abundant being imidacloprid-desnitro (up to 19% TRR in wheat straw). On the basis of this study it can be concluded that metabolism of imidacloprid in rotational crops proceeds according to a similar pathway as in primary crops.

1.1.3. Nature of residues in processed commodities

Under the peer review of Directive 91/414/EEC, the effects of processing on the nature of imidacloprid residues was investigated in hydrolysis studies by stimulating pasteurisation, baking, brewing, boiling and sterilisation processes (Germany, 2005). The results of a hydrolysis study, performed with radiolabelled methylene-^{14}C-imidacloprid, demonstrate that imidacloprid is stable under hydrolytic conditions and does not undergo degradation.

In principle, the effect of processing on the nature of the major metabolites observed in raw plant commodities should also be assessed. However, considering that an extensive degradation of imidacloprid (especially following soil and seed treatment), which proceeds through the 6-chloropyridinyl moiety, was observed in plant commodities, it is not expected that new metabolites are formed when metabolites including the 6-chloropyridinyl moiety are subject to standard hydrolysis conditions. Consequently, further studies investigating the degradation of those metabolites through standard hydrolysis are not considered necessary.

1.1.4. Methods of analysis in plants

In the framework of the peer review of Directive 91/414/EEC, an HPLC method and its independent laboratory validation (ILV) were found to be sufficiently validated for the enforcement of imidacloprid in high water content (tomatoes, apples, cabbages), high oil content (cotton seed, rape seed), high acid content (citrus) and dry commodities (wheat grain), as well as in hops. This method allows separate analysis of imidacloprid, metabolite imidacloprid-5-hydroxy (M01) and metabolite imidacloprid olefine, with an limit of quantification (LOQ) of 0.02 mg/kg for each compound in the main four matrices and an LOQ of 0.2 mg/kg for each compound in hops (Germany, 2008).

According to the RMS, the multi-residue Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method in combination with high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) is also sufficiently validated for the enforcement of imidacloprid with a LOQ of 0.01 mg/kg in high water content (cucumbers), high acid content (lemons, oranges) and in dry commodities (wheat flour) (Germany, 2015).

An additional HPLC–MS/MS method for the enforcement of imidacloprid validated in cocoa beans (that could be used for the enforcement in coffee beans) was also reported by the RMS in the framework of this review (Germany, 2015). Based on this method, there are indications that imidacloprid can be enforced in specific matrices such as coffee beans with an LOQ of 0.01 mg/kg, however a confirmatory method and an ILV are still missing.

According to the information provided by the EURLs, during routine analyses an LOQ of 0.01 mg/kg is achievable in the four main matrices by using the QuEChERS method (EURLs, 2016).

1.1.5. Stability of residues in plants

The storage stability of imidacloprid residues in various plant matrices was investigated in the framework of the peer review (EFSA, 2008a). Imidacloprid parent compound as well as mixtures of imidacloprid and its main metabolites (when analysed as sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety), were found to be stable under deep frozen conditions for at least 24 months in dry commodities, in commodities with high water, high acid and high oil content. Additional storage stability studies covering the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety were assessed by the JMPR. According to these studies, the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety is stable for up to 53 months in high oil content matrices, for up to 41 months in high water content commodities, for up to 34 months in dry commodities and for up to 25 months in coffee, stored under deep frozen conditions (FAO, 2008).

1.1.6. Proposed residue definitions

Considering that the plant metabolic pattern is covered by the toxicological studies on the active substance itself, and that the produced metabolites have the same toxicological profile as the parent compound, the peer review concluded to set the risk assessment residue definition for plants as the 'sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid'. No final decision on the enforcement residue definition was taken in the peer review. Two options were proposed:

- to consider parent imidacloprid as the main residue for enforcement;
- to establish enforcement residue definition the same as the risk assessment residue definition.

In the framework of this MRL review, the RMS proposed to consider parent compound only for enforcement. Based on the results of the metabolism in primary and rotational crops and considering that the 6-chloropyridinyl moiety is not specific to imidacloprid as it is also contained in other neonicotinoid pesticides, EFSA agrees with the RMS considering imidacloprid only a sufficient marker for enforcement. For risk assessment, the residue definition is confirmed as the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid. The same residue definitions apply to rotational crops and processed commodities.

It is noted that results from the available residue trials suggest that imidacloprid only could not be a sufficient marker in pulses and oilseeds. Nevertheless, the limited residue data available does not allow concluding if a different residue definition for enforcement is required for these crops. Therefore, the proposed residue definition for enforcement in pulses and oilseeds should be considered tentative only and may need to be reconsidered based on the results of the additional trials on dry beans, peanuts, beans and peas without pods required to support the existing import tolerances (see Sections 1.2.1 and 1.2.3).

It is underlined that all available metabolism studies were performed using pyridinyl-^{14}C-methylene labelled imidacloprid only. During the peer review, the expert meeting on residues estimated that the amount of cleaved metabolites was low in comparison to that of uncleaved metabolites, showing that this route of metabolism is minor in plants. In addition, further degradation of the imidazoline moiety to nitrosimine is not expected to be a preferred pathway. It was nevertheless concluded that the applicant should submit a robust scientific assessment/statement on possible formation of nitrosimines or other degradates of toxicological concern from the cleaved nitroimino-imidazoline moiety in plants. During the peer review, the applicant submitted a scientific statement on possible formation of nitrosimines or other degradates of toxicological concern from the cleaved nitroimino-imidazoline moiety in plant metabolism. These comments were however not peer reviewed but included in the peer review report (EFSA, 2008b). In the framework of this MRL review, EFSA considered the statement provided by the applicant sufficient to exclude the formation of nitrosimines or other

compounds containing the nitroimino-imidazoline moiety at significant levels. Therefore, it is concluded that the available studies are considered sufficient to elucidate the metabolism in plant and an additional metabolism study performed with imidacloprid labelled at the imidazolidine ring is not required.

A sufficiently validated analytical method is available for the enforcement of the proposed residue definition in high water content, high acid content and dry commodities at the LOQ of 0.01 mg/kg, in high oil content at the LOQ of 0.02 mg/kg and in hops at the LOQ of 0.2 mg/kg. There are indications that imidacloprid can be enforced in coffee beans with an LOQ of 0.01 mg/kg; however, a confirmatory method and an ILV are still missing and are required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of imidacloprid residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Germany, 2015), including additional data submitted during the completeness check (Chech Republic, 2016a,b; France, 2016; Germany, 2016; Greece, 2016; Hungary, 2016; Italy, 2016a,b; Netherlands, 2016; Portugal, 2016; Spain, 2016; EURLs, 2016). All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions. 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). Although MRLs and risk assessment values were also derived from the EU outdoor GAPs, as these uses are expected to be withdrawn according to the new conditions of approval, only data gaps relevant for the indoor uses and the import tolerances are reported below.

Residue trials are not available to support the **indoor** authorisations or the **import tolerances** on currants, gooseberries, rose hips, mulberries, azaroles, elderberries, pomegranate, lettuce and other salad plants. Therefore, MRL or risk assessment values for these crops could not be derived by EFSA and the following data gaps were identified:

- currants, gooseberries, rose hips, mulberries, azaroles, elderberries: complete data set compliant with the import tolerance GAP for these crops;
- pomegranates: complete data set compliant with the import tolerance GAP for this crop;
- lettuce and other salad plants: complete data set compliant with the indoor GAP for these crops.

For all other crops, available residue trials are sufficient to derive (tentative) MRL and risk assessment values, taking note of the following considerations:

- Citrus fruits, table and wine grapes and dry beans: only residue trials analysing for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety are available to support the import tolerance for these crops. Therefore, the derived MRLs are expected to be overestimated and full data sets supporting the import tolerance on these crops are still required;
- Pecans: only residue trials analysing for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety are available to support the import tolerance for this crop. However, the available trials are 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;
- Blueberries and cranberries: although not explicitly mentioned in the current guidance document, the extrapolation from blueberries to cranberries was considered acceptable as both crops belong to the *Vaccinium* genus. Nevertheless, only residue trials analysing for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety are available to support the import tolerance for these crops. Therefore, the derived MRL is expected to be overestimated and a full data set supporting the import tolerance on these crops is still required;
- Bananas: the number of residue trials supporting the import tolerance is not compliant with the data requirements for this crop. Moreover, residues were only analysed for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety. However, the available trials are 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;

- Okra: trials supporting the indoor GAP were overdosed. Although tentative MRL and risk assessment values can be derived from the available data, a full data set compliant with the indoor GAP for okra is still required;
- Cucurbits with inedible peel: the number of residue trials supporting the indoor GAP is not compliant with the data requirements for these crops. Moreover, the four trials on watermelons were overdosed. Although tentative MRL and risk assessment values can be derived from the available data, two additional trials on melons and 4 additional trials on watermelons, all compliant with the indoor GAP, are still required;
- Beans and peas with and without pods, peanuts: only residue trials analysing for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety are available to support the import tolerance for these crops. Moreover, all trials were performed according to a more critical GAP. Therefore, the derived MRLs are expected to be overestimated and full data sets supporting the import tolerance on these crops are still required;
- Coffee beans: the number of residue trials supporting the import tolerance is not compliant with the data requirements for this crop. Moreover, only residue trials performed according to a more critical GAP and analysing for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety are available. Therefore, the derived MRL is expected to be overestimated and a full data set supporting the import tolerance on this crop is still required.
- Hops: the number of residue trials supporting the import tolerance is not compliant with the data requirements for this crop. Moreover, residues were only analysed for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety and one of the residue trials was overdosed. Therefore, the derived MRL is expected to be overestimated and a full data set supporting the import tolerance on this crop is still required.

Available residue trials also allow deriving conversion factors from enforcement to risk assessment (CFs). Median CFs were derived for each commodity, considering only residues of parent and the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety above the LOQ. A CF of 1 was proposed when in all residue trials both imidacloprid and the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety were below the LOQ and when residues were analysed only according to the residue definition for risk assessment (mainly for the import tolerances).

It is noted that, according to the available residue trials, for some crops very high CFs were calculated. This was the case for beans without pods (derived CF of 10), dry peas (derived CF of 33) and beans without pods (derived CF of 10). In particular, in dry peas, the parent was not present at all, while the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety accounted for up to 0.53 mg/kg. Similarly, a very high CF (320) was calculated in one study on cotton seed processed into meal (see Section 1.2.3). While these results suggest that imidacloprid only could not be a sufficient marker for enforcement in pulses and oilseeds, the limited residue data available does not allow concluding if a different residue definition for enforcement is required for these crops. Therefore, it is underlined that based on the results of the additional trials on dry beans, peanuts, beans and peas without pods required to support the existing import tolerances, the residue definition for enforcement in pulses and oilseeds may need to be reconsidered.

1.2.2. Magnitude of residues in rotational crops

In the available confined rotational crop study, significant TRRs were measured in all rotated crops and at all plant-back intervals (PBIs). The lowest TRRs were found in wheat grains and red beet roots ranging from 0.03 (PBI of 271 and 408 days) to 0.07 mg/kg (PBI of 120 days). In all other rotated crops, TRRs were higher, accounting for up to 0.26 and 0.24 mg/kg in red beet leaves and Swiss chard and for up to 1.0 and 2.38 mg/kg in wheat forage and straw, respectively. Although residues in rotated crops decreased with soil ageing, TRR after the third rotation (408 days) were still significant, ranging from 0.03 mg/kg in wheat grain to 0.96 mg/kg in wheat straw (Germany, 2005). These results suggests possible soil uptake, even at long plant-back intervals.

Therefore, a field study was conducted with an application rate of 0.14 kg imidacloprid/ha. Following bare soil application, imidacloprid was incorporated into the soil at a depth of about 5 cm. Barley was used as a primary crop and was either destroyed and incorporated into soil simulating crop failure or grown until normal harvest, simulating normal rotation practice. Lettuce and turnip were sown as succeeding crops 30 days or 112 DAT. Since imidacloprid is used for seed treatment of cereals and several residue trials are available, small grain crops were not tested as rotational crops. At maturity, residues of imidacloprid were below the LOQ of 0.01 mg/kg in both crops and 'total residues'

according to the risk assessment residue definition were detected in turnip leaves and leaves of immature lettuce at levels below the LOQ of 0.05 mg/kg. The parent compound was also analysed in soil. Initial imidacloprid residues in soil (0–10 cm depth) were 0.08 mg/kg and declined to a minimum of 0.04 mg/kg, 212 DAT (Germany, 2005). Considering that imidacloprid was incorporated at a depth of 5 cm, it is expected that the rotated crops were exposed to a soil concentration two times higher compared to the analysed samples (0.16 and 0.08 mg/kg soil).

As imidacloprid is a persistent active substance expected to accumulate in soil following multiannual applications and the available studies demonstrated that it can be taken up from the soil by the plant, when assessing the magnitude of residues in rotational crops, EFSA considered not only the uses compliant with the new conditions of approval, but also the possible carry-over from the (former) authorised EU outdoor uses. In particular, in order to conclude if specific MRLs and/or risk mitigation measures should be recommended for rotational crops, imidacloprid concentrations measured in the tested soils detailed above were compared with the imidacloprid concentrations expected in soil following annual and multiannual applications according to the most critical indoor and outdoor EU GAPs, respectively.

1.2.2.1. Magnitude of residue in rotational crops considering the new conditions of approval (indoor uses only)

Considering the degradation rates of imidacloprid (see Section 1.1.2), the maximum application rate of 2 × 0.31 kg/ha per year (indoor soil application by drip irrigation on sweet peppers) assessed in this review, a soil bulk density of 1.5 g/cm^3, a soil depth of 20 cm and no crop interception, the soil concentration that would result from a single year use and the plateau concentration in soil taking into account accumulation over the years were calculated as 0.203 mg/kg soil and as 0.348 mg/kg soil, respectively.

On the basis of the same assumptions on soil depth and density with no crop interception, the same calculation was also performed for the following most critical GAP currently authorised on cucurbits with edible peel (indoor soil application by drip irrigation at 2 × 0.15 kg/ha) and expected to cover also the treatment conditions of the other indoor uses. For this GAP, the soil concentration that would result from a single year use and the plateau concentration in soil were calculated as 0.098 mg/kg soil and 0.168 mg/kg soil, respectively.

According to the results of these calculations, imidacloprid concentration tested in the rotational field studies (0.16 mg/kg soil) is not covering the soil concentration expected from annual and multiannual applications according to the most critical indoor GAP currently authorised for sweet peppers (0.203 mg/kg soil and 0.348 mg/kg soil). As a consequence, following both annual and multiannual applications of imidacloprid according to this indoor GAP, a possible uptake by crops grown in rotation cannot be excluded.

Therefore, field rotational crops studies covering the most critical indoor GAP on sweet peppers are still required. In the meanwhile, Member States granting authorisations for imidacloprid should take the appropriate risk mitigation measures (e.g. restricting the use only on sweet peppers grown with soil-less growing systems) in order to avoid the presence of significant residues in rotational crops.

For all other indoor uses assessed, based on the calculated plateau and the results of the field study, significant residues are not expected in rotational crops provided that imidacloprid is used according to the GAPs reported in this review.

1.2.2.2. Carry-over of residues in plant commodities due to (former) authorised EU outdoor uses

On the basis of the same assumptions on soil depth and density with no crop interception, the plateau in soil was also calculated for the most critical (former) authorised EU outdoor uses which remain possible uses until December 2018 (e.g. cereal and potato seed treatment).

An annual soil application rate of 0.213 kg/ha was used for the calculation. The value of 0.213 kg/ha represents a rotation of the use on potatoes (highest dose rate 0.34 kg/ha) followed by 3 years of use on winter cereals (highest dose rate 0.17 kg/ha), in line with the approach followed for the recent risk assessment on bees (see EFSA, 2018a for further details). The accumulated plateau concentration in soil resulting from many years of this rotation was calculated as 0.05 mg/kg.

According to the results of these calculations, imidacloprid concentrations tested in the rotational field studies (0.16 mg/kg soil) is covering the soil concentration expected from the multiannual applications according to the most critical EU outdoor GAPs. Therefore, based on the field study performed with rotated lettuce and turnip, a significant carry-over is not expected in leafy and root crops.

Considering the available metabolism study on cotton showing that, following seed treatment, imidacloprid is not translocated to the mature seeds (see Section 1.1.1), a significant carry-over can also be excluded for pulses and oilseeds. This is also confirmed by outdoor residue trials performed on rape seed and cotton seed following seed treatment at up to 1.4 kg a.s./100 kg seeds where residues of imidacloprid and 'total imidacloprid' in seeds were always below the LOQs of 0.01 and 0.05 mg/kg (Germany, 2015).

Nevertheless, the confined rotational crops study showed a significant soil uptake in cereal straw, grain and forage. Therefore, in order to estimate if specific temporary MRLs are required to cover the possible carry-over in these crops, EFSA considered the available outdoor residue trials on cereals reported in Appendix B.1.2.1. In cereals (barley and wheat), following seed treatment at 70 g a.s./100 kg seeds corresponding to 0.17 kg/ha (expected to result in a soil concentration of 0.056 mg/kg soil), residues of imidacloprid and 'total imidacloprid' in straw ranged from < 0.01 to 0.11 mg/kg and from < 0.02 to 0.28 mg/kg, respectively. In grain, residues of imidacloprid and 'total imidacloprid' were always below the LOQs of 0.01 and 0.05 mg/kg.

Based on the overall available data, it is therefore concluded that specific temporary MRLs covering the possible carry-over from (former) outdoor EU uses are not required for any plant commodity relevant for human consumption. However, as significant residues of parent and metabolites can be expected in cereals straw, their impact on the residues in livestock was considered further in section 2.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of residues in processed commodities from apples, citrus fruits, grapes, peaches, tomatoes, cucurbits with inedible peel, beans with pods, cotton seeds, olives, potatoes, head cabbages, peanuts, coffee beans and hops were reported in the framework of this review (Germany, 2015). In all studies, except for coffee beans and peanuts, residues were analysed simultaneously for imidacloprid and for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, in line with the proposed residue definitions.

Robust processing factors could be derived for citrus fruits (peeled and juice), apples (juice, sauce) and pears (juice), canned peaches, wine grapes (wet pomace, must, red wine and white wine), tomatoes paste, peeled cucurbits with inedible peel, beans with pods (cooked, canned), cotton seeds (crude oil) and olives for oil production (virgin oil, refined oil and press cake).

For all other processed commodities, no robust processing factors could be derived as the number of studies was not sufficient. Nevertheless, further processing studies are not required in this case as they are not expected to affect the outcome of the risk assessment. If more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

It is noted that in cotton seeds, parent was below the LOQ in both raw and processed commodities, while imidacloprid and its metabolites containing the 6-chloropyridinyl moiety were present at up to 2.7 mg/kg in the raw commodities and concentrated up to 3.2 mg/kg in meal. Similarly in beans with pods, while parent compound was present at very low levels in the raw and in the processed commodities, imidacloprid and its metabolites containing the 6-chloropyridinyl moiety were present at up to 0.39 mg/kg in the raw commodities and concentrated to up to 0.48 mg/kg in canned beans. As underlined in Section 1.2.1, these results suggest that imidacloprid only could not be a sufficient marker in pulses and oilseeds; nevertheless the limited data available does not allow concluding if a different residue definition for enforcement is required for these crops (see also Section 1.2.1).

1.2.4. Proposed MRLs

Consequently, when considering the magnitude of residues expected from the uses compliant with the new conditions of approval (indoor uses and import tolerances only), the available data were sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for currants, gooseberries, rose hips, mulberries, azaroles, elderberries, granate apples, lettuce and other salad plants where the available data were insufficient to derive even tentative MRLs.

Specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures (e.g. use only on sweet peppers grown with soil-less growing systems) in order to avoid significant residues to occur in rotational crops.

2. Residues in livestock

Imidacloprid is authorised for use on several crops (dry pulses, citrus fruits and peanuts) that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. As EU outdoor GAPs are expected to be withdrawn according to the new conditions of approval, **only indoor** uses and **import tolerances** were considered for the calculation of the livestock exposure. Moreover, in order to cover the carry-over in cereals due to the (former) authorised EU outdoor uses, the results from the available outdoor trials on wheat and barley (grain and straw) were also considered for the calculation of the livestock exposure. The input values for all relevant commodities are summarised in Appendix D.1. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in all commodities of animal origin.

Metabolism studies in lactating goats and laying hens were submitted and evaluated during the peer review (Germany, 2005).

In lactating goats fed for three consecutive days with imidacloprid at 10 mg/kg body weight (bw) per day, the parent compound dominates the metabolic pattern in milk, fat and muscles, representing up to 74% of TRR. In liver and kidney, a more complex metabolic pattern was observed with imidacloprid almost completely degraded and several different metabolites identified. In particular, glucuronide conjugates of hydroxy-metabolites, imidacloprid olefine metabolite (M06) and a glycine-conjugate of 6-chloropyridine-3-carboxylic acid were major constituents of the residue in kidneys accounting for 14%, 18% and 17% of the TRR, respectively. In liver, only imidacloprid-desnitro metabolite (M09) was identified above 10% of the TRR (16% TRR).

In hens fed with imidacloprid at 10 mg/kg bw per day, parent compound was still present at significant levels only in fat (12% TRR) while imidacloprid olefine metabolite (M06) was identified as the major constituent of the residue in liver, muscle, fat and eggs, representing 15%, 27%, 23% and 29% of the TRR, respectively.

Based on the results of the available metabolism studies, it is clear that the parent compound is almost completely degraded in the liver and kidney of ruminants and in poultry tissues and in eggs. Nevertheless, on the basis of livestock exposure resulting from the uses assessed in this review, no significant residues are expected in any animal commodities. This was also demonstrated by feeding studies performed in dairy goats and laying hens, with the lowest dose being 4.8N the expected critical exposure for ruminants and 15N the expected critical exposure for poultry. Under these conditions, total imidacloprid residues (analysed as the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety) were below the LOQ (0.02 mg/kg) in milk, eggs, muscle and fat. In liver and kidneys, total residues ranged from 0.02 to 0.05 mg/kg. This shows that at the calculated dietary burdens, no significant residues are expected in all animal tissues, in milk and in eggs.

Hence, the residue definition for enforcement in all animal commodities is proposed as parent compound only (by default) and MRLs and risk assessment values for the relevant commodities in ruminants and poultry can be established at the LOQ level. These MRLs are expected to cover the possible carry-over in cereal (grain and straw) due to the (former) authorised outdoor EU uses. For risk assessment, it is still proposed to keep the following residue definition as agreed during the peer review: sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid. As in the livestock feeding studies, residues were analysed only according to the risk assessment residue definition, a conversion factor of 1 is proposed for risk assessment.

It is underlined that, if additional uses leading to significant increase in livestock exposure will be granted in the future, the residue definition for animal commodities should be reconsidered (and eventually additional feeding studies performed according to the proposed residue definitions should be submitted).

Analytical methods for the enforcement of the proposed residue definition were evaluated during the peer review and showed that imidacloprid can be enforced in milk at the LOQ of 0.01 mg/kg and in animal tissues and in eggs at an LOQ of 0.03 mg/kg (Germany, 2008).

According to the EURL, based on the general experience with this compound, although only a screening method is available for animal commodities (except for honey validated down to 0.002 mg/kg), it is expected that imidacloprid residues can be enforced with an LOQ of 0.01 mg/kg in all commodities of animal origin (EURL, 2016).

3. Consumer risk assessment

In order to support risk managers in the decision making process, in the framework of this MRL review, three separate risk assessments were performed:

- A risk assessment reflecting the EU indoor GAPs and the uses authorised in third countries (import tolerances) only, in line with the new conditions of approval for imidacloprid (Section 3.1).
- A risk assessment reflecting all uses, including the EU outdoor GAPs that are expected to be withdrawn by Member States (Section 3.2). This calculation was performed to derive a list of alternative MRLs possibly safe for consumers that could be considered by risk managers to support emergency authorisations.
- An indicative risk assessment considering the CXLs only (Section 3.3).

Since according to the new conditions of approval, all EU outdoor uses are expected to be withdrawn by Member States and the CXLs are not compatible with the EU MRL (see also Section 3.3 for further details), only the calculations described under Section 3.1 and reflecting the new conditions of approval were considered by EFSA as a basis for the MRL recommendations.

3.1. Consumer risk assessment without consideration of the existing CXLs – Indoor uses and import tolerances

Chronic and acute exposure calculations for the **indoor uses** and the **import tolerances** reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). This calculation is also expected to cover the possible carry-over in cereals from the former authorised outdoor EU uses. Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix D. 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, 2009). For those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. According to the RMS, MRLs in the EU legislation are currently established for the parent compound only, but are actually based on data according to the so-called 'total residue' which is expected to cover the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety (Germany, 2015). Therefore, when considering the existing EU MRL, no conversion factor from enforcement to risk assessment was applied. All input values included in the exposure calculations are summarised in Appendix D.2.

The exposures calculated were compared with the toxicological reference values for imidacloprid, derived by EFSA (2008a) under Directive 91/414/EEC. The highest chronic exposure was calculated for WHO cluster diet B, representing 6% of the acceptable daily intake (ADI). With regard to the acute exposure, however, an exceedance of the acute reference dose (ARfD) was identified for escaroles, representing 109% of the ARfD. A second exposure calculation was therefore performed, excluding this crop. According to the results of this second calculation, the highest chronic exposure remained unchanged; the highest acute exposure was then calculated for cucumbers, representing 76% of the ARfD.

Based on these calculations, a potential risk to consumers was identified for the use of imidacloprid on escaroles and no further refinements of the risk assessment were possible. For the remaining commodities, although uncertainties remain due to the data gaps identified in the previous sections, the indicative exposure calculation did not indicate a risk to consumers.

3.2. Consumer risk assessment without consideration of the existing CXLs – all uses

Chronic and acute exposure calculations for **all uses** 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 D. 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, 2009). For those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. For the same reasons reported above, when considering the existing MRL, no conversion factor from enforcement to risk assessment was applied. All input values included in the exposure calculations are summarised in Appendix D.3.

The exposures calculated were compared with the toxicological reference values for imidacloprid, derived by EFSA (EFSA, 2008a) under Directive 91/414/EEC. The highest chronic exposure was calculated for WHO cluster diet B, representing 7% of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for escaroles, sweet peppers and kale, representing 270%, 231% and 108% of the ARfD, respectively. A second exposure calculation was therefore performed, considering fall-back GAPs for these commodities: NEU outdoor GAP for escarole and kale and EU indoor GAP for peppers. According to the results of the second calculation, the highest chronic exposure declined to 6% of the ADI for WHO Cluster diet B; the highest acute exposure was then calculated for cucumbers, representing 76% of the ARfD.

Based on these calculations, a potential risk to consumers was identified for the southern outdoor GAPs on escaroles, sweet peppers and kale. For these commodities, fall-back GAPs were identified in order to reduce the exposure of consumers. For the remaining commodities, although uncertainties remain due to the data gaps identified in the previous sections, the indicative exposure calculation did not indicate a risk to consumers.

3.3. Indicative consumer risk assessment of the existing CXLs

As the residue definition for enforcement of the CXLs (sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid) is not compatible with the residue definition for enforcement proposed by EFSA (imidacloprid only), for information purposes, EFSA has performed an indicative risk assessment with the existing CXLs only, considering the relevant data from the JMPR evaluations (FAO, 2008, 2015).

As the CXLs and the risk assessment values from JMPR were derived according to the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, the risk assessment input values as derived by the JMPR could be directly considered for an indicative risk assessment, without applying a conversion factor. An overview of the input values used for this exposure calculation is also provided in Appendix D.4.

Chronic and acute exposure calculations were performed using revision 2 of the EFSA PRIMo and the exposures calculated were compared with the toxicological reference values derived for imidacloprid. The highest chronic exposure was calculated for WHO Cluster diet B, representing 8% of the ADI. With regard to the acute exposure, an exceedance of the ARfD was identified for celery and kale, representing 184% and 169% of the ARfD, respectively. As this indicative assessment only aims to the identification of CXLs not safe for consumers, a further refinement of the risk assessment was not performed.

These calculations indicate a potential risk to consumers for the existing CXLs on celery and kales. For the remaining CXLs, although major uncertainties remain due to the data gaps identified in the previous sections, the indicative exposure calculation did not indicate a risk to consumers. However, considering that CXLs are currently expressed according to a residue definition for enforcement not compatible with the one proposed by EFSA, they are not recommended for inclusion in the EU legislation.

Conclusions

Based on the recent EFSA conclusions on the peer review of the updated pesticide risk assessment for bees, the conditions of approval for imidacloprid were recently restricted to uses in permanent greenhouses or for the treatment of seeds intended to be used only in permanent greenhouses, with crops staying within a permanent greenhouse during its entire life cycle. Member States were required to amend or withdraw their authorisations by 19 September 2018, with a maximum period of grace expiring on the 19 December 2018.

As the GAPs and the supporting residue data considered in this MRL review were collected before the new conditions of approval entering into force, the data assessed in the present reasoned opinion are reflecting not only the uses compliant with the new conditions of approval, but also the (former) authorised EU outdoor uses. In particular, in order to support risk managers in the decision making process, EFSA considered in this assessment:

- Residue data reflecting the EU indoor GAPs and the uses authorised in third countries (import tolerances) only, in line with the new conditions of approval for imidacloprid. This data was used to derive the MRL recommendations for plant and animal commodities as reported in the summary table and in Appendix B.4. These MRLs are also expected to cover the possible carry-over from the (former) authorised EU outdoor uses.

- Residue data reflecting all uses, including the EU outdoor GAPs. This data was used to derive a list of alternative MRLs possibly safe for consumers that could be considered by risk managers to support emergency authorisations. The list of alternative MRLs derived considering all uses and the results of the related risk assessment are reported respectively in Appendices G and B.3.2 to this reasoned opinion. Moreover, residue trials supporting the outdoor EU uses were also considered to assess the possible carry-over of imidacloprid in plant and animal commodities after the entry into force of the new conditions of approval.

The metabolism of imidacloprid was investigated in primary (fruit, root and leafy crops, cereals and pulses and oilseeds) and in rotational crops (root and leafy crops, cereals). Based on the results of the metabolism in primary and rotational crops the residue definition for enforcement in plant commodities is proposed as imidacloprid only. For risk assessment, the residue definition is confirmed as the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid. The same residue definitions apply to rotational crops and processed commodities.

It is noted that results from the available residue trials suggest that imidacloprid only could not be a sufficient marker in pulses and oilseeds. Nevertheless, the limited residue data available does not allow concluding if a different residue definition for enforcement is required for these crops. Therefore, the proposed residue definition for enforcement in pulses and oilseeds should be considered tentative only and, based on the results of the additional trials on dry beans, peanuts, beans and peas without pods required to support the existing import tolerances, may need to be reconsidered.

A sufficiently validated analytical method is available for the enforcement of the proposed residue definition in high water content, high acid content and dry commodities at the LOQ of 0.01 mg/kg, high oil content at the LOQ of 0.02 mg/kg and in hops at 0.2 mg/kg. There are indications that imidacloprid can be enforced in coffee beans with an LOQ of 0.01 mg/kg; however, a confirmatory method and an ILV are still missing. According to the EURLs, during routine analyses an LOQ of 0.01 mg/kg is achievable in the four main matrices.

Regarding the magnitude of residues expected in primary crops from the uses compliant with the new conditions of approval (indoor uses and import tolerances only), the available data were sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for currants, gooseberries, rose hips, mulberries, azaroles, elderberries, granate apples, lettuce and other salad plants where the available data were insufficient to derive even tentative MRLs.

As imidacloprid is a persistent active substance expected to accumulate in soil following multiannual applications and the available studies demonstrated that it can be taken up from the soil by the plant, in the assessment of the magnitude of residues in rotational crops, EFSA considered not only the uses compliant with the new conditions of approval, but also the possible carry-over from the (former) authorised EU outdoor uses.

When considering only the uses compliant with the new conditions of approval, it is concluded that specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures (e.g. use only on sweet peppers grown with soil-less growing systems) in order to avoid significant residues to occur in rotational crops.

When considering the possible carry-over of residues in plant commodities due to (former) authorised EU outdoor uses, it is concluded that specific temporary MRLs for plant commodities are not required to cover the possible carry-over from (former) outdoor EU uses. On other hand, as significant residues of parent and metabolites can be expected in cereals straw, their impact on the residues in livestock was considered further.

Imidacloprid is authorised for use on several crops (dry pulses, citrus fruits and peanuts) that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock according to OECD guidance. As EU outdoor GAPs are expected to be withdrawn according to the new conditions of approval, only indoor uses and import tolerances were considered for the calculation of the livestock exposure. Moreover, in order to cover the carry-over in cereals due to the (former) authorised EU outdoor uses, the results from the available outdoor trials on wheat and barley (grain and straw) were also considered for the calculation of the livestock exposure. Since, the dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM, the behaviour of residues was assessed in all commodities of animal origin.

Metabolism studies in lactating goats and laying hens were submitted and evaluated during the peer review. According to the results of these studies is clear that parent compound is almost completely degraded in liver and kidney of ruminants and in poultry tissues and eggs, with glucuronide

conjugates of hydroxy-metabolites, imidacloprid olefine metabolite (M06) and a glycine-conjugate of 6-chloropyridine-3-carboxylic acid, representing the main identified compounds. Nevertheless, on the basis of livestock exposure resulting from the uses assessed in this review, no significant residues are expected in animal commodities. Hence, the residue definition for enforcement in all animal commodities is proposed as parent compound only (by default) and MRLs and risk assessment values for the relevant commodities in ruminants and poultry can be established at the LOQ level. These MRLs are expected to cover the possible carry-over in cereal due to the (former) authorised outdoor EU uses. For risk assessment, it is still proposed to keep the following residue definition as agreed during the peer review: sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid. It is underlined that, if additional uses leading to significant increase in livestock exposure will be granted in the future, the residue definition for animal commodities should be reconsidered.

Analytical methods for the enforcement of the proposed residue definition were evaluated during the peer review and showed that imidacloprid can be enforced in milk at the LOQ of 0.01 mg/kg and in animal tissues and in eggs at an LOQ of 0.03 mg/kg. According to the EURLs, based on the general experience with this compound, although only a screening method is available for animal commodities (except for honey validated down to 0.002 mg/kg), it is expected that imidacloprid residues can be enforced with an LOQ of 0.01 mg/kg in all commodities of animal origin.

Chronic and acute exposure calculations resulting from the authorised **indoor uses** and **import tolerances** (in line with the new conditions of approval) reported in the framework of this review were performed using revision 2 of the EFSA PRIMo. This calculation is also expected to cover the possible carry-over in cereals from the former authorised outdoor EU uses. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. According to the RMS, MRLs in the EU legislation are currently established for the parent compound only, but are actually based on data according to the so-called 'total residue' which is expected to cover the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety. Therefore, when considering the existing EU MRL, no conversion factor from enforcement to risk assessment was applied. Based on these calculations, a potential risk to consumers was identified for the use of imidacloprid on escaroles and no further refinements of the risk assessment were possible. For the remaining commodities, although uncertainties remain due to the data gaps identified in the assessment, the indicative exposure calculation did not indicate a risk to consumers.

Chronic and acute exposure calculations for **all uses** (including the former authorised outdoor EU uses) reported in the framework of this review were also performed using revision 2 of the EFSA PRIMo (EFSA, 2007). For those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. For the same reasons reported above, when considering the existing MRL, no conversion factor from enforcement to risk assessment was applied. Based on these calculations, a potential risk to consumers was identified for the southern outdoor GAPs on escaroles, sweet peppers and kale. For these commodities fall-back GAPs were identified in order to reduce the exposure of consumers. For the remaining commodities, although uncertainties remain due to the data gaps identified in the assessment, the indicative exposure calculation did not indicate a risk to consumers.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for imidacloprid. Nevertheless, as the residue definition for enforcement of the CXLs is not compatible with the residue definition for enforcement proposed in the framework of this review, for information purposes, an indicative risk assessment was performed considering the existing CXLs only. These calculations indicate a potential risk to consumers for the existing CXLs on celery and kales. For the remaining CXLs, the indicative exposure calculation did not indicate a risk to consumers. However, considering that CXLs are currently expressed according to a residue definition for enforcement not compatible with the one proposed by EFSA, they are not recommended for inclusion in the EU legislation.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). It is underlined that only the authorised uses reflecting the new conditions of approval were considered by EFSA as a basis for the MRL recommendations. 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 summary table footnotes for details). In particular, some tentative MRLs and/or existing EU MRLs need to be confirmed by the following data:

- Additional residue trials on citrus fruits, table and wine grapes, blueberries, cranberries, currants, gooseberries, rose hips, mulberries, azaroles, elderberries, pomegranate, cucurbits with inedible peel, okra, lettuce and other salad plants, beans and peas with and without pods, dry beans, peanuts, coffee beans and hops.
- Confirmatory method and ILV of the analytical method for enforcement in coffee beans.

Moreover, EFSA identified the following data gap which is not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Field rotational crops studies covering the most critical indoor GAP on sweet peppers.

Pending the submission of this study, Member States granting authorisations for imidacloprid should take the appropriate risk mitigation measures (e.g. restricting the use only on sweet peppers grown with soil-less growing systems) in order to avoid the presence of significant residues in rotational crops.

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. Member States are in any case recommended to withdraw the indoor GAP on escaroles currently authorised as a risk for consumers could not be excluded for this use (Table 2).

Table 2: Summary table (based on GAPs compliant with the new conditions of approval)

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: imidacloprid					
110010	Grapefruit	1	1	0.9	Further consideration needed[(a)]
110020	Oranges	1	1	0.9	Further consideration needed[(a)]
110030	Lemons	1	1	0.9	Further consideration needed[(a)]
110040	Limes	1	1	0.9	Further consideration needed[(a)]
110050	Mandarins	1	1	0.9	Further consideration needed[(a)]
120010	Almonds	0.05*	0.01	–	Further consideration needed[(b)]
120020	Brazil nuts	0.05*	0.01	–	Further consideration needed[(b)]
120030	Cashew nuts	0.05*	0.01	–	Further consideration needed[(b)]
120040	Chestnuts	0.05*	0.01	–	Further consideration needed[(b)]
120050	Coconuts	0.05*	0.01	–	Further consideration needed[(b)]
120060	Hazelnuts	0.05*	0.01	–	Further consideration needed[(b)]
120070	Macadamia	0.05*	0.01	–	Further consideration needed[(b)]
120080	Pecans	0.05*	0.01	0.02*	Recommended[(c)]
120090	Pine nuts	0.05*	0.01	–	Further consideration needed[(b)]
120100	Pistachios	0.05*	0.01	–	Further consideration needed[(b)]
120110	Walnuts	0.05*	0.01	–	Further consideration needed[(b)]
130010	Apples	0.5	0.5	–	Further consideration needed[(b)]
130020	Pears	0.5	1	–	Further consideration needed[(b)]
140010	Apricots	0.5	1.5	–	Further consideration needed[(b)]
140020	Cherries	0.5	4	–	Further consideration needed[(b)]
140030	Peaches	0.5	1.5	–	Further consideration needed[(b)]
140040	Plums	0.3	1.5	–	Further consideration needed[(b)]
151010	Table grapes	1	1	0.7	Further consideration needed[(a)]
151020	Wine grapes	1	1	0.7	Further consideration needed[(a)]
152000	Strawberries	0.5	0.5	–	Further consideration needed[(b)]
153010	Blackberries	5	5	–	Further consideration needed[(b)]
153020	Dewberries	5	5	–	Further consideration needed[(b)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
153030	Raspberries	5	5	–	Further consideration needed[b]
154010	Blueberries	5	5	5	Further consideration needed[a]
154020	Cranberries	0.05*	0.05*	5	Further consideration needed[a]
154030	Currants (red, black and white)	5	5	5	Further consideration needed[d]
154040	Gooseberries	5	5	5	Further consideration needed[d]
154050	Rose hips	5	5	5	Further consideration needed[d]
154060	Mulberries	5	5	5	Further consideration needed[d]
154070	Azarole (Mediterranean medlar)	0.05*	5	0.05	Further consideration needed[d]
154080	Elderberries	5	5	5	Further consideration needed[d]
161030	Table olives	0.5	2	–	Further consideration needed[b]
161040	Kumquats	0.05*	1	–	Further consideration needed[b]
163020	Bananas	0.05*	0.05	0.01*	Recommended[c]
163030	Mangoes	0.2	0.2	–	Further consideration needed[b]
163050	Pomegranate	1	1	1	Further consideration needed[d]
211000	Potatoes	0.5	0.5	–	Further consideration needed[b]
212010	Cassava	0.5	0.5	–	Further consideration needed[b]
212020	Sweet potatoes	0.5	0.5	–	Further consideration needed[b]
212030	Yams	0.5	0.5	–	Further consideration needed[b]
212040	Arrowroot	0.5	0.5	–	Further consideration needed[b]
213010	Beetroot	0.5	0.5	–	Further consideration needed[b]
213020	Carrots	0.5	0.5	–	Further consideration needed[b]
213030	Celeriac	0.5	0.5	–	Further consideration needed[b]
213040	Horseradish	0.5	0.5	–	Further consideration needed[b]
213050	Jerusalem artichokes	0.5	0.5	–	Further consideration needed[b]
213060	Parsnips	0.5	0.5	–	Further consideration needed[b]
213070	Parsley root	0.5	0.5	–	Further consideration needed[b]
213080	Radishes	0.5	0.5	–	Further consideration needed[b]
213090	Salsify	0.5	0.5	–	Further consideration needed[b]
213100	Swedes	0.5	0.5	–	Further consideration needed[b]
213110	Turnips	0.5	0.5	–	Further consideration needed[b]
220020	Onions	0.1	0.1	–	Further consideration needed[b]
231010	Tomatoes	0.5	0.5	0.3	Recommended[c]
231020	Peppers	1	1	0.9	Recommended[c]
231030	Aubergines (egg plants)	0.5	0.2	0.3	Recommended[c]
231040	Okra, lady's fingers	0.5	-	0.5	Further consideration needed[e]
232010	Cucumbers	1	1	0.5	Recommended[c]
232020	Gherkins	0.5	-	0.4	Recommended[f]
232030	Courgettes	1	1	0.4	Recommended[c]
233010	Melons	0.5	0.2	0.15	Further consideration needed[a]
233020	Pumpkins	0.5	-	0.15	Further consideration needed[e]
233030	Watermelons	0.2	0.2	0.15	Further consideration needed[a]
234000	Sweet corn	0.1	0.02*	–	Further consideration needed[b]
241010	Broccoli	0.5	0.5	–	Further consideration needed[b]
241020	Cauliflower	0.5	0.5	–	Further consideration needed[b]
242010	Brussels sprouts	0.5	0.5	–	Further consideration needed[b]
242020	Head cabbage	0.5	0.5	–	Further consideration needed[b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
243020	Kale	0.3	5	–	Further consideration needed[(b)]
251010	Lamb's lettuce	2	-	2	Further consideration needed[(g)]
251020	Lettuce	2	2	2	Further consideration needed[(d)]
251030	Escarole (broad-leaf endive)	1	-	–	Further consideration needed[(h)]
251040	Cress	2	-	2	Further consideration needed[(g)]
251050	Land cress	2	-	2	Further consideration needed[(g)]
251070	Red mustard	2	-	2	Further consideration needed[(g)]
251080	Leaves and sprouts of *Brassica* spp.	2	-	2	Further consideration needed[(g)]
256080	Basil	2	20	–	Further consideration needed[(b)]
260010	Beans (fresh, with pods)	2	2	5	Further consideration needed[(a)]
260020	Beans (fresh, without pods)	2	2	2	Further consideration needed[(a)]
260030	Peas (fresh, with pods)	5	5	5	Further consideration needed[(a)]
260040	Peas (fresh, without pods)	2	2	2	Further consideration needed[(a)]
270030	Celery	2	6	–	Further consideration needed[(b)]
270060	Leek	0.05*	0.05*	–	Further consideration needed[(b)]
300010	Beans (dry)	2	2	2	Further consideration needed[(a)]
300020	Lentils (dry)	2	2	–	Further consideration needed[(b)]
300030	Peas (dry)	2	2	–	Further consideration needed[(b)]
300040	Lupins (dry)	2	2	–	Further consideration needed[(b)]
401020	Peanuts	1	1	0.5	Further consideration needed[(a)]
401050	Sunflower seed	0.1	0.05*	–	Further consideration needed[(b)]
401060	Rape seed	0.1	0.05*	–	Further consideration needed[(b)]
401070	Soya bean	0.05*	3	–	Further consideration needed[(b)]
402010	Olives for oil production	1	2	–	Further consideration needed[(b)]
500010	Barley grain	0.1	0.05	–	Further consideration needed[(b)]
500020	Buckwheat grain	0.1	0.05	–	Further consideration needed[(b)]
500030	Maize grain	0.1	0.05	–	Further consideration needed[(b)]
500040	Millet grain	0.05*	0.05	–	Further consideration needed[(b)]
500050	Oats grain	0.1	0.05	–	Further consideration needed[(b)]
500060	Rice grain	1.5	0.05	–	Further consideration needed[(b)]
500070	Rye grain	0.1	0.05	–	Further consideration needed[(b)]
500080	Sorghum grain	0.05*	0.05	–	Further consideration needed[(b)]
500090	Wheat grain	0.1	0.05	–	Further consideration needed[(b)]
610000	Tea (dried leaves and stalks,fermented or otherwise of *Camellia sinensis*)	0.05*	50	–	Further consideration needed[(b)]
620000	Coffee beans	1	1	1	Further consideration needed[(a)]
700000	Hops (dried),including hop pellets and unconcentrated powder	10	10	15	Further consideration needed[(a)]
900010	Sugar beet (root)	0.5	0.5	–	Further consideration needed[(b)]
1011010	Swine muscle	0.1	0.1	0.03*	Recommended[(c)]
1011020	Swine fat (free of lean meat)	0.05*	0.1	0.03*	Recommended[(c)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1011030	Swine liver	0.3	0.3	0.03*	Recommended[(c)]
1011040	Swine kidney	0.3	0.3	0.03*	Recommended[(c)]
1012010	Bovine muscle	0.1	0.1	0.03*	Recommended[(c)]
1012020	Bovine fat	0.05*	0.1	0.03*	Recommended[(c)]
1012030	Bovine liver	0.3	0.3	0.03*	Recommended[(c)]
1012040	Bovine kidney	0.3	0.3	0.03*	Recommended[(c)]
1013010	Sheep muscle	0.1	0.1	0.03*	Recommended[(c)]
1013020	Sheep fat	0.05*	0.1	0.03*	Recommended[(c)]
1013030	Sheep liver	0.3	0.3	0.03*	Recommended[(c)]
1013040	Sheep kidney	0.3	0.3	0.03*	Recommended[(c)]
1014010	Goat muscle	0.1	0.1	0.03*	Recommended[(c)]
1014020	Goat fat	0.05*	0.1	0.03*	Recommended[(c)]
1014030	Goat liver	0.3	0.3	0.03*	Recommended[(c)]
1014040	Goat kidney	0.3	0.3	0.03*	Recommended[(c)]
1015010	Horse muscle	0.1	0.1	0.03*	Recommended[(c)]
1015020	Horse fat	0.05*	0.1	0.03*	Recommended[(c)]
1015030	Horse liver	0.3	0.3	0.03*	Recommended[(c)]
1015040	Horse kidney	0.3	0.3	0.03*	Recommended[(c)]
1016010	Poultry muscle	0.05*	0.02	0.03*	Recommended[(c)]
1016020	Poultry fat	0.05*	0.02	0.03*	Recommended[(c)]
1016030	Poultry liver	0.05*	0.05	0.03*	Recommended[(c)]
1016040	Poultry kidney	0.05*	0.05	0.03*	Recommended[(c)]
1020010	Cattle milk	0.1	0.1	0.01*	Recommended[(c)]
1020020	Sheep milk	0.1	0.1	0.01*	Recommended[(c)]
1020030	Goat milk	0.1	0.1	0.01*	Recommended[(c)]
1020040	Horse milk	0.1	0.1	0.01*	Recommended[(c)]
1030000	Birds' eggs	0.05*	0.02	0.03*	Recommended[(c)]
–	Other commodities of plant and animal origin	Regulation (EU) No 491/2014	–	–	Further consideration needed[(i)]

MRL: maximum residue level; GAP: Good Agricultural Practice; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): 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 (assuming the existing residue definition); CXL is not compatible with EU residue definitions (combination E-II in Appendix E).
(b): There are no relevant INDOOR authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix E).
(c): 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 not compatible with EU residue definitions (combination G-II in Appendix E).
(d): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); CXL is not compatible with EU residue definitions (combination C-II in Appendix E).
(e): 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 (assuming the existing residue definition); no CXL is available (combination E-I 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; no CXL is available (combination G-I in Appendix E).
(g): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(h): GAP evaluated at EU level is not supported by data and a risk to consumers cannot be excluded for the existing EU MRL; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-I in Appendix E).
(i): There are no relevant INDOOR 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
bw	body weight
CAC	Codex Alimentarius Commission

CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
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)
EC	emulsifiable concentrate
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
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
MRL	maximum residue level
MS	Member States
MW	molecular weight
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
R_{ber}	statistical calculation of the MRL by using a non-parametric 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
SEU	southern European Union
SL	soluble concentrate
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TAR	total applied radioactivity
TRR	total radioactive residue
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Summary of authorised uses considered for the review of MRLs

Critical outdoor GAPs for northern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Apples	*Malus domestica*	NEU	Outdoor	NL	Insects	WG	700.0	g/kg	Foliar treatment – spraying	70	79		1			0.07	0.11	kg a.i./ ha	14	Covers also CZ GAP. More critical GAPs authorised in BE (2 × 0.125 g/ha) and DE (2 × 0.175 g/ ha) are not sufficiently supported by data
Pears	*Pyrus communis*	NEU	Outdoor	NL	Insects	WG	700.0	g/kg	Foliar treatment – spraying	71	79		1				0.08	kg a.i./ ha	14	Post-flowering uses
Quinces	*Cydonia oblonga*	NEU	Outdoor	AT					Foliar treatment – spraying	70	79		1			0.07	0.11	kg a.i./ ha	14	BBCH 54 or 70-79 or 91-92
Apricots	*Armeniaca vulgaris,* syn: *Prunus armeniaca*	NEU	Outdoor	DE					Foliar treatment – spraying	71			1				0.11	kg a.i./ ha	21	Application rate for standard tree of 3 m height
Peaches	*Persica vulgaris,* syn: *Prunus persica*	NEU	Outdoor	DE					Foliar treatment – spraying	71			1				0.11	kg a.i./ ha	21	Application rate for standard tree of 3 m height
Table grapes	*Vitis vinifera*	NEU	Outdoor	AT					Foliar treatment – spraying	73	81		1				0.11	kg a.i./ ha	35	Growth stage 13–59 or 73–81
Wine grapes	*Vitis vinifera*	NEU	Outdoor	AT					Foliar treatment – spraying	73	81		1				0.11	kg a.i./ ha	35	Application rate for standard tree of 3 m height

Critical outdoor GAPs for northern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Potatoes	*Solanum tuberosum* subsp. *tuberosum*	NEU	Outdoor	DE					Seed treatment – general (see also comment field)	0	0		1				0.01	kg a.i./ 100 kg	n.a.	Sowing rate: max. 28 dt/ha (dt = 0.1 t), dose rate corresponding: 0.34 kg/ha A no residue situation can be anticipated for foliar application, CZ (1 × 0.06 kg/ ha; PHI: 14) and HU GAPs (2 × 0.06 kg/ ha; PHI: 28)
Garlic	*Allium sativum*	NEU	Outdoor	DE					Seed treatment – general (see also comment field)	0	0		1				4.50	kg a.i./ 100 kg	n.a.	Sowing rate: 4 u/ha 1 u = 250,000 seeds Dose rate: 0.045 kg a.i. = 0.075 kg Pdt/u (Pdt: formulated product) corresponding to 0.18 kg/ha

Critical outdoor GAPs for northern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Onions	*Allium cepa* Common Onion group	NEU	Outdoor	DE					Seed treatment – general (see also comment field)	0	0		1				4.50	kg a.i./ 100 kg	n.a.	Sowing rate: 9 u/ha 1 u = 250,000 seeds Dose rate: 0.020 kg a.i. = 0.029 kg Pdt/u corresponding to 0.18 kg/ha
Shallots	*Allium cepa* Aggregatum group, syn: *Allium ascalonicum*	NEU	Outdoor	DE					Seed treatment – general (see also comment field)	0	0		1				4.50	kg a.i./ 100 kg	n.a.	Sowing rate: 9 u/ha 1 u = 250,000 seeds Dose rate: 0.020 kg a.i. = 0.029 kg Pdt/u corresponding to 0.18 kg/ha
Spring onions	*Allium cepa* Common Onion group; *Allium fistulosum*	NEU	Outdoor	DE					Seed treatment – general (see also comment field)	0	0		1				4.50	kg a.i./ 100 kg	n.a.	Sowing rate: 9 u/ha 1 u = 250000 seeds Dose rate: 0.020 kg a.i. = 0.029 kg Pdt/u corresponding to 0.18 kg/ha

Critical outdoor GAPs for northern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Broccoli	*Brassica oleracea* var. *italica*	NEU	Outdoor	NL					Soil treatment – general (see also comment field)	11	12		1				0.18	kg a.i./ ha	n.a.	Tray treatment before re-planting Max. 50,000 plts (plants)/ha corresponding to 3.6 mg a.s./ plant Nursery up to BBCH 12 can be in glasshouse, culture in field
Cauliflowers	*Brassica oleracea* var. *botrytis*	NEU	Outdoor	NL					Soil treatment – general (see also comment field)	11	12		1				0.18	kg a.i./ ha	n.a.	Tray treatment before re-planting Max. 50,000 plts (plants)/ha (plts: plants) corresponding to 3.6 mg a.s./ plant Nursery up to BBCH 12 can be in glasshouse, culture in field
Brussels sprouts	*Brassica oleracea* var. *gemmifera*	NEU	Outdoor	PL					Foliar treatment – spraying	n.a.	n.a.		1				0.10	kg a.i./ ha	14	

Critical outdoor GAPs for northern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Head cabbages	*Brassica oleracea* var. *capitata*	NEU	Outdoor	NL	Insects	WG	700.0	g/kg	Soil treatment – general (see also comment field)	11	12		1				0.18	kg a.i./ ha	n.a.	Tray treatment before re-planting Max. 50,000 plts (plants)/ ha corresponding to 3.6 mg a.s./plant Nursery up to BBCH 12 can be in glasshouse, culture in field
Chinese cabbages	*Brassica rapa* subsp. *pekinensis*	NEU	Outdoor	NL	Insects	WG	700.0	g/kg	Soil treatment – general (see also comment field)	11	12		1				0.18	kg a.i./ ha	n.a.	Tray treatment before re-planting Max. 50,000 plts (plants)/ ha corresponding to 3.6 mg a.s./plant Nursery up to BBCH 12 can be in glasshouse, culture in field

Critical outdoor GAPs for northern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Kales	*Brassica oleracea* var. *sabellica; Brassica oleracea* var. *viridis*	NEU	Outdoor	NL	Insects	WG	700.0	g/kg	Soil treatment – general (see also comment field)	11	12		1				0.18	kg a.i./ ha	n.a.	Tray treatment before re-planting Max. 50,000 plts (plants)/ ha corresponding to 3.6 mg a.s./plant Nursery up to BBCH 12 can be in glasshouse, culture in field
Kohlrabies	*Brassica oleracea* var. *gongylodes*	NEU	Outdoor	DE					Seed treatment – general (see also comment field)	0	0		1				0.16	kg a.i./ unit	n.a.	Sowing rate: 0.9 seed units/ ha Dose rate: 0.164 kg a.i./ seed unit corresponding to 0.15 kg/ha Leaves nor suitable for human or animal consumption
Lettuces	*Lactuca sativa*	NEU	Outdoor	NL, CZ, BE, DE	Insects	WG	700.0	g/kg	Seed treatment – general	0	0		1				0.12	kg a.i./ ha	n.a.	
Escaroles	*Cichorium endivia* var. *latifolia*	NEU	Outdoor	NL	Insects	WG	700.0	g/kg	Seed treatment – general	0	0		1				0.12	kg a.i./ ha	n.a.	

Critical outdoor GAPs for northern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Cresses	*Lepidium sativum* subsp. *sativum*	NEU	Outdoor	NL	Insects	WG	700.0	g/kg	Seed treatment – general	0	0		1				0.12	kg a.i./ ha	n.a.	
Land cresses	*Barbarea verna*	NEU	Outdoor	NL	Insects	WG	700.0	g/kg	Seed treatment – general (see also comment field)	0	0		1				0.12	kg a.i./ ha	n.a.	
Red mustards	*Brassica juncea* var. *rugosa*	NEU	Outdoor	NL	Insects	WG	700.0	g/kg	Seed treatment – general	0	0		1				0.12	kg a.i./ ha	n.a.	
Baby leaf crops	Not specified	NEU	Outdoor	NL	Insects	WG	700.0	g/kg	Seed treatment – general	0	0		1				0.12	kg a.i./ ha	n.a.	
Witloofs	*Cichorium intybus* Foliosum group	NEU	Outdoor	NL	insects	WG	700.0	g/kg	Seed treatment – spraying (see also comment field)	0	0		1				0.18	kg a.i./ ha	n.a.	Treatment on the seed in the furrow
Leeks	*Allium ampeloprasum ampeloprasum* Leek group, syn: *Allium porrum*	NEU	Outdoor	DE					Seed treatment – general (see also comment field)	0	0		1				0.05	kg a.i./ unit	n.a.	Sowing rate: 2 u/ha 1u = 250,000 seeds Dose rate: 0.045 kg a.i. = 0.0643 kg Ptd/ u = 0.09 kg a.i./ha

Critical outdoor GAPs for northern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Barley	*Hordeum vulgare*	NEU	Outdoor	FR, BE					Seed treatment – general (see also comment field)	0	0		1				0.07	kg a.i./ 100 kg	n.a.	Sowing rate: 1.8 dt/ha Dose rate: 0.13 kg a.i./ha Winter cereals only
Oat	*Avena sativa*	NEU	Outdoor	FR					Seed treatment – general (see also comment field)	0	0		1				0.07	kg a.i./ 100 kg	n.a.	Sowing rate: 1.6 dt/ha Dose rate: 0.070 kg a.i./ dt = 0.200 L Pdt (product)/ dt = 0.11 kg/ ha Winter cereals only
Rye	*Secale cereale*	NEU	Outdoor	FR					Seed treatment – general (see also comment field)	0	0		1				0.07	kg a.i./ 100 kg	n.a.	Sowing rate: 1.8 dt/ha Dose rate: 0.070 kg a.i./ dt = 0.200 L Pdt/dt = 0.13 kg/ha Winter cereals only
Wheat	*Triticum aestivum*	NEU	Outdoor	FR					Seed treatment – general (see also comment field)	0	0		1				0.07	kg a.i./ 100 kg	n.a.	Sowing rate: 2.4 dt/ha Dose rate: 0.070 kg a.i./ dt = 0.17 kg/ ha Winter cereals only
Hops	*Humulus lupulus*	NEU	Outdoor	DE, CZ, BE					Foliar treatment – spraying	35	85		1				0.12	kg a.i./ ha	35	

Critical outdoor GAPs for northern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Sugar beets	*Beta vulgaris* subsp. *vulgaris* var. *altissima*	NEU	Outdoor	DE, FR, CZ, BE					Seed treatment – general (see also comment field)	0	0		1				0.09	kg a.i./ unit	n.a.	Sowing rate: 1.3 u/ha 1 u = 100,000 seeds Dose rate: 0.090 kg a.i. = 0.150 kg Pdt (product)/u = 0.118 kg a.i./ ha
Fodder beets	*Beta vulgaris* subsp. *vulgaris* var. *crassa*	NEU	Outdoor	DE, FR, CZ, BE					Seed treatment – general (see also comment field)	0	0		1				0.09	kg a.i./ unit	n.a.	Sowing rate: 1.3 u/ha 1 u = 100,000 seeds Dose rate: 0.090 kg a.i. = 0.118 kg a.i./ ha

Critical outdoor GAPs for southern Europe

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Grapefruits	*Citrus paradisi*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	69			1			0.18	0.30	kg a.i./ ha	14	A more critical GAP authorised in PT (2 × 0.3 kg/ha) is not sufficiently supported by data (only 3 trials available)
Oranges	*Citrus sinensis*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	69			1			0.18	0.30	kg a.i./ ha	14	A more critical GAP authorised in PT (2 × 0.3 kg/ha) is not sufficiently supported by data (only 3 trials available)
Lemons	*Citrus limon*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	69			1				0.30	kg a.i./ ha	14	
Limes	*Citrus aurantiifolia*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	69			1				0.30	kg a.i./ ha	14	
Mandarins	*Citrus reticulata,* syn: *Citrus deliciosa*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	69			1				0.30	kg a.i./ ha	14	
Almonds	*Amygdalus communis,* syn: *Prunus dulcis*	SEU	Outdoor	IT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	69			1			0.07	0.10	kg a.i./ ha	14	

Critical outdoor GAPs for southern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Apples	*Malus domestica*	SEU	Outdoor	IT	Aphids, *Psylla*, leaf miners	SL	200.0	g/L	Foliar treatment – spraying	71	79		1			0.07	0.15	kg a.i./ ha	14	More critical/ different GAPs authorised in ES (2 × 0.175 kg/ha) and in PT (2 × 0.1 kg/ha) are not sufficiently supported by data
Pears	*Pyrus communis*	SEU	Outdoor	EL	*Cacopsylla pyri*	SL	200.0	g/L	Foliar treatment – spraying	71	79		1				0.15	kg a.i./ ha	7	Covers also IT GAP. More critical/ different GAPs authorised in ES (2 × 0.175 kg/ha) and in PT (2 × 0.1 kg/ha) are not sufficiently supported by data
Apricots	*Armeniaca vulgaris,* syn: *Prunus armeniaca*	SEU	Outdoor	EL, PT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71	79		2			0.08	0.15	kg a.i./ ha	14	
Cherries	*Cerasus avium,* syn: *Prunus avium*	SEU	Outdoor	PT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71		1	2			0.07	0.10	kg a.i./ ha	14	
Peaches	*Persica vulgaris,* syn: *Prunus persica*	SEU	Outdoor	ES, PT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71	79		2			0.10	0.15	kg a.i./ ha	14	

Critical outdoor GAPs for southern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Plums	*Prunus domestica*	SEU	Outdoor	ES	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71	79		2				0.10	kg a.i./ ha	21	A different GAP authorised in IT (1 × 0.15 kg/ha; PHI: 14 days) is not sufficiently supported by data
Table grapes	*Vitis vinifera*	SEU	Outdoor	ES, PT, IT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71	81		1				0.10	kg a.i./ ha	14	
Wine grapes	*Vitis vinifera*	SEU	Outdoor	ES, PT, IT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71	81		1				0.10	kg a.i./ ha	14	
Table olives	*Olea europaea*	SEU	Outdoor	ES	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	79	85	1	5				0.02	kg a.i./ ha	7	Covers also IT GAP
Avocados	*Persea americana*	SEU	Outdoor	PT	Avocado lace bug	SL	200.0	g/L	Foliar treatment – spraying	71		1	2				0.20	kg a.i./ ha	30	
Mangoes	*Mangifera indica*	SEU	Outdoor	PT	APHIDS	SL	200.0	g/L	Foliar treatment – spraying	71		1	2				0.20	kg a.i./ ha	30	
Potatoes	*Solanum tuberosum* subsp. *tuberosum*	SEU	Outdoor	PT	Aphids and Colorado potato beetle	SL	200.0	g/L	Foliar treatment – spraying	45	97	1	2			0.10	0.13	kg a.i./ ha	14	Covers also EL and IT GAPs. A different GAP (in-furrow application at 2 × 0.175) authorised in ES is not supported by data

Critical outdoor GAPs for southern Europe																					
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application											PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate					
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Tomatoes	*Lycopersicon esculentum*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1				0.15	kg a.i./ ha	3	Covers drip application and EL GAP (2 × 0.1; PHI: 7 days)
Sweet peppers	*Capsicum annuum*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1				0.15	kg a.i./ ha	3	
Aubergines	*Solanum melongena*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1				0.15	kg a.i./ ha	3	Covers drip application and EL GAP (2 × 0.1; PHI: 7 days)
Okra	*Abelmoschus esculentus*	SEU	Outdoor	PT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71			1				0.10	kg a.i./ ha	3	
Cucumbers	*Cucumis sativus*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	71			1				0.15	kg a.i./ ha	7	
Gherkins	*Cucumis sativus*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	71			1				0.15	kg a.i./ ha	7	
Courgettes	*Cucurbita pepo* Zucchini group	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	71			1				0.15	kg a.i./ ha	7	
Melons	*Cucumis melo*	SEU	Outdoor	IT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71			1				0.15	kg a.i./ ha	7	A different GAP authorised in PT (2 × 0.10 kg/ha; PHI: 3 days) is not sufficiently supported by data

Critical outdoor GAPs for southern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Pumpkins	*Cucurbita maxima*	SEU	Outdoor	PT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	71		1	2				0.10	kg a.i./ ha	3	
Watermelons	*Citrullus vulgaris,* syn: *Citrullus lanatus*	SEU	Outdoor	IT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71			1				0.15	kg a.i./ ha	7	A different GAP authorised in PT (2 × 0.10 kg/ha; PHI: 3 days) is not sufficiently supported by data
Broccoli	*Brassica oleracea* var. *italica*	SEU	Outdoor	ES, PT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	13	48		2			0.03	0.12	kg a.i./ ha	14	
Cauliflowers	*Brassica oleracea* var. *botrytis*	SEU	Outdoor	ES, PT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	13	48	1	2			0.03	0.12	kg a.i./ ha	14	
Brussels sprouts	*Brassica oleracea* var. *gemmifera*	SEU	Outdoor	ES	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	13	48		2			0.03	0.12	kg a.i./ ha	15	
Head cabbages	*Brassica oleracea* var. *capitata*	SEU	Outdoor	IT, PT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	13			1				0.10	kg a.i./ ha	14	
Chinese cabbages	*Brassica rapa* subsp. *pekinensis*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	69			1				0.10	kg a.i./ ha	14	
Kales	*Brassica oleracea* var. *sabellica; Brassica oleracea* var. *viridis*	SEU	Outdoor	IT, PT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	69			1				0.10	kg a.i./ ha	14	

Critical outdoor GAPs for southern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Lamb's lettuces	*Valerianella locusta*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Lettuces	*Lactuca sativa*	SEU	Outdoor	ES	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	13	48		2			0.11	0.13	kg a.i./ ha	7	
Escaroles	*Cichorium endivia* var. *latifolia*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Cresses	*Lepidium sativum* subsp. *sativum*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Land cresses	*Barbarea verna*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Roman rocket	*Eruca sativa*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Red mustards	*Brassica juncea* var. *rugosa*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Baby leaf crops	Not specified	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Chervil	*Anthriscus cerefolium*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Chives	*Allium schoenoprasum*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Celery leaves	*Apium graveolens* var. *secalinum*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	

Critical outdoor GAPs for southern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Parsley	*Petroselinum crispum*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Sage	*Salvia officinalis*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Rosemary	*Rosmarinus officinalis*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Thyme	*Thymus vulgaris*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Basil	*Ocimum basilicum*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Laurel	*Laurus nobilis*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Tarragon	*Artemisia dracunculus*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	20			1			0.04	0.10	kg a.i./ ha	3	
Beans (with pods)	*Phaseolus vulgaris*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	71			1				0.10	kg a.i./ ha	3	
Beans (without pods)	*Phaseolus vulgaris*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	71			1				0.10	kg a.i./ ha	3	
Cardoons	*Cynara cardunculus* Cardoon group	SEU	Outdoor	IT	Aphids	OD	200.0	g/L	Foliar treatment – spraying	41	47		1			0.08	0.10	kg a.i./ ha	3	

Critical outdoor GAPs for southern Europe																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Globe artichokes	*Cynara cardunculus* Globe artichoke group	SEU	Outdoor	EL					Foliar treatment – spraying	13	48		2				0.10	kg a.i./ ha	3	
Peas (dry)	*Pisum sativum*	SEU	Outdoor	IT					Foliar treatment – spraying	71	77	1	2			0.08	0.09	kg a.i./ ha	28	
Cotton seeds	*Gossypium barbadense; Gossypium herbaceum*	SEU	Outdoor	EL	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71	83		2	14			0.10	kg a.i./ ha	28	
Olives for oil production	*Olea europaea* var. *europaea*	SEU	Outdoor	IT	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	69			1				0.13	kg a.i./ ha	7	Trials reported expected to cover also the EL GAP (2 × 0.08; PHI: 7 days)
Barley	*Hordeum vulgare*	SEU	Outdoor	FR					Seed treatment – general (see also comment field)	0	0		1				0.07	kg a.i./ 100 kg	n.a.	Sowing rate: 1.6 dt/ha Dose rate: 0.070 kg a.i./ dt = 0.200 L Pdt (product)/ dt = 0.11 kg a.i./ha
Oat	*Avena sativa*	SEU	Outdoor	FR					Seed treatment – general (see also comment field)	0	0		1				0.07	kg a.i./ 100 kg	n.a.	Sowing rate: 1.6 dt/ha Dose rate: 0.070 kg a.i./ dt = 0.200 L Pdt/dt = 0.11 kg a.i./ha

Critical outdoor GAPs for southern Europe

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Wheat	*Triticum aestivum*	SEU	Outdoor	FR					Seed treatment – general (see also comment field)	0	0		1				0.07	kg a.i./ 100 kg	n.a.	Sowing rate: 1.6 dt/ha Dose rate: 0.070 kg a.i./ dt = 0.200 L Pdt/dt = 0.11 kg a.i./ha
Sugar beets	*Beta vulgaris* subsp. *vulgaris* var. *altissima*	SEU	Outdoor	ES, EL					Seed treatment – general (see also comment field)	0	0		1				0.09	kg a.i./ unit	n.a.	Sowing rate: 1.5– 1.8 u/ha 1 u = 100,000 seeds Dose rate: 0.091 kg a.i./u = 0.130 kg Pdt/u

Critical indoor GAPs for northern and southern Europe (including post-harvest treatments)

Crop		Region	Outdoor/ Indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Tomatoes	*Lycopersicon esculentum*	NEU/ SEU	Indoor	ES, EL	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	15	83	1	2	14		0.10	0.15	kg a.i./ ha	3	Covers the IT and PT GAPs. A more critical GAP authorised in AT and FI (2 × 0.25 kg/ ha; PHI: 1 day) is not supported by data

Critical indoor GAPs for northern and southern Europe (including post-harvest treatments)

Crop		Region	Outdoor/ Indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Sweet peppers	*Capsicum annuum*	NEU/ SEU	Indoor	FI					Soil treatment – general (see also comment field)	10	89	1	2				0.31	kg a.i./ ha	3	Apply in irrigation water
Aubergines	*Solanum melongena*	NEU/ SEU	Indoor	ES, EL	Aphids, white fly	SL	200.0	g/L	Foliar treatment – spraying	15	83	1	2	14		0.10	0.15	kg a.i./ ha	3	Covers treatment by drip irrigation (3 × 0.14; PHI: 1 day)
Okra	*Abelmoschus esculentus*	NEU/ SEU	Indoor	PT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71			1				0.10	kg a.i./ ha	3	
Cucumbers	*Cucumis sativus*	NEU/ SEU	Indoor	NL	Aphids	WG	700.0	g/kg	Soil treatment – general (see also comment field)	11	81		2				0.01	kg a.i./ unit	1	Unit: 1,000 plants corresponding to 10 mg/ plant. Apply in irrigation water
Gherkins	*Cucumis sativus*	NEU/ SEU	Indoor	AT					Soil treatment – general (see also comment field)	10	89		2				0.15	kg a.i./ ha	1	Apply in irrigation water max. 15,000 plts/ ha
Courgettes	*Cucurbita pepo* Zucchini group	NEU/ SEU	Indoor	AT					Soil treatment – general (see also comment field)	10	89		2				0.15	kg a.i./ ha	1	Apply in irrigation watermax. 15,000 plts (plants)/ha

Critical indoor GAPs for northern and southern Europe (including post-harvest treatments)

Crop		Region	Outdoor/ Indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Melons	*Cucumis melo*	NEU/ SEU	Indoor	PT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71			2				0.10	kg a.i./ ha	3	A more critical GAP authorised in EL (2 × 0.15 kg/ha) is not sufficiently supported by data
Watermelons	*Citrullus vulgaris,* syn: *Citrullus lanatus*	NEU/ SEU	Indoor	PT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71			2				0.10	kg a.i./ ha	3	A more critical GAP authorised in EL (2 × 0.15 kg/ha) is not sufficiently supported by data
Pumpkins	*Cucurbita maxima*	NEU/ SEU	Indoor	PT	Aphids	SL	200.0	g/L	Foliar treatment – spraying	71			2				0.10	kg a.i./ ha	3	
Lamb's lettuces	*Valerianella locusta*	NEU/ SEU	Indoor	IT	Sucking insects	WG	700.0	g/kg	Soil treatment – general (see also comment field)	0	18		1				0.12	kg a.i./ ha	n.a.	Watering, before planting
Lettuces	*Lactuca sativa*	NEU/ SEU	Indoor	IT, CZ, DE	Sucking insects	WG	700.0	g/kg	Soil treatment – general (see also comment field)	0	18		1				0.12	kg a.i./ ha	n.a.	Watering, before planting

Critical indoor GAPs for northern and southern Europe (including post-harvest treatments)

Crop		Region	Outdoor/ Indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Escaroles	*Cichorium endivia* var. *latifolia*	NEU/ SEU	Indoor	DE, IT	Sucking insects	SC	200.0	g/L	Soil treatment – general (see also comment field)	0	18		1				0.12	kg a.i./ ha	n.a.	Watering, before planting
Cresses	*Lepidium sativum* subsp. *sativum*	NEU/ SEU	Indoor	DE, IT	Sucking insects	SC	200.0	g/L	Soil treatment – general (see also comment field)	0	18		1				0.12	kg a.i./ ha	n.a.	Watering, before planting
Land cresses	*Barbarea verna*	NEU/ SEU	Indoor	DE, IT	Sucking insects	SC	200.0	g/L	Soil treatment – general (see also comment field)	0	18		1				0.12	kg a.i./ ha	n.a.	Watering, before planting
Red mustards	*Brassica juncea* var. *rugosa*	NEU/ SEU	Indoor	DE, IT	Sucking insects	SC	200.0	g/L	Soil treatment – general (see also comment field)	0	18		1				0.12	kg a.i./ ha	n.a.	Watering, before planting
Baby leaf crops	Not specified	NEU/ SEU	Indoor	DE, IT	Sucking insects	SC	200.0	g/L	Soil treatment – general (see also comment field)	0	18		1				0.12	kg a.i./ ha	n.a.	Watering, before planting
Beans (with pods)	*Phaseolus vulgaris*	NEU/ SEU	Indoor	IT					Foliar treatment – spraying				1				0.10	kg a.i./ ha	3	

Critical GAPs for import tolerances (non-European indoor, outdoor or post-harvest treatments)

Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Grapefruits	*Citrus paradisi*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	2			0.14	0.28	kg a.i./ ha	0	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Oranges	*Citrus sinensis*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	2			0.14	0.28	kg a.i./ ha	0	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Lemons	*Citrus limon*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	2			0.14	0.28	kg a.i./ ha	0	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Limes	*Citrus aurantiifolia*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	2			0.14	0.28	kg a.i./ ha	0	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Mandarins	*Citrus reticulata,* syn: *Citrus deliciosa*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	2			0.14	0.28	kg a.i./ ha	0	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Pecans	*Carya illinoinensis*	Non-EU	Outdoor	USA					Foliar treatment – spraying				4			0.05	0.10	kg a.i./ ha	7	Maximum rate allowed per crop season: 0.40 kg a.i./ha GAP USA: 3 × 0.112 kg a.i./ha

Critical GAPs for import tolerances (non-European indoor, outdoor or post-harvest treatments)																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Table grapes	*Vitis vinifera*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	2				0.06	kg a.i./ ha	0	It covers also application, e.g. via chemigation into root zone: subsurface side-dress or hill drench with maximum rate allowed per crop season: 0.56 kg a.i./ha
Wine grapes	*Vitis vinifera*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	2				0.06	kg a.i./ ha	0	It covers also application, e.g. via chemigation into root zone: subsurface side-dress or hill drench with maximum rate allowed per crop season: 0.56 kg a.i./ha
Blueberries	*Vaccinium angustifolium; Vaccinium corymbosum; Vaccinium formosum; Vaccinium virgatum*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	5			0.04	0.11	kg a.i./ ha	3	Maximum rate allowed per crop season: 0.56 kg a.i./ha

Critical GAPs for import tolerances (non-European indoor, outdoor or post-harvest treatments)																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Cranberries	*Vaccinium macrocarpon*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	5			0.04	0.11	kg a.i./ ha	3	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Currants	*Ribes nigrum; Ribes rubrum*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	5			0.04	0.11	kg a.i./ ha	3	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Gooseberries	*Ribes uva-crispa*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	5			0.04	0.11	kg a.i./ ha	3	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Rose hips	*Rosa canina; Rosa majalis; Rosa rugosa*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	5			0.04	0.11	kg a.i./ ha	3	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Mulberries	*Morus alba; Morus nigra*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	5			0.04	0.11	kg a.i./ ha	3	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Azaroles	*Crataegus azarolus*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	5			0.04	0.11	kg a.i./ ha	3	Maximum rate allowed per crop season: 0.56 kg a.i./ha

Critical GAPs for import tolerances (non-European indoor, outdoor or post-harvest treatments)																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Elderberries	*Sambucus nigra*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	5			0.04	0.11	kg a.i./ ha	3	Maximum rate allowed per crop season: 0.56 kg a.i./ha
Bananas	*Musa acuminata; Musa balbisiana; Musa acuminata x Musa balbisiana*	Non-EU	Outdoor	Cameroon					Local treatment – drenching								0.50	kg a.i./ ha	n.a.	Application done at the base of the plant by drenching. The dose rate corresponds to 0.25 g per plant with 2000 plants/ ha.
Pomegranate (Granate apples)	*Punica granatum*	Non-EU	Outdoor	USA					Soil treatment – general (see also comment field)			1	2			0.28	0.56	kg a.i./ ha	0	Maximum rate allowed per crop season: 0.56 kg a.i./ha application via chemigation into the root zone
Beans (with pods)	*Phaseolus vulgaris*	Non-EU	Outdoor	USA					Soil treatment – general (see also comment field)			1	2			0.28	0.42	kg a.i./ ha	21	USA: foliar spray 1–3 × 0.049 kg a.i./ha

Critical GAPs for import tolerances (non-European indoor, outdoor or post-harvest treatments)																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Beans (without pods)	*Phaseolus vulgaris*	Non-EU	Outdoor	USA					Soil treatment – general (see also comment field)			1	2			0.28	0.42	kg a.i./ ha	21	USA: foliar spray 1–3 × 0.049 kg a.i./ha
Peas (with pods)	*Pisum sativum*	Non-EU	Outdoor	USA					Soil treatment – general (see also comment field)			1	2			0.28	0.42	kg a.i./ ha	21	Maximum rate allowed per crop season: 0.42 kg a.i./ ha; Application e.g. via chemigation into root zone; narrow band or in-furrow spray or post-seeding drench
Peas (without pods)	*Pisum sativum*	Non-EU	Outdoor	USA					Soil treatment – general (see also comment field)			1	2			0.28	0.42	kg a.i./ ha	21	Maximum rate allowed per crop season: 0.42 kg a.i./ ha; Application e.g. via chemigation into root zone; narrow band or in-furrow spray or post-seeding drench

Critical GAPs for import tolerances (non-European indoor, outdoor or post-harvest treatments)																				
Crop		Region	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Beans (dry)	*Phaseolus vulgaris*	Non-EU	Outdoor	USA					Foliar treatment – general (see also comment field)			1	2			0.28	0.52	kg a.i./ ha	7	Seed treatment + soil application + foliar spray applications
Peanuts	*Arachis hypogaea*	Non-EU	Outdoor	USA					Soil treatment – general (see also comment field)				1			0.28	0.42	kg a.i./ ha	14	Maximum rate allowed per crop season: 0.42 kg a.i./ haApplication via in-furrow spray during planting or chemigation into root zone
Coffee beans	*Coffea arabica; Coffea canephora,* syn: *Coffea robusta; Coffea liberica*	Non-EU	Outdoor	USA					Soil treatment – general (see also comment field)			1	2			0.28	0.56	kg a.i./ ha	7	USA: foliar spray 1–5 × 0.112 kg a.i./ha
Hops	*Humulus lupulus*	Non-EU	Outdoor	USA					Foliar treatment – spraying			1	3				0.11	kg a.i./ ha	28	Maximum rate allowed per crop season: 0.34 kg a.i./ha

MRL: maximum residue level; GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; NEU: northern European Union; SEU: southern European Union; a.i.: active ingredient; WG: water-dispersible granule; SL: soluble concentrate; a.s.: active substance; SC: suspension concentrate.

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)**
	Fruit crops	Apples	Foliar, 375 g a.s./ha	0, 14
		Tomatoes	Foliar, 0.25 kg/ha	4, 7, 14, 21
		Eggplants	Soil granules, 400 g/ha	14, 35, 49, 67, 69
	Root crops	Potatoes	Soil granules, 1250 g/ha	129
			Foliar, 134 g/ha	7, 28, 64
	Leafy crops	Tobacco	1 Soil and 3 foliar, 740 g/ha (total rate)	14
	Cereals/grass crops	Rice	Soil granules, 500 g/ha	79
			Seed (nursery box), 320 and 1260 g/ha with 200 box/ha	65, 124
		Maize	Seed, 721 g/100 kg seeds	33, 61, 134
	Pulses/oilseeds	Cotton	Seed, 460 g/100 kg seeds	211
	Metabolism studies with [Pyridinyl-^{14}C-methylene]-imidacloprid only, considered acceptable Source: Germany (2005)			

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**
	Root/tuber crops	Red beet	Bare soil, 454 g a.s./ha	30, 120, 271
	Leafy crops	Swiss chards	Bare soil, 454 g a.s./ha	30, 120, 271
	Cereal (small grain)	Wheat	Bare soil, 454 g a.s./ha	30, 120, 271
	Source: Germany (2005)			

Processed commodities (hydrolysis study)	**Conditions**	**Investigated?**
	Pasteurisation (20 min, 90°C, pH 4)	Yes
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes
	Sterilisation (20 min, 120°C, pH 6)	Yes
	Source: Germany (2005)	

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring (RD-Mo)	All plant commodities with exception of pulses and oilseeds: Imidacloprid Pulses and oilseeds: Imidacloprid (tentative, pending submission of trials supporting the import tolerances on dry beans, peanuts, beans and peas without pods)
Plant residue definition for risk assessment (RD-RA)	Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid
Conversion factor (monitoring to risk assessment)	See Appendix B.1.2.1

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	High water content, high acid content, dry commodities: • QuEChERS (HPLC–MS/MS) • LOQ: 0.01 mg/kg • Source: Germany (2015) High oil content commodities: • HPLC–MS/MS • LOQ: 0.02 mg/kg • Source: Germany (2008) Hops: • HPLC–MS/MS • LOQ: 0.2 mg/kg • Source: Germany (2008) Coffee beans (validated in cocoa beans): • HPLC–MS/MS • LOQ: 0.01 mg/kg • ILV and confirmatory method not available • Source: Germany (2015) According to the EURLs, during routine analyses an LOQ of 0.01 mg/kg is achievable in the four main matrices (EURLs, 2016)

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability (months/years)**
	High water content	Apples, potatoes, lettuce, cauliflowers, tomatoes, sugar beet	–18	24 months
	High oil content	Cotton seeds, sunflower seeds	–18	24 months
	Dry	Corn, wheat, barley	–18	24 months
	High acid content	Lemons, oranges	–18	24 months
	Others	Straw, hops (dry cones)	–18	24 months
	Source: Germany (2005) The demonstrated storage stability period covers both imidacloprid and the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety Additional storage stability studies covering the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety were assessed by the JMPR. According to these studies, the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety is stable for up to 53 months in high oil content matrices (peanuts), for up to 41 months in high water content commodities (radish roots), for up to 34 months in dry commodities (dry peas) and for up to 25 months in coffee, stored under deep frozen conditions (FAO, 2008)			

B.1.2. Magnitude of residues in plants

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

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Numbers in bold represent MRL and risk assessment values derived from uses compliant with the new conditions of approval in EU							
Citrus fruits	SEU	**Oranges** **Mo:** 0.082; 0.17; 0.10; 0.072; 0.067; 0.093; 0.087; 0.21 **RA:** 0.15; 0.23; 0.12; 0.20; 0.081; 0.11; 0.13; 0.23 **Mandarins** **Mo:** 0.10; 0.23; 0.19; 0.17; 0.19; 0.17; 0.21; 0.25 **RA:** 0.13; 0.35; 0.24; 0.20; 0.26; 0.25; 0.29; 0.34	Combined data set on oranges and mandarins compliant with GAP (Germany, 2015). Extrapolation to all citrus fruits possible MRL_{OECD} = 0.45	0.5	0.25	0.17	1.4
	Import (USA)	**Grapefruits** **Mo:** – **RA:** 0.30; 0.32; 0.17; 0.17; 0.14; 0.18 **Oranges** **Mo:** – **RA:** 0.61; 0.28; 0.18; 0.26; 0.29; 0.26; 0.34; 0.21; 0.15; 0.36; 0.36; 0.37 **Lemons** **Mo:** – **RA:** 0.31; 0.62; 0.33; 0.19; 0.265	Combined data set on grapefruit, oranges and lemons compliant with GAP for citrus fruits. Residues analysed only according to the risk assessment residue definition (Germany, 2015) MRL_{OECD} = 0.87	**0.9** (tentative)[e]	**0.62**	**0.28**	**1.0**

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Almonds	SEU	**Mo:** < 0.01 **RA:** < 0.05	Residue trial performed with 2 applications instead of 1 is acceptable as the first application done at an early growth stage is not expected to have an impact on the final residue level and residues were below the LOQ (Italy, 2016a). Trials performed according to a more critical GAP and used to support the import tolerance on pecans, confirm a no residue situation	0.02*	0.02	0.02	1.0
Pecans	Import (USA)	**Pecans:** **Mo:** – **RA:** 5 x < 0.01 **Almonds:** **Mo:** – **RA:** 5 x < 0.01	Combined data set on pecans and almonds performed at 2 × 0.2 kg/ha. Residues analysed only according to the risk assessment residue definition but trials acceptable since residues were below the LOQ (Germany, 2015)	**0.02***	**0.02**	**0.02**	**1.0**
Apples Quinces	NEU	**Mo:** 0.04; 0.03; 0.02; 0.02; 0.01; < 0.01; < 0.01; 0.01; 0.013; 0.017; < 0.01; 0.02; 0.03; 0.02 **RA:** 0.08; 0.06; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; 0.08; < 0.05; < 0.05; < 0.05; 0.05; 0.06	Trials on apples. First 8 trials compliant with GAP or with dose rate within 25% deviation. Other trials performed with 2 applications acceptable since the first application done at an early stage is not expected to impact the final residue level (Germany, 2015). Extrapolation to quinces possible MRL_{OECD} = 0.06	0.06	0.04	0.02	2.5
	SEU	**Apples** **Mo:** 0.04; 0.02; 0.017; 0.023; 0.023; < 0.01; 0.011; 0.013 **RA:** 0.06; 0.06; 0.086; 0.046; 0.035; < 0.03; < 0.03; < 0.03 **Pears** **Mo:** 0.06; 0.035; 0.018 **RA:** 0.08; 0.052; 0.081	Combined data set on apples (8) and pears (3). First 2 trials on apples and first trial on pears compliant with GAP. Other trials performed with 2 applications acceptable since first application done at early stage is not expected to impact final residue level (Germany, 2015). No authorised for use on quinces in SEU MRL_{OECD} = 0.08	0.09	0.06	0.02	2.2

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Pears	NEU	**Mo:** 0.04; 0.03; 0.02; 0.02; 0.01; < 0.01; < 0.01; 0.01; 0.013; 0.017; < 0.01; 0.02; 0.03; 0.02 **RA:** 0.08; 0.06; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; 0.08; < 0.05; < 0.05; < 0.05; 0.05; 0.06	Trials on apples. First 8 trials compliant with GAP or with dose rate within 25% deviation. Other trials performed with 2 applications acceptable since first application done at early stage is not expected to impact final residue level (Germany, 2015). Extrapolation to pears possible MRL_{OECD} = 0.06	0.06	0.04	0.02	2.5
	SEU	**Apples** **Mo:** 0.04; 0.02; 0.035; 0.015; 0.011; 0.017 **RA:** 0.06; 0.06; 0.089; < 0.03; < 0.03; < 0.03 **Pears** **Mo:** 0.08 **RA:** 0.10	Combined data set on apples and pears. First 2 trials on apples and trial on pears compliant with GAP. Other trials performed with 2 applications acceptable since first application done at early stage is not expected to impact final residue level (Germany, 2015) MRL_{OECD} = 0.13	0.15 (tentative)[f]	0.08	0.02	2.0
Apricots	NEU	–	No residue trials compliant with GAP	–	–	–	–
	SEU	**Mo:** 0.04; 0.03; 0.06; 0.09; 0.09; 0.06; 0.06; 0.01; 0.06; 0.07 **RA:** 0.06; 0.06; 0.12; 0.19; 0.12; 0.15; 0.10; < 0.05; 0.12; 0.15	Trials on peaches compliant with GAP. Extrapolation to apricots tentatively possible pending submission of residue trials on apricots (Germany, 2015) MRL_{OECD} = 0.17	0.2 (tentative)[f]	0.09	0.06	2.0
Cherries (sweet)	SEU	**Mo:** 0.11; 0.07; 0.09; 0.05 **RA:** 0.28; 0.16; 0.22; 0.11	Trials on cherries compliant with GAP (Germany, 2015; Portugal, 2016) MRL_{OECD} = 0.24	0.3	0.11	0.08	2.4

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Peaches	NEU	**Mo:** < 0.01 **RA:** < 0.05	Trial on peaches compliant with GAP (Germany, 2016)	–	–	–	–
	SEU	**Mo:** 0.04; 0.03; 0.06; 0.09; 0.09; 0.06; 0.06; 0.01; 0.06; 0.07 **RA:** 0.06; 0.06; 0.12; 0.19; 0.12; 0.15; 0.10; < 0.05; 0.12; 0.15	Trials on peaches compliant with GAP (Germany, 2015) MRL_{OECD} = 0.17	0.2	0.09	0.06	2.0
Plums	SEU	**Mo:** < 0.01; < 0.01; 0.01; 0.03 **RA:** < 0.05; < 0.05; < 0.05; 0.12	Trials on plums compliant with GAP (Germany, 2015) R_{ber} = 0.05 MRL_{OECD} = 0.06	0.07 (tentative)[f]	0.03	0.01	4.0
Table grapes Wine grapes	NEU	**Mo:** 0.05; 0.05; 0.04; 0.08; 0.056; 0.06; 0.024; 0.11 **RA:** 0.08; 0.12; 0.10; 0.15; 0.11; 0.15; 0.074; 0.19	Trials on grapes. First 4 trials performed with 2 applications acceptable since first application, done at early growth stage, is not expected to impact final residue level. Other trials overdosed (Germany, 2015) MRL_{OECD} = 0.18	0.2	0.11	0.05	2.2
	SEU	**Mo:** 0.02; 0.03; 0.03; 0.03; 0.01; < 0.01; 0.07; 0.01 **RA:** 0.06; 0.06; 0.05; 0.07; < 0.05; < 0.05; 0.09; < 0.05	Trials on grapes compliant with GAP (Germany, 2015) MRL_{OECD} = 0.11	0.15	0.07	0.03	2.0
	Import (USA)	**Mo:** – **RA:** < 0.05; 0.05; 0.06; 0.06; 0.06; 0.11; 0.11; 0.11; 0.12; 0.12; 0.16; 0.17; 0.19; 0.2; 0.21; 0.61	Trials on grapes compliant with GAP. Residues analysed only according to the risk assessment residue definition (Germany, 2015) MRL_{OECD} = 0.69	**0.7** (tentative)[e]	**0.61**	**0.12**	**1.0**

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Blueberries Cranberries	Import (USA)	**Mo:** – **RA:** 0.35; 0.39; 0.48; 0.86; 1.1; 1.9; 2.56	Trials on blueberries compliant with GAP. Although not explicitly mentioned in the (European Commission, 2017), extrapolation from blueberries to cranberries is acceptable (both crops belong to the *Vaccinium* genus). Residues analysed only according to the residue definition for risk assessment (Germany, 2015) MRL_{OECD} = 4.47	**5** (tentative)[e]	**2.56**	**0.86**	**1.0**
Currants (black, red and white) Gooseberries (green, red and yellow) Rose hips Mulberries (black and white) Azaroles/Mediterranean medlars Elderberries	Import (USA)	–	No residue trials compliant with GAP	–	–	–	–
Table olives	SEU	**Mo:** 0.40; 0.40; 0.03; 0.30; 0.05; 0.02; 0.42; 0.11 **RA:** 0.71; 1.1; 0.14; 0.63; 0.11; < 0.05; 0.49; 0.22	Trials on olives compliant with GAP (Germany, 2015) MRL_{OECD} = 0.94	1	0.42	0.21	2.2
Avocados	SEU	–	No residue trials available	–	–	–	–
Bananas	Import (Cameroon)	**Mo:** – **RA:** 4 × < 0.01	Trials on banana compliant with GAP for soil treatment. Residues analysed only according to the residue definition for risk assessment is acceptable since residues always below the LOQ (Germany, 2015)	**0.01***	**0.01**	**0.01**	**1.0**
Mangoes	SEU	–	–	–	–	–	–
Pomegranates/Granate apples/	Import (USA)	–	No residue trials compliant with GAP for soil treatment	–	–	–	–

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Potatoes	NEU	**Mo:** 0.01; 0.01; 0.02; 0.02 **RA:** < 0.05; < 0.05; < 0.05; < 0.05	Trials on potatoes compliant with GAP for seed treatment (Germany, 2015) MRL_{OECD} = 0.04	0.05 (tentative)[f]	0.02	0.02	2.5
	SEU	**Mo:** 7 × < 0.01 **RA:** 7 × < 0.05	Trials on potatoes with dose rate within 25% deviation (Portugal, 2016; Greece, 2016)	0.01*	0.01	0.01	1.0
Garlic Onions Shallots Spring onions/green onions and Welsh onions	NEU	**Mo:** < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; 0.03 **RA:** < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; 0.06	Trials on onions compliant with GAP for seed treatment. Extrapolation to bulb vegetables possible (Germany, 2015) MRL_{OECD} = 0.04	0.04	0.03	0.01	2.0
Tomatoes Aubergines/eggplants	SEU	**Mo:** 0.012; 0.013; 0.021; 0.03; 0.021; 0.013; < 0.01; < 0.01 **RA:** < 0.03; 0.034; 0.059; 0.051; 0.037; < 0.03; < 0.03; < 0.03	Trials on tomatoes compliant with GAP (Italy, 2016a). Extrapolation to aubergines possible MRL_{OECD} = 0.04	0.05	0.03	0.01	2.4
	EU	**Tomatoes** **Mo:** 0.06; 0.09; 0.06; 0.2; 0.14; 0.07; 0.07; 0.06; 0.09; 0.10; 0.06; 0.12; 0.09; 0.11 **RA:** 0.18; 0.14; 0.10; 0.29; 0.19; 0.09; 0.11; 0.07; 0.14; 0.15; 0.06; 0.17; 0.15; 0.21 **Aubergines** **Mo:** 0.08; < 0.01 **RA:** 0.14; < 0.03	Combined data set on tomatoes and aubergines compliant with GAP (Greece, 2016; Italy 2016a). Extrapolation to aubergines possible MRL_{OECD} = 0.26	**0.3**	**0.20**	**0.09**	**1.6**

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Sweet peppers/bell peppers	SEU	**Mo:** 1.4; 0.022; 0.04; 0.078 **RA:** 1.5; 0.047; 0.095; 0.16	Trials on peppers compliant with GAP (Germany, 2015) MRL_{OECD} = 3.09	4 (tentative)[f]	1.40	0.06	2.1
	EU	**Mo:** 0.48; 0.14; 0.15; 0.16; 0.48; 0.07; 0.09; 0.31 **RA:** 0.61; 0.16; 0.19; 0.16; 0.62; 0.08; 0.22; 0.39	Trials on peppers compliant with GAP for soil treatment (Germany, 2015) MRL_{OECD} = 0.9	**0.9**	**0.48**	**0.16**	**1.3**
Okra/lady's fingers	SEU	**Mo:** 1.4; 0.022; 0.04; 0.078 **RA:** 1.5; 0.047; 0.095; 0.16	Trials on peppers overdosed (1 × 0.150 instead of 0.1 kg/ha) tentatively extrapolated to okra (Germany, 2015) MRL_{OECD} = 3.09	4 (tentative)[g]	1.40	0.06	2.1
	EU	**Mo:** 0.047; 0.20; 0.32; 0.066; 0.05; 0.051; 0.13; 0.082 **RA:** 0.063; 0.25; 0.35; 0.17; 0.056; 0.075; 0.20; 0.087	Trials on peppers overdosed (1 × 0.150 instead of 0.1 kg/ha) tentatively extrapolated to okra (Germany, 2015) MRL_{OECD} = 0.51	**0.5** (tentative)[g]	**0.32**	**0.07**	**1.3**
Cucumbers	SEU	**Mo:** 0.025; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; 0.014; 0.033 **RA:** 0.031; < 0.03; < 0.03; < 0.03; < 0.03; < 0.03; 0.035; 0.038	Trials on courgettes compliant with GAP. Extrapolation to cucumbers possible (Germany, 2015) MRL_{OECD} = 0.05	0.05	0.03	0.01	1.2
	EU	**Mo:** < 0.01; < 0.01; 0.11; 0.03; 0.21; 0.05; 0.17; 0.09; 0.18; 0.06; 0.23 **RA:** 0.16; 0.06; 0.56; 0.29; 0.93; 0.50; 0.76; 0.39; 0.35; 0.13; 0.25	Trials on cucumbers compliant with GAP for soil treatment (Germany, 2015; Italy, 2016a) MRL_{OECD} = 0.43	**0.5**	**0.23**	**0.09**	**4.5**

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Courgettes Gherkins	SEU	**Mo:** 0.025; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; 0.014; 0.033 **RA:** 0.031; < 0.03; < 0.03; < 0.03; < 0.03; < 0.03; 0.035; 0.038	Trials on courgettes compliant with GAP. Extrapolation to gherkins possible (Germany, 2015) MRL_{OECD} = 0.05	0.05	0.03	0.01	1.2
	EU	**Mo:** 0.01; < 0.01; 0.11; 0.03; 0.21; 0.05; 0.17; 0.09; 0.18; 0.06 **RA:** 0.16; 0.06; 0.56; 0.29; 0.93; 0.50; 0.76; 0.39; 0.35; 0.13	Trials on cucumbers compliant with GAP for soil treatment on gherkins and courgettes (Germany, 2015) MRL_{OECD} = 0.38	**0.4**	**0.21**	**0.08**	**4.8**
Melons Watermelons	SEU	**Mo:** < 0.01; < 0.01; < 0.01; 0.011; 0.015; 0.018; 0.015; 0.012 **RA:** < 0.03; < 0.03; < 0.03; 0.033; 0.078; 0.035; 0.039; 0.04	Trials on melons compliant with GAP. Extrapolation to watermelons possible (Germany, 2015) MRL_{OECD} = 0.03	0.03	0.02	0.01	3.0
	EU	**Melons** **Mo:** 0.07; < 0.01 **RA:** 0.18; 0.12 **Watermelons** **Mo:** 0.02; 0.01; 0.01; 0.04 **RA:** 0.06; < 0.05; < 0.05; 0.11	Combined data set of trials on melons compliant with GAP and on watermelons overdosed (Greece, 2016; Portugal, 2016) MRL_{OECD} = 0.12	**0.15** (tentative)[f],[g]	**0.07**	**0.02**	**2.9**

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Pumpkins	SEU	**Mo:** < 0.01; < 0.01; < 0.01 **RA:** 0.08; < 0.05; < 0.05	Trials on melons compliant with GAP for pumpkins (Portugal, 2016). CF calculated from indoor data set considered more robust as based on a larger number of positive trials	0.01* (tentative)[f]	0.01	0.01	2.9
	EU	**Melons** **Mo:** 0.07; < 0.01 **RA:** 0.18; 0.12 **Watermelons** **Mo:** 0.02; 0.01; 0.01; 0.04 **RA:** 0.06; < 0.05; < 0.05; 0.11	Combined data set of trials on melons compliant with GAP and on watermelons overdosed (Greece, 2016; Portugal, 2016) tentatively extrapolated to pumpkins MRL_{OECD} = 0.12	**0.15** (tentative)[f],[g]	**0.07**	**0.02**	**2.9**
Broccoli Cauliflowers	NEU	**Mo:** 21 × < 0.01 **RA:** 21 × < 0.05	Combined data set on cauliflowers (2), Brussels sprouts (8), Chinese cabbage (2) and head cabbage (9) compliant with GAP for soil treatment on brassicas except Brussels sprouts (Germany, 2015)	0.01*	0.01	0.01	1.0
	SEU	**Cauliflowers** **Mo:** < 0.01; 0.01; 0.01; < 0.01; < 0.01; 0.02 **RA:** 0.07; 0.06; 0.09; < 0.050; < 0.05; 0.05 **Broccoli** **Mo:** 0.07; 0.02; 0.03; 0.02; 0.01; 0.01; < 0.01; < 0.01 **RA:** 0.31; 0.10; 0.29; 0.08; 0.05; 0.09; 0.11; 0.07	Combined data set on cauliflowers and broccoli compliant with GAP for soil treatment on flowering brassica (Germany, 2015) MRL_{OECD} = 0.08	0.09	0.07	0.01	6.5
Brussels sprouts	NEU	**Mo:** 0.056; 0.038; 0.01; < 0.01 **RA:** 0.092; 0.061; < 0.03; < 0.03	Trials on Brussels sprouts compliant with GAP (Germany, 2015) MRL_{OECD} = 0.12	0.15	0.06	0.02	1.6
	SEU	–	No residue trials compliant with GAP	–	–	–	–

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Head cabbages	NEU	**Mo:** 21 × < 0.01 **RA:** 21 × < 0.05	See broccoli and cauliflowers NEU	0.01*	0.01	0.01	1.0
	SEU	**Mo:** 0.064; < 0.01; < 0.01; 0.015; < 0.01; < 0.01; 0.02; < 0.01; < 0.01; < 0.01; < 0.01; 0.01 **RA:** 0.10; < 0.03; < 0.03; 0.041; < 0.05; < 0.05; 0.12; < 0.05; < 0.05; < 0.05; 0.08; 0.05	Trials on head cabbages. First 4 trials compliant with GAP. Other trials performed with 2 applications instead of 1 tentatively considered (Germany, 2015) MRL_{OECD} = 0.08	0.08 (tentative)[g]	0.06	0.01	5.0
Chinese cabbages/pe-tsai Kales	NEU	**Mo:** 21 × < 0.01 **RA:** 21 × < 0.05	See broccoli and cauliflowers NEU.	0.01*	0.01	0.01	1.0
	SEU	**Mo:** 0.035; 0.034; 0.17; < 0.01 **RA:** 0.28; 0.24; 0.70; 0.09	Trials on kale compliant with GAP (Germany, 2015). Extrapolation to Chinese cabbages possible MRL_{OECD} = 0.35	0.5	0.17	0.03	7.5
Kohlrabies	NEU	–	No residue trials compliant with GAP	–	–	–	–
Lamb's lettuces/corn salads Escaroles/broad-leaved endives Cresses and other sprouts and shoots Land cresses Roman rocket/rucola Red mustards Baby leaf crops (including *Brassica* species) Fresh herbs	NEU	**Mo:** < 0.01; 0.01; 0.02; 0.01; 0.02; 0.02; 0.03; < 0.01 **RA:** < 0.05; < 0.05; 0.07; < 0.05; < 0.05; < 0.05; 0.06; < 0.05	Trials on lettuce compliant with GAP for seed treatment. Extrapolation to other salad plants possible (Germany, 2015). Not authorised for use on lamb's lettuce, rockets and fresh herbs in NEU MRL_{OECD} = 0.05	0.05	0.03	0.02	2.5
	SEU	**Mo:** 0.95; 0.12; 0.15; 0.25; 0.14; 0.20; 0.23; 0.80; 0.38 **RA:** 1.5; 0.66; 0.27; 0.41; 0.38; 0.59; 0.87; 1.2; 0.98	Trials on lettuce performed with 2 applications instead of 1. First 7 trials on open leaf varieties. Extrapolation to salads (except lettuce) and fresh herbs possible (Germany, 2015) MRL_{OECD} = 1.58	2	0.95	0.23	2.6
	EU	–	No residue trials available. Not authorised for indoor use on rockets and fresh herbs	–	–	–	–

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Lettuce	NEU	**Mo:** < 0.01; 0.01; 0.02; 0.01; 0.02; 0.02; 0.03; < 0.01 **RA:** < 0.05; < 0.05; 0.07; < 0.05; < 0.05; < 0.05; 0.06; < 0.05	Trials on lettuce compliant with GAP for seed treatment (Germany, 2015) MRL_{OECD} = 0.05	0.05	0.03	0.02	2.5
	SEU	**Mo:** 0.33; 0.018; 0.17; 0.049; 0.14; 0.17; 0.16; 0.07 **RA:** 0.80; 0.16; 0.28; 0.30; 0.55; 0.80; 0.69; 0.50	Trials on lettuce open leaf varieties with dose rate within 25% deviation (Germany, 2015) MRL_{OECD} = 0.53	0.6	0.33	0.15	4.5
	EU	–	No residue trials available.	–	–	–	–
Witloofs/Belgian endives	NEU	**Mo:** 6 × < 0.01 **RA:** 6 × < 0.05	Trials on witloof compliant with GAP for seed treatment (Germany, 2015)	0.01*	0.01	0.01	1.0
Beans with pods Peas with pods	SEU	**Mo:** < 0.01; 0.078; 0.015; 0.093; 0.16; 0.025; 0.11; 0.071 **RA:** < 0.03; 0.18; 0.092; 0.33; 0.32; 0.21; 0.31; 0.22	Trials on beans with pods compliant with GAP (Germany, 2015). No authorised for use on peas with pods in SEU MRL_{OECD} = 0.28	0.3	0.16	0.07	3.1
	EU	**Mo:** 0.15; 0.14; 0.085; 0.064; 0.082; 0.19; 0.25; 0.072 **RA:** 0.42; 0.42; 0.32; 0.16; 0.31; 0.24; 0.31; 0.29	Trials on beans with pods compliant with GAP (Germany, 2015). No authorised for indoor use on peas with pods MRL_{OECD} = 0.39	**0.4**	**0.25**	**0.11**	**2.9**
	Import (USA)	**Beans with pods** **Mo:** – **RA:** 0.61; 0.80; 0.23; 0.45 **Peas with pods** **Mo:** – **RA:** 0.19; 3.13; 0.88; 0.22	Combined data set on beans with pods and peas with pods performed according to a more critical GAP (1 seed treatment followed by 1 soil and 3 foliar sprays). Residues analysed only according to the residue definition for risk assessment (Germany, 2015) MRL_{OECD} = 4.71	**5** (tentative) (e),(g)	**3.13**	**0.53**	**1.0**

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Beans without pods Peas without pods	SEU	**Mo:** < 0.01; < 0.01; < 0.01; < 0.01 **RA:** 0.11; < 0.03; < 0.03; 0.10	Trials on beans without pods compliant with GAP (Germany, 2015). No authorised for use on peas without pods in SEU MRL_{OECD} = 0.01	0.01* (tentative)[f]	0.01	0.01	10
	Import (USA)	**Beans without pods** **Mo:** – **RA:** 0.12; 0.25; 0.17; < 0.05; < 0.05 **Peas without pods** **Mo:** – **RA:** 0.51; 0.38; 0.26; 0.83; 0.99	Combined data set on beans without pods and peas without pods performed according to a more critical GAP (1 seed treatment followed by 1 soil and 3 foliar sprays). Residues analysed only according to the residue definition for risk assessment (Germany, 2015) MRL_{OECD} = 1.66	**2** (tentative)[e],[g]	**0.99**	**0.26**	**1.0**
Cardoons	SEU	–	No residue trials available.	–	–	–	–
Globe artichokes	SEU	**Mo:** 0.09; 0.09; 0.11; 0.12; 0.10; 0.14 **RA:** 0.15; 0.13; 0.19; 0.18; 0.18; 0.21	Trials on globe artichokes compliant with GAP (Germany, 2015) MRL_{OECD} = 0.32	0.4	0.14	0.11	1.6
Leeks	NEU	**Mo:** 4 × < 0.01 **RA:** 4 × < 0.05	Trials on leeks overdosed (seed treatment performed at 0.06 kg/unit instead of 0.045 kg/unit) acceptable since residues were always below the LOQ (Germany, 2015)	0.01*	0.01	0.01	1.0

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Beans (dry)	Import (USA)	**Dry beans** **Mo:** – **RA:** 0.71; 0.59; 0.69; 0.99; 0.21; 0.13; 0.20; 0.34; 0.79; 0.49; 0.25 **Dry peas** **Mo:** – **RA:** 0.121; 0.181; 0.269; 0.684; 0.811; 0.864	Combined data set on dry beans and dry peas compliant with GAP. Residues analysed only according to the risk assessment residue definition (Germany, 2015) MRL_{OECD} = 1.66	**2** (tentative)[e]	**0.99**	**0.49**	**1.0**
Peas (dry)	SEU	**Mo:** < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01 **RA:** 0.41; 0.31; 0.53; 0.22; 0.23; 0.33; 0.35	Trials on dry peas compliant with GAP (Germany, 2015)	0.01* (tentative)[f]	0.01	0.01	33
Peanuts/groundnuts	Import (USA)	**Mo:** – **RA:** < 0.05; < 0.05; < 0.05; 0.18; 0.355; 0.095; 0.10; < 0.05; 0.14; 0.20; 0.21; 0.115	Trials on peanuts performed according to a more critical GAP for soil treatment (1 soil application followed by 3 foliar applications) used to derive a tentative MRL. Residues analysed only according to the residue definition for risk assessment (Germany, 2015) MRL_{OECD} = 0.5	**0.5** (tentative)[e],[g]	**0.36**	**0.11**	**1.0**
Cotton seeds	SEU	–	No residue trials available.	–	–	–	–
Olives for oil production	SEU	**Mo:** 0.16; 0.44; 0.16; 0.20; 0.09; 0.04; 0.11; 0.01 **RA:** 0.29; 0.79; 0.26; 0.43; 0.26; 0.15; 0.22; 0.08	Trials on olives with dose rate within 25% deviation (4) and with 2 applications instead of 1 (4) acceptable as the first application at early growth stage is not expected to have a significant impact on the final residue level (Germany, 2015; Italy, 2016b) MRL_{OECD} = 0.68	0.7	0.44	0.14	2.1

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Barley grains Oat grains Rye grains Wheat grains	NEU	**Barley** **Mo:** 10 × < 0.01 **RA:** 2 × < 0.02; 3 × < 0.03; 5 × < 0.05 **Wheat** **Mo:** 10 × < 0.01 **RA:** 2 × < 0.02; 2 × < 0.03; 6 × < 0.05	Combined data set on barley and wheat compliant with GAP for seed treatment. Extrapolation to oats and rye possible (Germany, 2015)	0.01*	0.01	0.01	1.0
	SEU	**Barley** **Mo:** < 0.01 **RA:** < 0.03 **Wheat** **Mo:** 7 × < 0.01 **RA:** 3 × < 0.03; 4 × < 0.05	Combined data set on barley and wheat compliant with GAP for seed treatment (Germany, 2015; France, 2016). Extrapolation to barley, oats and wheat possible. No authorised for use on rye in SEU	0.01*	0.01	0.01	1.0

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Barley straw Oat straw Rye straw Wheat straw	NEU	**Barley** **Mo:** < 0.1; < 0.1; < 0.05; < 0.05; < 0.1; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01 **RA:** < 0.05; < 0.05; 0.11; 0.28; < 0.05; < 0.03; < 0.03; < 0.03; < 0.02; < 0.02 **Wheat** **Mo:** < 0.1; 0.05; < 0.05; 0.05; < 0.1; < 0.10; < 0.01; < 0.01; < 0.01; < 0.01 **RA:** < 0.05; 0.11; 0.08; 0.21; < 0.05; 0.13; < 0.03; < 0.03; < 0.02; < 0.02	Combined data set on barley and wheat compliant with GAP for seed treatment. Extrapolation to rye and oats possible (Germany, 2015) MRL_{OECD} = 0.2	0.2 (tentative)[h]	0.10	0.05	2.2
	SEU	**Barley** **Mo:** < 0.01 **RA:** < 0.03 **Wheat** **Mo:** 6 × < 0.01; 0.015 **RA:** 2 × < 0.03; 4 × < 0.05; 0.16	Combined data set on barley and wheat compliant with GAP for seed treatment (Germany, 2015; France, 2016). Extrapolation to barley, oats and wheat possible. CF calculated from NEU considered more robust as based on a larger number of positive trials. No authorised for use on rye in SEU MRL_{OECD} = 0.02	0.02 (tentative)[h]	0.02	0.01	2.2
Coffee beans	Import (USA)	**Mo:** – **RA:** 0.18; 0.235; 0.285; 0.37; 0.47	Trials on coffee beans performed at a more critical GAP (5 foliar spray instead of 2 soil applications). Residues analysed only according to the risk assessment residue definition (Germany, 2015) MRL_{OECD} = 0.92	**1** (tentative)[e],[f],[h],[i]	**0.47**	**0.29**	**1.0**

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Hops	NEU	**Mo:** 8 × < 0.2 **RA:** 0.48; 0.59; 0.73; 0.73; 0.81; 1.2; 1.3; 1.6	Trials on hops compliant with GAP (Germany, 2015) MRL_{OECD} = 0.2	0.2	0.20	0.20	3.9
	Import (USA)	**Mo:** – **RA:** 1.04; 4.58; 4.76	Trials on hops. Last trial overdosed (performed with 3 applications at 0.17–0.25 kg/ha) considered on a tentative basis. Residues analysed only according to the risk assessment residue definition (Germany, 2015) MRL_{OECD} = 11.85	**15** (tentative)[e],[f],[g]	**4.76**	**4.58**	**1.0**
Sugar beet roots Fodder beet roots	NEU	**Mo:** 15 × < 0.01 **RA:** 15 × < 0.05	Trials on sugar beet compliant with GAP for seed treatment (except one trial overdosed but acceptable since residues below the LOQ). Extrapolation to fodder beet possible (Germany, 2015)	0.01*	0.01	0.01	1.0
	SEU	**Mo:** 3 × < 0.01 **RA:** 3 ×< 0.05	Trials on sugar beet compliant with GAP for seed treatment or with dose rate within the 25% variation (Germany, 2015). No authorised for use on fodder beet in SEU	0.01*	0.01	0.01	1.0
Sugar beet tops Fodder beet tops	NEU	**Mo:** 15 × < 0.01 **RA:** 10 × < 0.05; 0.06; 0.07; 0.11; 0.11; 0.14	Trials on sugar beet compliant with GAP for seed treatment (except one trial overdosed but acceptable since residues below the LOQ). Extrapolation to fodder beet possible (Germany, 2015)	0.01* (tentative)[h]	0.01	0.01	11
	SEU	**Mo:** < 0.01; < 0.01; < 0.01 **RA:** < 0.05; 0.063; 0.066	Trials on sugar beet compliant with GAP for seed treatment or with dose rate within the 25% variation (Germany, 2015). No authorised for use on fodder beet in SEU	0.01* (tentative)[h]	0.01	0.01	6.5

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Mo: monitoring; RA: risk assessment.
*: 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, EU: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Conversion factor for risk assessment; median of the individual conversion factors at the supported PHI for each residues trial. CF was calculated considering only residues of parent and the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety above LOQ. A CF of 1 was proposed when in all residue trials both imidacloprid and the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety were below the LOQ and when residues were analysed only according to the residue definition for risk assessment (mainly for the import tolerances).
(e): Tentative MRL derived from residue trials with samples analysed only according to the risk assessment residue definition.
(f): Tentative MRL is derived based on a reduced number of trials.
(g): Tentative MRL is derived based on trials performed according to a more critical GAP.
(h): Tentative MRL is derived in future view of setting MRLs in livestock feed items.
(i): Tentative MRL is derived as a confirmatory method and an ILV are still required for the enforcement in coffee beans.

B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)	In the available confined rotational crop study performed with a bare soil application at 0.454 kg/ha, the lowest total radioactive residues (TRR) were found in wheat grains and red beet roots ranging from 0.03 to 0.07 mg/kg. In all other rotated crops, TRRs were higher, accounting for up to 0.26 and 0.24 mg/kg in red beet leaves and Swiss chard and for up to 1.0 and 2.38 mg/kg in wheat forage and straw, respectively. Although residues in rotated crops decreased with soil ageing, TRR after the third rotation (408 days) were still significant, ranging from 0.03 mg/kg in wheat grain to 0.96 mg/kg in wheat straw. These results suggests possible soil uptake, even at long plant-back intervals
Field rotational crop study	In the available rotational crop field study performed with a bare soil application of imidacloprid at 1 × 0.15 kg/ha, no residues above the LOQ of 0.05 mg/kg were found in rotational crops. Nevertheless, imidacloprid concentration tested in the rotational field studies (0.16 mg/kg soil) is not covering the soil concentration expected from annual and multiannual applications according to the most critical indoor GAP currently authorised for sweet peppers (calculated as 0.203 mg/kg soil and as 0.348 mg/kg soil, respectively). Consequently, following both annual and multiannual applications of imidacloprid according to the most critical GAP currently authorised for sweet peppers, a possible uptake by crops grown in rotation cannot be excluded

LOQ: limit of quantification; GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

Processed commodity	Number of studies[a]	Processing factor (PF)		CF_P[b]
		Individual values	Median PF	
Robust processing factors (sufficiently supported by data)				
Citrus fruits, peeled	3	0.08; 0.14; 0.18	0.14	2.0
Citrus fruits, juice	3	0.12; 0.14; 0.17	0.14	2.5
Apples and pears, juice	6	0.30; 0.67; 0.50; 0.50; 0.50; 0.25	0.5	2.1
Apples, sauce	6	0.30; 0.67; 0.75; 0.50; 0.50; 0.25	0.5	2.1
Peaches, canned	4	0.25; 0.50; 0.50; 0.57	0.5	1.1
Wine grapes, wet pomace	9	3.8; 7.0; 2.13; 3.18; 1.99; 1.48; 2.12; 1.81; 2.94	2.13	1.7
Wine grapes, must	11	2.0; 1.75; 2.25; 1.4; 1.5; 0.87; 1.12; 0.29; 1.21; 0.92; 0.44	1.21	1.7
Wine grapes, red wine (unheated)	4	1.0; 1.5; 0.98; 0.81	0.99	2.1
Wine grapes, white wine	7	2.0; 1.75; 1.2; 1.02; 0.3; 1.07; 0.38	1.07	1.9
Tomatoes, paste	4	2.5; 1.5; 7.25; 2.0	2.25	3.2
Melons, pumpkins and watermelons, peeled	16	3.0; 1.04; 0.48; 0.38; 2 × 0.33; 2 × 0.83; 0.48; 2 × 0.91; 0.48; 0.55; 2 × 0.67; 0.56	0.61	1.0
Beans (with pods), cooked	3	< 0.33; < 0.5; 1.0	< 0.5	33
Beans (with pods), canned	3	0.33; < 0.5; 1.0	0.5	14
Cotton seeds, crude oil	3	1.0; 1.0; 1.0	1.0	1.0
Olives for oil production, virgin oil after cold press	5	0.11; 0.25; 0.18; 0.50; 0.17	0.18	1.0
Olives for oil production, refined oil after warm press	4	0.25; 0.09; 0.50; 0.06	0.17	1.0
Olives for oil production, press cake	5	1.44; 1.0; 1.27; 2.0; 1.0	1.27	1.6

Processed commodity	Number of studies[a]	Processing factor (PF)		CF_P[b]
		Individual values	Median PF	
Indicative processing factors (limited data set)				
Oranges, marmalade	2	0.71; 0.83	0.77	1.4
Apples and pears, dry pomace	2	2.5; 3.4	2.96	2.5
Cherries, jam	2	0.33; 0.50	0.42	2.2
Table grapes, dried (raisins)	1	5.50	5.5	2.4
Wine grapes, juice	1	0.13	0.13	1.0
Potatoes, peeled and boiled	2	0.5; 1.0	0.75	1.0
Potatoes, fried	1	0.5	0.5	1.0
Potatoes, dry pulp	2	< 2.5; < 5.0	< 1.75	1.0
Tomatoes, ketchup	2	1.5; 2.0	1.75	2.7
Tomatoes, juice	1	1.5	1.5	3.3
Head cabbages, cooked	2	0.29; 0.91	0.6	2.0
Head cabbages, sauerkraut	2	0.29; 1.1	0.69	1.8
Head cabbages, sauerkraut juice	2	0.29; 1.0	0.65	1.9
Peanuts, crude oil	2	0.20; 0.31	0.26[c]	1.0[d]
Peanuts, meal/press cake	2	2.48; 3.06	2.77[c]	1.0[d]
Cotton seeds, refined oil	1	1.0	1.0	1.0
Cotton seeds, meal/press cake	1	1.0	1.0	320
Coffee beans, roasted beans	1	0.43	0.43[c]	1.0[d]
Coffee beans, instant coffee	1	1.35	1.35[c]	1.0[d]
Hops, beer	2	< 0.01; < 0.01	< 0.01	2.0

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing study.
(c): Since residues were not analysed for parent compound, the processing factor is calculated according to the residue definition for risk assessment and is indicative only.
(d): Since residues were analysed only according to the risk assessment residue definition, a conversion factor from enforcement to risk assessment of 1 is proposed.

B.2. Residues in livestock

Relevant groups	Dietary burden expressed in				Most critical diet[a]	Most critical commodity[a]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Med.	Max.	Med.	Max.			
Cattle (all diets)	0.029	0.031	0.76	0.80	Cattle (dairy)	Grapefruits, dried pulp	Yes
Cattle (dairy only)	0.029	0.031	0.76	0.80	Cattle (dairy)	Grapefruits, dried pulp	Yes
Sheep (all diets)	0.011	0.014	0.26	0.33	Sheep (lamb)	Bean, seed	Yes
Sheep (ewe only)	0.009	0.011	0.26	0.33	Sheep (ram/ewe)	Bean, seed	Yes
Swine (all diets)	0.013	0.013	0.57	0.57	Swine (breeding)	Grapefruits, dried pulp	Yes
Poultry (all diets)	0.011	0.012	0.16	0.17	Poultry (turkey)	Bean, seed	Yes
Poultry (layer only)	0.011	0.012	0.16	0.17	Poultry (layer)	Bean, seed	Yes

bw: body weight; DM: dry matter.
(a): Calculated for the maximum dietary burden.

B.2.1. Nature of residues and methods of analysis in livestock

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

Livestock (available studies)	**Animal**	**Dose (mg/kg bw per day)**	**Duration (days)**	**N rate/comment**
	Laying hen	10–50	3	833–4167N compared to the maximum dietary burden calculated for poultry
	Lactating goat	10	3	323N compared to the maximum dietary burden calculated for cattle
	Source: Germany (2005)			

Time needed to reach a plateau concentration in milk and eggs (days)	3 (according to the livestock feeding study)
Metabolism in rat and ruminant similar (Yes/No)	Yes
Animal residue definition for monitoring (RD-Mo)	Imidacloprid, by default
Animal residue definition for risk assessment (RD-RA)	Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid
Conversion factor (monitoring to risk assessment)	See Table B.2.2.1
Fat soluble residues (Yes/No)	No
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Muscle, fat, liver, kidney and eggs: • HPLC–MS/MS • LOQ: 0.03 mg/kg • Source: Germany (2008) Milk: • HPLC–MS/MS • LOQ: 0.01 mg/kg • Source: Germany (2008) Honey: • LC–MS/MS (QuEChERS) • LOQ: 0.002 mg/kg • Source: EURLs (2016) According to the EURLs, based on the general experience with this compound, it is expected that imidacloprid residues can be enforced with an LOQ of 0.01 mg/kg in all commodities of animal origin (EURLs, 2016)

bw: body weight; HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; LC–MS/MS: liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability (months/years)
	Poultry	Muscle	–18	12 months
	Poultry	Liver	–18	12 months
	Bovine	Kidney	–18	12 months
	Bovine	Fat	–18	12 months
	Bovine	Milk	–18	12 months
	Poultry	Egg	–18	12 months
	The demonstrated storage stability period covers imidacloprid and metabolites (M01, M06, M09, M14) Source: Germany (2005)			

B.2.2. Magnitude of residues in livestock

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

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)	CF[c]
	Mean	Highest	STMR[a] (mg/kg)	HR[b] (mg/kg)		
Cattle (all diets) Closest feeding level (0.15 mg/kg bw; 4.8N rate)[d]						
Muscle	< 0.02	< 0.02	< 0.03	< 0.03	0.03*	1.0
Fat	< 0.02	< 0.02	< 0.03	< 0.03	0.03*	1.0
Liver	0.05	0.05	< 0.03	< 0.03	0.03*	1.0
Kidney	0.03	0.03	< 0.03	< 0.03	0.03*	1.0
Cattle (dairy only) Closest feeding level (0.15 mg/kg bw; 4.8N rate)[d]						
Milk[e]	< 0.02	n.a.	0.01	0.01	0.01*	1.0
Sheep (all diets)[f] Closest feeding level (0.15 mg/kg bw; 11N rate)[d]						
Muscle	< 0.02	< 0.02	< 0.03	< 0.03	0.03*	1.0
Fat	< 0.02	< 0.02	< 0.03	< 0.03	0.03*	1.0
Liver	0.05	0.05	< 0.03	< 0.03	0.03*	1.0
Kidney	0.03	0.03	< 0.03	< 0.03	0.03*	1.0
Sheep (dairy only)[f] Closest feeding level (0.15 mg/kg bw; 14N rate)[d]						
Milk[e]	< 0.02	n.a.	0.01	0.01	0.01*	1.0
Swine[f] Closest feeding level (0.15 mg/kg bw; 12N rate)[d]						
Muscle	< 0.02	< 0.02	< 0.03	< 0.03	0.03*	1.0
Fat	< 0.02	< 0.02	< 0.03	< 0.03	0.03*	1.0
Liver	0.05	0.05	< 0.03	< 0.03	0.03*	1.0
kidney	0.03	0.03	< 0.03	< 0.03	0.03*	1.0
Poultry (all diets) Closest feeding level (0.18 mg/kg bw; 15N rate)[d]						
Muscle	< 0.02	< 0.02	< 0.03	< 0.03	0.03*	1.0
Fat	< 0.02	< 0.02	< 0.03	< 0.03	0.03*	1.0
Liver	0.04	0.05	< 0.03	< 0.03	0.03*	1.0

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)	CF[(c)]
	Mean	Highest	STMR[(a)] (mg/kg)	HR[(b)] (mg/kg)		
Poultry (layer only) Closest feeding level (0.18 mg/kg bw; 15N rate)[(d)]						
Egg	< 0.02	< 0.02	< 0.03	< 0.03	0.03*	1.0

MRL: maximum residue level; CF: conversion factor for enforcement residue definition to risk assessment residue definition; STMR: supervised trials median residue; HR: highest residue; bw: body weight.
*: Indicates that the MRL is proposed at the limit of quantification.
n.a.: not applicable.
n.r.: not reported.
(a): The mean residue level for milk and the median residue levels for eggs and tissues were recalculated at the 1N rate for the median dietary burden.
(b): The mean residue level in milk and the highest residue levels in eggs and tissues were recalculated at the 1N rate for the maximum dietary burden.
(c): As reported residue levels were analysed according to the residue definition for risk assessment, a CF of 1 is proposed from enforcement to risk assessment.
(d): Closest feeding level and N dose rate related to the maximum dietary burden.
(e): Highest residue level from day 1 to day 28 (daily mean of 3 cows).
(f): 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.

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs – Indoor uses and import tolerances

ADI	0.06 mg/kg bw per day (EFSA, 2008a)
Highest IEDI, according to EFSA PRIMo	**Scenario EU1** (**without risk mitigation measures):** 6% ADI (WHO cluster diet B) **Scenario EU2** (**with risk mitigation measures):** 6% ADI (WHO cluster diet B)
Assumptions made for the calculations	**Scenario EU1** (**without risk mitigation measures):** The calculation is based on the median residue levels in the raw agricultural commodities, except for citrus fruits and cucurbits with inedible peel where the relevant peeling factors were applied For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation **Scenario EU2** (**with risk mitigation measures):** The EU MRL for escaroles was disregarded (assuming that the authorisation for this crop will be withdrawn)

ARfD	0.08 mg/kg bw (EFSA, 2008a)
Highest IESTI, according to EFSA PRIMo	**Scenario EU1** (**without risk mitigation measures):** 109% ARfD (escarole) **Scenario EU2** (**with risk mitigation measures):** 76% ARfD (cucumbers)
Assumptions made for the calculations	**Scenario EU1** (**without risk mitigation measures):** The calculation is based on the highest residue levels in the raw agricultural commodities, except for citrus fruits and cucurbits with inedible peel where the relevant peeling factors were applied For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation **Scenario EU2** (**with risk mitigation measures):** The EU MRL for escaroles was disregarded (assuming that the authorisation for this crop will be withdrawn)

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

B.3.2. Consumer risk assessment without consideration of the existing CXLs – all uses

ADI	0.06 mg/kg bw per day (EFSA, 2008a)
Highest IEDI, according to EFSA PRIMo	**Scenario EU1** (**without risk mitigation measures):** 7% ADI (WHO cluster diet B) **Scenario EU2** (**with risk mitigation measures):** 6% ADI (WHO cluster diet B)
Assumptions made for the calculations	**Scenario EU1** (**without risk mitigation measures):** The calculation is based on the median residue levels in the raw agricultural commodities, except for citrus fruits and cucurbits with inedible peel where the relevant peeling factors were applied For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation **Scenario EU2** (**with risk mitigation measures):** The median residue levels for escarole, sweet peppers and kale, resulting from the GAPs of concern (SEU outdoor), are replaced by the median residue levels resulting from the fall-back GAPs (NEU outdoor for escarole and kale and EU indoor for peppers)

ARfD	0.08 mg/kg bw (EFSA, 2008a)
Highest IESTI, according to EFSA PRIMo	**Scenario EU1** (**without risk mitigation measures):** 270% ARfD (escarole) 231% ARfD (sweet peppers) 108% ARfD (kale) **Scenario EU2** (**with risk mitigation measures):** 76% ARfD (cucumbers)
Assumptions made for the calculations	**Scenario EU1** (**without risk mitigation measures):** The calculation is based on the highest residue levels in the raw agricultural commodities, except for citrus fruits and cucurbits with inedible peel where the relevant peeling factors were applied For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation **Scenario EU2** (**with risk mitigation measures):** The highest residue levels for escarole, sweet peppers and kale, resulting from the GAPs of concern (SEU outdoor), are replaced by the highest residue levels resulting from the fall-back GAPs (NEU outdoor for escarole and kale and EU indoor for peppers)

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; ARfD: acute reference dose; IESTI: international estimated short-term intake; CXL: codex maximum residue limit; MRL: maximum residue level; GAP: Good Agricultural Practice; SEU: southern European Union; NEU: northern European Union.

B.3.3. Consumer risk assessment with consideration of the existing CXLs

ADI	0.06 mg/kg bw per day (EFSA, 2008a)
Highest IEDI, according to EFSA PRIMo	**Indicative results considering CXLs only:** 8% ADI (WHO Cluster diet B)
Assumptions made for the calculations	CXLs have been established for imidacloprid (as sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid). However, this residue definition for enforcement is not compatible with the residue for enforcement proposed by EFSA. Therefore, a consumer risk assessment including CXLs values together with EU MRLs could not be performed As CXLs were derived according to residue definition for risk assessment, an indicative risk assessment with the existing CXLs only, was performed. The input values as derived by the JMPR could directly be considered, without applying any conversion factor. The calculation is based on the median residue levels in the raw agricultural commodities, except for citrus fruits where the relevant peeling factor was applied

ARfD	0.08 mg/kg bw (EFSA, 2008a)
Highest IESTI, according to EFSA PRIMo	**Indicative results considering CXLs only:** 184% ARfD (celery) 169% ARfD (kale)
Assumptions made for the calculations	CXLs have been established for imidacloprid (as sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid). However, this residue definition for enforcement is not compatible with the residue for enforcement proposed by EFSA. Therefore, a consumer risk assessment including CXLs values together with EU MRLs could not be performed As CXLs were derived according to residue definition for risk assessment, an indicative risk assessment with the existing CXLs only, was performed. The input values as derived by the JMPR could directly be considered, without applying any conversion factor. The calculation is based on the highest residue levels in the raw agricultural commodities, except for citrus fruits where the relevant peeling factor was applied

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

B.4. Proposed MRLs (based on GAPs compliant with the new conditions of approval)

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: imidacloprid					
110010	Grapefruit	1	1	0.9	Further consideration needed[(a)]
110020	Oranges	1	1	0.9	Further consideration needed[(a)]
110030	Lemons	1	1	0.9	Further consideration needed[(a)]
110040	Limes	1	1	0.9	Further consideration needed[(a)]
110050	Mandarins	1	1	0.9	Further consideration needed[(a)]
120010	Almonds	0.05*	0.01	–	Further consideration needed[(b)]
120020	Brazil nuts	0.05*	0.01	–	Further consideration needed[(b)]
120030	Cashew nuts	0.05*	0.01	–	Further consideration needed[(b)]
120040	Chestnuts	0.05*	0.01	–	Further consideration needed[(b)]
120050	Coconuts	0.05*	0.01	–	Further consideration needed[(b)]
120060	Hazelnuts	0.05*	0.01	–	Further consideration needed[(b)]
120070	Macadamia	0.05*	0.01	–	Further consideration needed[(b)]
120080	Pecans	0.05*	0.01	0.02*	Recommended[(c)]
120090	Pine nuts	0.05*	0.01	–	Further consideration needed[(b)]
120100	Pistachios	0.05*	0.01	–	Further consideration needed[(b)]
120110	Walnuts	0.05*	0.01	–	Further consideration needed[(b)]
130010	Apples	0.5	0.5	–	Further consideration needed[(b)]
130020	Pears	0.5	1	–	Further consideration needed[(b)]
140010	Apricots	0.5	1.5	–	Further consideration needed[(b)]
140020	Cherries	0.5	4	–	Further consideration needed[(b)]
140030	Peaches	0.5	1.5	–	Further consideration needed[(b)]
140040	Plums	0.3	1.5	–	Further consideration needed[(b)]
151010	Table grapes	1	1	0.7	Further consideration needed[(a)]
151020	Wine grapes	1	1	0.7	Further consideration needed[(a)]
152000	Strawberries	0.5	0.5	–	Further consideration needed[(b)]
153010	Blackberries	5	5	–	Further consideration needed[(b)]
153020	Dewberries	5	5	–	Further consideration needed[(b)]
153030	Raspberries	5	5	–	Further consideration needed[(b)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
154010	Blueberries	5	5	5	Further consideration needed[a]
154020	Cranberries	0.05*	0.05*	5	Further consideration needed[a]
154030	Currants (red, black and white)	5	5	5	Further consideration needed[d]
154040	Gooseberries	5	5	5	Further consideration needed[d]
154050	Rose hips	5	5	5	Further consideration needed[d]
154060	Mulberries	5	5	5	Further consideration needed[d]
154070	Azarole (Mediterranean medlar)	0.05*	5	0.05	Further consideration needed[d]
154080	Elderberries	5	5	5	Further consideration needed[d]
161030	Table olives	0.5	2	–	Further consideration needed[b]
161040	Kumquats	0.05*	1	–	Further consideration needed[b]
163020	Bananas	0.05*	0.05	0.01*	Recommended[c]
163030	Mangoes	0.2	0.2	–	Further consideration needed[b]
163050	Pomegranate	1	1	1	Further consideration needed[d]
211000	Potatoes	0.5	0.5	–	Further consideration needed[b]
212010	Cassava	0.5	0.5	–	Further consideration needed[b]
212020	Sweet potatoes	0.5	0.5	–	Further consideration needed[b]
212030	Yams	0.5	0.5	–	Further consideration needed[b]
212040	Arrowroot	0.5	0.5	–	Further consideration needed[b]
213010	Beetroot	0.5	0.5	–	Further consideration needed[b]
213020	Carrots	0.5	0.5	–	Further consideration needed[b]
213030	Celeriac	0.5	0.5	–	Further consideration needed[b]
213040	Horseradish	0.5	0.5	–	Further consideration needed[b]
213050	Jerusalem artichokes	0.5	0.5	–	Further consideration needed[b]
213060	Parsnips	0.5	0.5	–	Further consideration needed[b]
213070	Parsley root	0.5	0.5	–	Further consideration needed[b]
213080	Radishes	0.5	0.5	–	Further consideration needed[b]
213090	Salsify	0.5	0.5	–	Further consideration needed[b]
213100	Swedes	0.5	0.5	–	Further consideration needed[b]
213110	Turnips	0.5	0.5	–	Further consideration needed[b]
220020	Onions	0.1	0.1	–	Further consideration needed[b]
231010	Tomatoes	0.5	0.5	0.3	Recommended[c]
231020	Peppers	1	1	0.9	Recommended[c]
231030	Aubergines (egg plants)	0.5	0.2	0.3	Recommended[c]
231040	Okra, lady's fingers	0.5	–	0.5	Further consideration needed[e]
232010	Cucumbers	1	1	0.5	Recommended[c]
232020	Gherkins	0.5	–	0.4	Recommended[f]
232030	Courgettes	1	1	0.4	Recommended[c]
233010	Melons	0.5	0.2	0.15	Further consideration needed[a]
233020	Pumpkins	0.5	–	0.15	Further consideration needed[e]
233030	Watermelons	0.2	0.2	0.15	Further consideration needed[a]
234000	Sweet corn	0.1	0.02*	–	Further consideration needed[b]
241010	Broccoli	0.5	0.5	–	Further consideration needed[b]
241020	Cauliflower	0.5	0.5	–	Further consideration needed[b]
242010	Brussels sprouts	0.5	0.5	–	Further consideration needed[b]
242020	Head cabbage	0.5	0.5	–	Further consideration needed[b]
243020	Kale	0.3	5	–	Further consideration needed[b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
251010	Lamb's lettuce	2	–	2	Further consideration needed[(g)]
251020	Lettuce	2	2	2	Further consideration needed[(d)]
251030	Escarole (broad-leaf endive)	1	–	–	Further consideration needed[(h)]
251040	Cress	2	–	2	Further consideration needed[(g)]
251050	Land cress	2	–	2	Further consideration needed[(g)]
251070	Red mustard	2	–	2	Further consideration needed[(g)]
251080	Leaves and sprouts of *Brassica* spp.	2	–	2	Further consideration needed[(g)]
256080	Basil	2	20	–	Further consideration needed[(b)]
260010	Beans (fresh, with pods)	2	2	5	Further consideration needed[(a)]
260020	Beans (fresh, without pods)	2	2	2	Further consideration needed[(a)]
260030	Peas (fresh, with pods)	5	5	5	Further consideration needed[(a)]
260040	Peas (fresh, without pods)	2	2	2	Further consideration needed[(a)]
270030	Celery	2	6	–	Further consideration needed[(b)]
270060	Leek	0.05*	0.05*	–	Further consideration needed[(b)]
300010	Beans (dry)	2	2	2	Further consideration needed[(a)]
300020	Lentils (dry)	2	2	–	Further consideration needed[(b)]
300030	Peas (dry)	2	2	–	Further consideration needed[(b)]
300040	Lupins (dry)	2	2	–	Further consideration needed[(b)]
401020	Peanuts	1	1	0.5	Further consideration needed[(a)]
401050	Sunflower seed	0.1	0.05*	–	Further consideration needed[(b)]
401060	Rape seed	0.1	0.05*	–	Further consideration needed[(b)]
401070	Soya bean	0.05*	3	–	Further consideration needed[(b)]
402010	Olives for oil production	1	2	–	Further consideration needed[(b)]
500010	Barley grain	0.1	0.05	–	Further consideration needed[(b)]
500020	Buckwheat grain	0.1	0.05	–	Further consideration needed[(b)]
500030	Maize grain	0.1	0.05	–	Further consideration needed[(b)]
500040	Millet grain	0.05*	0.05	–	Further consideration needed[(b)]
500050	Oats grain	0.1	0.05	–	Further consideration needed[(b)]
500060	Rice grain	1.5	0.05	–	Further consideration needed[(b)]
500070	Rye grain	0.1	0.05	–	Further consideration needed[(b)]
500080	Sorghum grain	0.05*	0.05	–	Further consideration needed[(b)]
500090	Wheat grain	0.1	0.05	–	Further consideration needed[(b)]
610000	Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0.05*	50	–	Further consideration needed[(b)]
620000	Coffee beans	1	1	1	Further consideration needed[(a)]
700000	Hops (dried), including hop pellets and unconcentrated powder	10	10	15	Further consideration needed[(a)]
900010	Sugar beet (root)	0.5	0.5	–	Further consideration needed[(b)]
1011010	Swine muscle	0.1	0.1	0.03*	Recommended[(c)]
1011020	Swine fat (free of lean meat)	0.05*	0.1	0.03*	Recommended[(c)]
1011030	Swine liver	0.3	0.3	0.03*	Recommended[(c)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1011040	Swine kidney	0.3	0.3	0.03*	Recommended[(c)]
1012010	Bovine muscle	0.1	0.1	0.03*	Recommended[(c)]
1012020	Bovine fat	0.05*	0.1	0.03*	Recommended[(c)]
1012030	Bovine liver	0.3	0.3	0.03*	Recommended[(c)]
1012040	Bovine kidney	0.3	0.3	0.03*	Recommended[(c)]
1013010	Sheep muscle	0.1	0.1	0.03*	Recommended[(c)]
1013020	Sheep fat	0.05*	0.1	0.03*	Recommended[(c)]
1013030	Sheep liver	0.3	0.3	0.03*	Recommended[(c)]
1013040	Sheep kidney	0.3	0.3	0.03*	Recommended[(c)]
1014010	Goat muscle	0.1	0.1	0.03*	Recommended[(c)]
1014020	Goat fat	0.05*	0.1	0.03*	Recommended[(c)]
1014030	Goat liver	0.3	0.3	0.03*	Recommended[(c)]
1014040	Goat kidney	0.3	0.3	0.03*	Recommended[(c)]
1015010	Horse muscle	0.1	0.1	0.03*	Recommended[(c)]
1015020	Horse fat	0.05*	0.1	0.03*	Recommended[(c)]
1015030	Horse liver	0.3	0.3	0.03*	Recommended[(c)]
1015040	Horse kidney	0.3	0.3	0.03*	Recommended[(c)]
1016010	Poultry muscle	0.05*	0.02	0.03*	Recommended[(c)]
1016020	Poultry fat	0.05*	0.02	0.03*	Recommended[(c)]
1016030	Poultry liver	0.05*	0.05	0.03*	Recommended[(c)]
1016040	Poultry kidney	0.05*	0.05	0.03*	Recommended[(c)]
1020010	Cattle milk	0.1	0.1	0.01*	Recommended[(c)]
1020020	Sheep milk	0.1	0.1	0.01*	Recommended[(c)]
1020030	Goat milk	0.1	0.1	0.01*	Recommended[(c)]
1020040	Horse milk	0.1	0.1	0.01*	Recommended[(c)]
1030000	Birds' eggs	0.05*	0.02	0.03*	Recommended[(c)]
–	Other commodities of plant and animal origin	Regulation (EU) No 491/2014	–	–	Further consideration needed[(i)]

MRL: maximum residue level; GAP: Good Agricultural Practice; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): 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 (assuming the existing residue definition); CXL is not compatible with EU residue definitions (combination E-II in Appendix E).
(b): There are no relevant INDOOR authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix E).
(c): 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 not compatible with EU residue definitions (combination G-II in Appendix E).
(d): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); CXL is not compatible with EU residue definitions (combination C-II in Appendix E).
(e): 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 (assuming the existing residue definition); no CXL is available (combination E-I 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; no CXL is available (combination G-I in Appendix E).
(g): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(h): GAP evaluated at EU level is not supported by data and a risk to consumers cannot be excluded for the existing EU MRL; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-I in Appendix E).
(i): There are no relevant INDOOR 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(Indoor EU.1 and IT)

Imidacloprid			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.06**	ARfD (mg/kg bw):	**0.08**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	1 6
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
5.7	WHO Cluster diet B	1.7	Gooseberries	1.2	Lettuce	0.7	Tomatoes	
4.4	NL child	1.1	Currants (red, black and white)	0.5	Milk and cream	0.4	Beans (with pods)	
3.5	DE child	0.7	Currants (red, black and white)	0.5	Oranges	0.4	Cucumbers	
3.0	IE adult	1.0	Currants (red, black and white)	0.3	Lettuce	0.2	Wine grapes	
3.0	UK Toddler	1.1	Currants (red, black and white)	0.6	Beans	0.3	Milk and cream	
3.0	WHO regional European diet	1.3	Lettuce	0.2	Tomatoes	0.2	Peas (with pods)	
2.9	ES adult	1.8	Lettuce	0.2	Beans (with pods)	0.2	Tomatoes	
2.9	FR toddler	1.0	Beans (with pods)	0.7	Milk and cream	0.3	Courgettes	
2.9	ES child	1.4	Lettuce	0.3	Oranges	0.2	Tomatoes	
2.7	WHO cluster diet E	0.4	Currants (red, black and white)	0.3	Wine grapes	0.3	Lettuce	
2.5	WHO Cluster diet F	1.0	Lettuce	0.3	Currants (red, black and white)	0.2	Tomatoes	
2.4	UK Infant	0.6	Milk and cream	0.6	Currants (red, black and white)	0.4	Beans	
2.2	NL general	0.4	Lettuce	0.2	Beans (with pods)	0.2	Currants (red, black and white)	
2.1	DK child	1.1	Cucumbers	0.5	Lettuce	0.2	Milk and cream	
2.1	IT adult	1.3	Lettuce	0.3	Tomatoes	0.1	Beans (with pods)	
2.0	FR infant	0.7	Beans (with pods)	0.4	Milk and cream	0.4	Courgettes	
1.8	IT kids/toddler	1.0	Lettuce	0.3	Tomatoes	0.1	Courgettes	
1.8	FR all population	0.8	Wine grapes	0.3	Lettuce	0.1	Beans (with pods)	
1.8	UK vegetarian	0.5	Lettuce	0.3	Beans	0.2	Wine grapes	
1.7	FI adult	0.6	Currants (red, black and white)	0.3	Lettuce	0.2	Cucumbers	
1.7	SE general population 90th percentile	0.2	Cucumbers	0.2	Milk and cream	0.2	Tomatoes	
1.5	WHO cluster diet D	0.3	Currants (red, black and white)	0.2	Tomatoes	0.1	Cucumbers	
1.4	UK Adult	0.4	Lettuce	0.2	Wine grapes	0.2	Beans	
1.3	PT General population	0.5	Wine grapes	0.2	Tomatoes	0.1	Beans	
1.0	LT adult	0.3	Cucumbers	0.2	Lettuce	0.2	Currants (red, black and white)	
0.8	DK adult	0.3	Wine grapes	0.2	Cucumbers	0.1	Tomatoes	
0.8	PL general population	0.4	Gooseberries	0.2	Tomatoes	0.1	Table grapes	

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

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

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

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

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

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		1	No of commodities for which ARfD/ADI is exceeded (IESTI 2):		1	No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	No of commodities for which ARfD/ADI is exceeded (IESTI 2):		---
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
109.3	Scarole (broad-leaf	1/0.91	109.3	Scarole (broad-leaf	1/0.91	34.0	Courgettes	1.008/-	25.6	Courgettes	1.008/-
75.7	Cucumbers	1.035/-	75.7	Cucumbers	1.035/-	27.5	Lettuce	2/-	25.5	Cucumbers	1.035/-
67.3	Lettuce	2/-	58.0	Currants (red,	5/-	25.5	Cucumbers	1.035/-	24.2	Table grapes	0.61/-
58.6	Courgettes	1.008/-	49.9	Table grapes	0.61/-	24.2	Table grapes	0.61/-	20.7	Beans (with pods)	3.13/-
58.0	Currants (red, black	5/-	44.4	Beans (with pods)	3.13/-	20.7	Beans (with pods)	3.13/-	18.1	Wine grapes	0.61/-
No of critical MRLs (IESTI 1)		1				**No of critical MRLs (IESTI 2)**		1			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		1				No of commodities for which ARfD/ADI is exceeded:		---			
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
100.1	Elderberry juice	5/4.99				2.9	Wine	0.61/-			
63.2	Cuurant juice	5/-				2.2	Orange juice	0.1736/-			
25.1	Grape juice	0.61/-				0.8	Tomato (preserved-	0.32/-			
23.2	Blueberries	2.56/-				0.3	Raisins	0.61/-			
10.7	Orange juice	0.1736/-									

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

**) pTMRL: provisional temporary MRL.

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

Conclusion:

For Imidacloprid, 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 (IESTI 1) exceeded the ARfD/ADI for 1 commodities.

Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.

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

- PRIMo(Indoor EU.2 and IT)

Imidacloprid			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.06**	ARfD (mg/kg bw):	**0.08**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	1 6
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
5.7	WHO Cluster diet B	1.7	Gooseberries	1.2	Lettuce	0.7	Tomatoes	
4.4	NL child	1.1	Currants (red, black and white)	0.5	Milk and cream,	0.4	Beans (with pods)	
3.5	DE child	0.7	Currants (red, black and white)	0.5	Oranges	0.4	Cucumbers	
3.0	IE adult	1.0	Currants (red, black and white)	0.3	Lettuce	0.2	Wine grapes	
3.0	UK Toddler	1.1	Currants (red, black and white)	0.6	Beans	0.3	Milk and cream	
3.0	WHO regional European diet	1.3	Lettuce	0.2	Tomatoes	0.2	Peas (with pods)	
2.9	ES adult	1.8	Lettuce	0.2	Beans (with pods)	0.2	Tomatoes	
2.9	FR toddler	1.0	Beans (with pods)	0.7	Milk and cream	0.3	Courgettes	
2.9	ES child	1.4	Lettuce	0.3	Oranges	0.2	Tomatoes	
2.7	WHO cluster diet E	0.4	Currants (red, black and white)	0.3	Wine grapes	0.3	Lettuce	
2.5	WHO Cluster diet F	1.0	Lettuce	0.3	Currants (red, black and white)	0.2	Tomatoes	
2.4	UK Infant	0.6	Milk and cream	0.6	Currants (red, black and white)	0.4	Beans	
2.2	NL general	0.4	Lettuce	0.2	Beans (with pods)	0.2	Currants (red, black and white)	
2.1	DK child	1.1	Cucumbers	0.5	Lettuce	0.2	Milk and cream	
2.1	IT adult	1.3	Lettuce	0.3	Tomatoes	0.1	Beans (with pods)	
2.0	FR infant	0.7	Beans (with pods)	0.4	Milk and cream	0.4	Courgettes	
1.8	IT kids/toddler	1.0	Lettuce	0.3	Tomatoes	0.1	Courgettes	
1.8	FR all population	0.8	Wine grapes	0.3	Lettuce	0.1	Beans (with pods)	
1.8	UK vegetarian	0.5	Lettuce	0.3	Beans	0.2	Wine grapes	
1.7	FI adult	0.6	Currants (red, black and white)	0.3	Lettuce	0.2	Cucumbers	
1.7	SE general population 90th percentile	0.2	Cucumbers	0.2	Milk and cream	0.2	Tomatoes	
1.5	WHO cluster diet D	0.3	Currants (red, black and white)	0.2	Tomatoes	0.1	Cucumbers	
1.4	UK Adult	0.4	Lettuce	0.2	Wine grapes	0.2	Beans	
1.3	PT General population	0.5	Wine grapes	0.2	Tomatoes	0.1	Beans	
1.0	LT adult	0.3	Cucumbers	0.2	Lettuce	0.2	Currants (red, black and white)	
0.8	DK adult	0.3	Wine grapes	0.2	Cucumbers	0.1	Tomatoes	
0.8	PL general population	0.4	Gooseberries	0.2	Tomatoes	0.1	Table grapes	

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

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.
For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
75.7	Cucumbers	1.035/-	75.7	Cucumbers	1.035/-	34.0	Courgettes	1.008/-	25.6	Courgettes	1.008/-
67.3	Lettuce	2/-	58.0	Currants (red,	5/-	27.5	Lettuce	2/-	25.5	Cucumbers	1.035/-
58.6	Courgettes	1.008/-	49.9	Table grapes	0.61/-	25.5	Cucumbers	1.035/-	24.2	Table grapes	0.61/-
58.0	Currants (red, black	5/-	44.4	Beans (with pods)	3.13/-	24.2	Table grapes	0.61/-	20.7	Beans (with pods)	3.13/-
49.9	Table grapes	0.61/-	41.8	Courgettes	1.008/-	20.7	Beans (with pods)	3.13/-	18.1	Wine grapes	0.61/-
No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			

Processed commodities

No of commodities for which ARfD/ADI is exceeded: 1						No of commodities for which ARfD/ADI is exceeded: ---					
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
100.1	Elderberry juice	5/4.99				2.9	Wine	0.61/-			
63.2	Cuurant juice	5/-				2.2	Orange juice	0.1736/-			
25.1	Grape juice	0.61/-				0.8	Tomato (preserved-	0.32/-			
23.2	Blueberries	2.56/-				0.3	Raisins	0.61/-			
10.7	Orange juice	0.1736/-									

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL.
***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
For Imidacloprid, 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, the ARfD/ADI was exceeded in one or several cases.

- PRIMo(EU.1, All uses)

Imidacloprid			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.06**	ARfD (mg/kg bw):	**0.08**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
1	7
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
7.1	WHO Cluster diet B	1.7	Gooseberries	1.0	Tomatoes	0.9	Olives for oil production	
4.9	DE child	1.0	Apples	0.7	Currants (red, black and white)	0.5	Oranges	
4.8	NL child	1.1	Currants (red, black and white)	0.5	Apples	0.4	Beans (with pods)	
4.1	IE adult	1.0	Currants (red, black and white)	0.3	Avocados	0.3	Wine grapes	
3.5	UK Toddler	1.1	Currants (red, black and white)	0.6	Beans	0.4	Sugar beet (root)	
3.2	WHO cluster diet E	0.4	Currants (red, black and white)	0.3	Wine grapes	0.2	Beans (with pods)	
3.0	FR toddler	1.0	Beans (with pods)	0.3	Potatoes	0.3	Courgettes	
2.8	WHO regional European diet	0.4	Lettuce	0.4	Tomatoes	0.3	Potatoes	
2.5	ES child	0.5	Lettuce	0.3	Olives for oil production	0.3	Tomatoes	
2.4	UK Infant	0.6	Currants (red, black and white)	0.4	Beans	0.2	Peas (without pods)	
2.3	SE general population 90th percentile	0.3	Potatoes	0.3	Tomatoes	0.2	Cucumbers	
2.3	WHO cluster diet D	0.3	Tomatoes	0.3	Currants (red, black and white)	0.3	Potatoes	
2.3	DK child	1.1	Cucumbers	0.2	Apples	0.2	Tomatoes	
2.3	WHO Cluster diet F	0.3	Lettuce	0.3	Currants (red, black and white)	0.2	Tomatoes	
2.2	NL general	0.2	Beans (with pods)	0.2	Currants (red, black and white)	0.2	Oranges	
2.2	PT General population	0.5	Wine grapes	0.3	Potatoes	0.3	Tomatoes	
2.2	ES adult	0.6	Lettuce	0.3	Tomatoes	0.2	Beans (with pods)	
2.1	FR infant	0.7	Beans (with pods)	0.4	Courgettes	0.3	Potatoes	
2.0	FR all population	0.8	Wine grapes	0.1	Tomatoes	0.1	Beans (with pods)	
1.9	UK vegetarian	0.3	Beans	0.2	Tomatoes	0.2	Wine grapes	
1.8	IT kids/toddler	0.5	Tomatoes	0.3	Lettuce	0.1	Wheat	
1.8	IT adult	0.4	Lettuce	0.4	Tomatoes	0.1	Beans (with pods)	
1.7	FI adult	0.6	Currants (red, black and white)	0.2	Cucumbers	0.1	Tomatoes	
1.5	UK Adult	0.2	Wine grapes	0.2	Beans	0.1	Tomatoes	
1.5	PL general population	0.4	Gooseberries	0.3	Tomatoes	0.2	Potatoes	
1.2	LT adult	0.3	Cucumbers	0.2	Tomatoes	0.2	Potatoes	
1.1	DK adult	0.3	Wine grapes	0.2	Cucumbers	0.1	Tomatoes	

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

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

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

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

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

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): 3			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 2			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
269.9	Scarole (broad-leaf	2.47/0.91	269.9	Scarole (broad-leaf	2.47/0.91	60.1	Peppers	2.94/-	56.9	Chinese cabbage	1.275/-
231.4	Peppers	2.94/1.27	165.3	Peppers	2.94/1.77	56.9	Chinese cabbage	1.275/-	42.9	Peppers	2.94/-
107.7	Kale	1.275/1.18	77.0	Kale	1.275/-	34.0	Courgettes	1.008/-	27.4	Scarole (broad-leaf endive)	2.47/-
75.7	Cucumbers	1.035/-	75.7	Cucumbers	1.035/-	32.5	Kale	1.275/-	25.6	Courgettes	1.008/-
59.2	Chinese cabbage	1.275/-	59.2	Chinese cabbage	1.275/-	28.0	Avocados	1/-	25.5	Cucumbers	1.035/-
No of critical MRLs (IESTI 1) 3						**No of critical MRLs (IESTI 2)** 2					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: 1						No of commodities for which ARfD/ADI is exceeded: ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
100.1	Elderberry juice	5 / 4.99				2.9	Wine	0.61/-			
63.2	Cuurant juice	5/-				2.2	Orange juice	0.1736/-			
25.1	Grape juice	0.61/-				1.2	Apple juice	0.15/-			
23.2	Blueberries	2.56/-				1.1	Tomato (preserved-fresh)	0.48/-			
10.7	Orange juice	0.1736/-				0.5	Peach preserved with syrup	0.18/-			

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

**) pTMRL: provisional temporary MRL.

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

Conclusion:

For Imidacloprid 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 (IESTI 1) exceeded the ARfD/ADI for 3 commodities.

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

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

- PRIMo(EU.2, All uses)

Imidacloprid			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.06**	ARfD (mg/kg bw):	**0.08**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
1	7
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
6.9	WHO Cluster diet B	1.7	Gooseberries	1.0	Tomatoes	0.9	Olives for oil production	
4.8	DE child	1.0	Apples	0.7	Currants (red, black and white)	0.5	Oranges	
4.5	NL child	1.1	Currants (red, black and white)	0.5	Apples	0.4	Beans (with pods)	
4.0	IE adult	1.0	Currants (red, black and white)	0.3	Avocados	0.3	Wine grapes	
3.5	UK Toddler	1.1	Currants (red, black and white)	0.6	Beans	0.4	Sugar beet (root)	
3.1	WHO cluster diet E	0.4	Currants (red, black and white)	0.3	Wine grapes	0.2	Beans (with pods)	
2.9	FR toddler	1.0	Beans (with pods)	0.3	Potatoes	0.3	Courgettes	
2.7	WHO regional European diet	0.4	Lettuce	0.4	Tomatoes	0.3	Potatoes	
2.5	ES child	0.5	Lettuce	0.3	Olives for oil production	0.3	Tomatoes	
2.4	UK Infant	0.6	Currants (red, black and white)	0.4	Beans	0.2	Peas (without pods)	
2.3	SE general population 90th percentile	0.3	Potatoes	0.3	Tomatoes	0.2	Cucumbers	
2.3	DK child	1.1	Cucumbers	0.2	Apples	0.2	Tomatoes	
2.3	WHO Cluster diet F	0.3	Lettuce	0.3	Currants (red, black and white)	0.2	Tomatoes	
2.2	WHO cluster diet D	0.3	Tomatoes	0.3	Currants (red, black and white)	0.3	Potatoes	
2.2	PT General population	0.5	Wine grapes	0.3	Potatoes	0.3	Tomatoes	
2.2	ES adult	0.6	Lettuce	0.3	Tomatoes	0.2	Beans (with pods)	
2.1	FR infant	0.7	Beans (with pods)	0.4	Courgettes	0.3	Potatoes	
2.1	NL general	0.2	Beans (with pods)	0.2	Currants (red, black and white)	0.2	Oranges	
1.9	FR all population	0.8	Wine grapes	0.1	Tomatoes	0.1	Beans (with pods)	
1.8	UK vegetarian	0.3	Beans	0.2	Tomatoes	0.2	Wine grapes	
1.8	IT kids/toddler	0.5	Tomatoes	0.3	Lettuce	0.1	Wheat	
1.7	IT adult	0.4	Lettuce	0.4	Tomatoes	0.1	Beans (with pods)	
1.7	FI adult	0.6	Currants (red, black and white)	0.2	Cucumbers	0.1	Tomatoes	
1.5	UK Adult	0.2	Wine grapes	0.2	Beans	0.1	Tomatoes	
1.5	PL general population	0.4	Gooseberries	0.3	Tomatoes	0.2	Potatoes	
1.2	LT adult	0.3	Cucumbers	0.2	Tomatoes	0.2	Potatoes	
1.1	DK adult	0.3	Wine grapes	0.2	Cucumbers	0.1	Tomatoes	

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

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
75.7	Cucumbers	1.035/-	75.7	Cucumbers	1.035/-	56.9	Chinese cabbage	1.275/-	56.9	Chinese cabbage	1.275/-
59.2	Chinese cabbage	1.275/-	59.2	Chinese cabbage	1.275/-	34.0	Courgettes	1.008/-	25.6	Courgettes	1.008/-
58.6	Courgettes	1.008/-	58.0	Currants (red,	5/-	28.0	Avocados	1/-	25.5	Cucumbers	1.035/-
58.0	Currants (red, black	5/-	49.9	Table grapes	0.61/-	25.5	Cucumbers	1.035/-	24.2	Table grapes	0.61/-
49.9	Lettuce	1.485/-	44.4	Beans (with pods)	3.13/-	24.2	Table grapes	0.61/-	20.7	Beans (with pods)	3.13/-
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: 1						**No of commodities for which ARfD/ADI is exceeded:** ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
100.1	Elderberry juice	5/4.99				2.9	Wine	0.61/-			
63.2	Cuurant juice	5/-				2.2	Orange juice	0.1736/-			
25.1	Grape juice	0.61/-				1.2	Apple juice	0.15/-			
23.2	Blueberries	2.56/-				1.1	Tomato (preserved-fresh)	0.48/-			
10.7	Orange juice	0.1736/-				0.5	Peach preserved with syrup	0.18/-			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL.
***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
For Imidacloprid, 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, the ARfD/ADI was exceeded in one or several cases.

- PRIMo(CXL)

Imidacloprid			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.06**	ARfD (mg/kg bw):	**0.08**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
2	8
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
8.2	WHO Cluster diet B	1.1	Olives for oil production	0.7	Wheat	0.5	Lettuce	
7.2	IE adult	1.4	Tea (dried leaves and stalks)	0.4	Pears	0.4	Herbs	
6.6	NL child	0.9	Milk and cream,	0.7	Apples	0.5	Potatoes	
6.5	DE child	1.4	Apples	0.5	Oranges	0.4	Milk and cream	
6.0	UK Toddler	1.9	Sugar beet (root)	0.6	Beans	0.6	Milk and cream	
5.5	UK Infant	1.2	Milk and cream	0.8	Sugar beet (root)	0.6	Tea (dried leaves and stalks)	
4.9	FR toddler	1.2	Milk and cream	0.7	Beans (with pods)	0.4	Potatoes	
4.8	WHO cluster diet E	0.4	Herbs	0.4	Soya bean	0.4	Tea (dried leaves and stalks)	
4.3	WHO regional European diet	0.6	Lettuce	0.4	Tea (dried leaves and stalks)	0.3	Potatoes	
4.1	ES child	0.6	Lettuce	0.4	Olives for oil production	0.4	Milk and cream,	
4.1	WHO cluster diet D	0.6	Herbs	0.5	Wheat	0.4	Tea (dried leaves and stalks)	
3.8	DK child	0.8	Cucumbers	0.5	Wheat	0.4	Pears	
3.6	FR infant	0.8	Milk and cream	0.6	Beans (with pods)	0.3	Courgettes	
3.4	WHO Cluster diet F	0.5	Lettuce	0.4	Soya bean	0.3	Wheat	
3.4	PT General population	0.5	Wine grapes	0.4	Potatoes	0.3	Wheat	
3.2	SE general population 90th percentile	0.4	Milk and cream	0.3	Potatoes	0.3	Wheat	
3.1	ES adult	0.8	Lettuce	0.2	Olives for oil production	0.2	Pears	
2.9	UK vegetarian	0.5	Tea (dried leaves and stalks,	0.3	Sugar beet (root)	0.3	Beans	
2.9	IT kids/toddler	0.6	Wheat	0.4	Lettuce	0.2	Pears	
2.9	NL general	0.2	Potatoes	0.2	Kale	0.2	Milk and cream	
2.6	IT adult	0.6	Lettuce	0.3	Wheat	0.2	Peaches	
2.5	UK Adult	0.6	Tea (dried leaves and stalks,	0.3	Sugar beet (root)	0.2	Wine grapes	
2.4	FR all population	0.7	Wine grapes	0.3	Wheat	0.1	Lettuce	
1.7	DK adult	0.3	Wine grapes	0.2	Wheat	0.2	Milk and cream	
1.7	FI adult	0.2	Milk and cream	0.2	Tea (dried leaves and stalks)	0.1	Cucumbers	
1.6	LT adult	0.3	Potatoes	0.2	Apples	0.2	Cucumbers	
1.6	PL general population	0.3	Potatoes	0.2	Apples	0.2	Pears	

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

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

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

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

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

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		**2**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**2**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**---**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**---**
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
183.6	Celery	3.2/1.74	183.6	Celery	3.2/1.74	92.2	Celery	3.2/-	68.1	Celery	3.2/-
169.0	Kale	2/1.18	120.8	Kale	2/1.65	51.0	Kale	2/-	37.9	Kale	2/-
80.8	Pears	0.71/-	58.1	Pears	0.71/-	24.2	Table grapes	0.61/-	24.2	Table grapes	0.61/-
57.5	Tea	50/-	57.5	Tea	50/-	19.2	Tea	50/-	19.2	Tea	50/-
57.1	Peaches	0.77/-	49.9	Table grapes	0.61/-	19.1	Pears	0.71/-	18.1	Wine grapes	0.61/-
No of critical MRLs (IESTI 1)		2				**No of critical MRLs (IESTI 2)**		2			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		**---**				**No of commodities for which ARfD/ADI is exceeded:**		**---**			
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
56.1	Elderberry juice	2.8/-				3.1	Orange juice	0.2464/-			
42.0	Raspberries juice	2.8/-				2.9	Wine	0.61/-			
35.4	Cuurant juice	2.8/-				1.9	Peach preserved with	0.77/-			
25.4	Blueberries	2.8/-				1.9	Apple juice	0.23/-			
25.1	Grape juice	0.61/-				0.7	Tomato (preserved-fresh)	0.29/-			

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

**) pTMRL: provisional temporary MRL.

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

Conclusion:

For Imidacloprid 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 (IESTI 1) exceeded the ARfD/ADI for 2 commodities.

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

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	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid				
Reflecting the new conditions of approval				
Citrus fruits, dried pulp	2.80	$STMR_{Mo} \times CF \times PF^{(a)}$ (tentative)	2.80	$STMR_{Mo} \times CF \times PF^{(a)}$ (tentative)
Bean, seed (dry)	0.49	$STMR_{Mo} \times CF$ (tentative)	0.49	$STMR_{Mo} \times CF$ (tentative)
Cowpea, seed	0.49	$STMR_{Mo} \times CF$ (tentative)	0.49	$STMR_{Mo} \times CF$ (tentative)
Peanut, meal	0.30	$STMR_{Mo} \times CF \times PF$ (tentative)	0.30	$STMR_{Mo} \times CF \times PF$ (tentative)
Covering the possible carry-over due to (former) authorised EU outdoor uses				
Barley, oat, rye, triticale and wheat grain	0.01*	$STMR_{Mo} \times CF$	0.01*	$STMR_{Mo} \times CF$
Brewer's grain, dried	0.01*	$STMR_{Mo}^{(b)} \times CF$	0.01*	$STMR_{Mo}^{(b)} \times CF$
Wheat, distiller's grain (dry)	0.01*	$STMR_{Mo}^{(b)} \times CF$	0.01*	$STMR_{Mo}^{(b)} \times CF$
Wheat gluten, meal	0.01*	$STMR_{Mo}^{(b)} \times CF$	0.01*	$STMR_{Mo}^{(b)} \times CF$
Wheat, milled by-products	0.01*	$STMR_{Mo}^{(b)} \times CF$	0.01*	$STMR_{Mo}^{(b)} \times CF$
Barley, oat, rye, triticale and wheat, straw	0.11	$STMR_{Mo} \times CF$	0.22	$HR_{Mo} \times CF$

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement residue definition to risk assessment residue definition; Mo: monitoring.
*: Indicates that the input value is proposed at the limit of quantification.
(a): For dried pulp of citrus fruits, in the absence of processing factors supported by data, a default processing factor of 10 was included in the calculation to consider the potential concentration of residues in this commodity.
(b): For processed commodities from cereals, no default processing factor was applied because imidacloprid residues in the raw commodities are below the LOQ and concentration of residues in these commodities is not expected.

D.2. Consumer risk assessment without consideration of the existing CXLs – Indoor uses and Import tolerances

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid				
Commodities for which a risk for consumers was identified are reported in bold				
Citrus fruits	0.08	$STMR_{Mo} \times PF \times CF_P$ (tentative)	0.17	$HR_{Mo} \times PF \times CF_P$ (tentative)
Pecans	0.02*	$STMR_{Mo} \times CF$	0.02*	$HR_{Mo} \times CF$
Table grapes	0.12	$STMR_{Mo} \times CF$ (tentative)	0.61	$HR_{Mo} \times CF$ (tentative)
Wine grapes	0.12	$STMR_{Mo} \times CF$ (tentative)	0.61	$HR_{Mo} \times CF$ (tentative)
Blueberries	0.86	$STMR_{Mo} \times CF$ (tentative)	2.56	$HR_{Mo} \times CF$ (tentative)
Cranberries	0.86	$STMR_{Mo} \times CF$ (tentative)	2.56	$HR_{Mo} \times CF$ (tentative)
Currants (black, red and white)	5	EU MRL	5	EU MRL
Gooseberries (green, red and yellow)	5	EU MRL	5	EU MRL
Rose hips	5	EU MRL	5	EU MRL

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Mulberries (black and white)	5	EU MRL	5	EU MRL
Azaroles/Mediterranean medlars	0.05	EU MRL	0.05	EU MRL
Elderberries	5	EU MRL	5	EU MRL
Bananas	0.01*	$STMR_{Mo} \times CF$	0.01*	$HR_{Mo} \times CF$
Granate apples/pomegranates	1	EU MRL	1	EU MRL
Tomatoes	0.14	$STMR_{Mo} \times CF$	0.32	$HR_{Mo} \times CF$
Sweet peppers/bell peppers	0.20	$STMR_{Mo} \times CF$	0.62	$HR_{Mo} \times CF$
Aubergines/eggplants	0.14	$STMR_{Mo} \times CF$	0.32	$HR_{Mo} \times CF$
Okra/lady's fingers	0.10	$STMR_{Mo} \times CF$ (tentative)	0.41	$HR_{Mo} \times CF$ (tentative)
Cucumbers	0.41	$STMR_{Mo} \times CF$	1.04	$HR_{Mo} \times CF$
Gherkins Courgettes	0.36	$STMR_{Mo} \times CF$	1.01	$HR_{Mo} \times CF$
Cucurbits with inedible peel	0.01	$STMR_{Mo} \times PF \times CF$ (tentative)	0.04	$STMR_{Mo} \times PF \times CF$ (tentative)
Lamb's lettuces/corn salads	2	EU MRL	2	EU MRL
Lettuces	2	EU MRL	2	EU MRL
Escaroles/broad-leaved endives	1	EU MRL	1	EU MRL
Cresses and other sprouts and shoots	2	EU MRL	2	EU MRL
Land cresses	2	EU MRL	2	EU MRL
Red mustards	2	EU MRL	2	EU MRL
Baby leaf crops (including brassica species)	2	EU MRL	2	EU MRL
Beans (with pods)	0.53	$STMR_{Mo} \times CF$ (tentative)	3.13	$HR_{Mo} \times CF$ (tentative)
Beans (without pods)	0.26	$STMR_{Mo} \times CF$ (tentative)	0.99	$HR_{Mo} \times CF$ (tentative)
Peas (with pods)	0.53	$STMR_{Mo} \times CF$ (tentative)	3.13	$HR_{Mo} \times CF$ (tentative)
Peas (without pods)	0.26	$STMR_{Mo} \times CF$ (tentative)	0.99	$HR_{Mo} \times CF$ (tentative)
Beans (dry)	0.49	$STMR_{Mo} \times CF$ (tentative)	0.99	$HR_{Mo} \times CF$ (tentative)
Peanuts/groundnuts	0.11	$STMR_{Mo} \times CF$ (tentative)	0.36	$HR_{Mo} \times CF$ (tentative)
Coffee beans	0.29	$STMR_{Mo} \times CF$ (tentative)	0.47	$HR_{Mo} \times CF$ (tentative)
Hops	4.58	$STMR_{Mo} \times CF$ (tentative)	4.76	$HR_{Mo} \times CF$ (tentative)
Swine meat	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Swine fat	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Swine liver	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Swine kidney	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Swine muscle	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Ruminant meat	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Ruminant fat	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Ruminant liver	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Ruminant kidney	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Poultry meat	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Poultry fat	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Poultry liver	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$
Ruminant milk	0.01*	$STMR_{Mo} \times CF$	0.01*	$HR_{Mo} \times CF$
Bird's eggs	0.03*	$STMR_{Mo} \times CF$	0.03*	$HR_{Mo} \times CF$

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement residue definition to risk assessment residue definition; Mo: monitoring; MRL: maximum residue level.
*: Indicates that the input value is proposed at the limit of quantification.

D.3. Consumer risk assessment without consideration of the existing CXLs – All uses

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid				
Commodities for which a risk for consumers was identified are reported in bold				
Citrus fruits	0.08	$STMR_{Mo} \times PF \times CF_p$ (tentative)	0.17	$HR_{Mo} \times PF \times CF_p$ (tentative)
Almonds	0.02*	$STMR_{Mo} \times CF$	0.02*	$HR_{Mo} \times CF$
Pecans	0.02*	$STMR_{Mo} \times CF$	0.02*	$HR_{Mo} \times CF$
Apples	0.05	$STMR_{Mo} \times CF$	0.15	$HR_{Mo} \times CF$
Pears	0.05	$STMR_{Mo} \times CF$	0.20	$HR_{Mo} \times CF$
Quinces	0.05	$STMR_{Mo} \times CF$	0.10	$HR_{Mo} \times CF$
Apricots	0.12	$STMR_{Mo} \times CF$ (tentative)	0.18	$HR_{Mo} \times CF$ (tentative)
Cherries (sweet)	0.19	$STMR_{Mo} \times CF$	0.26	$HR_{Mo} \times CF$
Peaches	0.12	$STMR_{Mo} \times CF$	0.18	$HR_{Mo} \times CF$
Plums	0.04	$STMR_{Mo} \times CF$ (tentative)	0.12	$HR_{Mo} \times CF$ (tentative)
Table grapes	0.12	$STMR_{Mo} \times CF$ (tentative)	0.61	$HR_{Mo} \times CF$ (tentative)
Wine grapes	0.12	$STMR_{Mo} \times CF$ (tentative)	0.61	$HR_{Mo} \times CF$ (tentative)
Blueberries	0.86	$STMR_{Mo} \times CF$ (tentative)	2.56	$HR_{Mo} \times CF$ (tentative)
Cranberries	0.86	$STMR_{Mo} \times CF$ (tentative)	2.56	$HR_{Mo} \times CF$ (tentative)
Currants (black, red and white)	5	EU MRL	5	EU MRL
Gooseberries (green, red and yellow)	5	EU MRL	5	EU MRL
Rose hips	5	EU MRL	5	EU MRL
Mulberries (black and white)	5	EU MRL	5	EU MRL
Azaroles/Mediterranean medlars	0.05	EU MRL	0.05	EU MRL
Elderberries	5	EU MRL	5	EU MRL
Table olives	0.45	$STMR_{Mo} \times CF$	0.92	$HR_{Mo} \times CF$
Avocados	1	EU MRL	1	EU MRL
Bananas	0.01*	$STMR_{Mo} \times CF$	0.01*	$HR_{Mo} \times CF$
Mangoes	0.2	EU MRL	0.2	EU MRL
Granate apples/pomegranates	1	EU MRL	1	EU MRL
Potatoes	0.04	$STMR_{Mo} \times CF$ (tentative)	0.05	$HR_{Mo} \times CF$ (tentative)
Garlic Onions Shallots	0.02	$STMR_{Mo} \times CF$	0.06	$HR_{Mo} \times CF$
Spring onions/green onions and Welsh onions	0.02	$STMR_{Mo} \times CF$	0.06	$HR_{Mo} \times CF$
Tomatoes Aubergines/eggplants	0.20	$STMR_{Mo} \times CF$	0.48	$HR_{Mo} \times CF$
Sweet peppers/bell peppers	0.33	$STMR_{Mo} \times CF$ (tentative)	2.94	$HR_{Mo} \times CF$ (tentative)
	0.20	$STMR_{Mo} \times CF$ (fall-back)	0.62	$HR_{Mo} \times CF$ (fall-back)
Okra/lady's fingers	0.16	$STMR_{Mo} \times CF$ (tentative)	2.94	$HR_{Mo} \times CF$ (tentative)
Cucumbers	0.41	$STMR_{Mo} \times CF$	1.04	$HR_{Mo} \times CF$
Gherkins Courgettes	0.36	$STMR_{Mo} \times CF$	1.01	$HR_{Mo} \times CF$
Cucurbits with inedible peel	0.01	$STMR_{Mo} \times PF \times CF$ (tentative)	0.04	$HR_{Mo} \times PF \times CF$ (tentative)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Broccoli Cauliflowers	0.07	$STMR_{Mo}$ × CF	0.46	HR_{Mo} × CF
Brussels sprouts	0.04	$STMR_{Mo}$ × CF	0.09	HR_{Mo} × CF
Head cabbages	0.05	$STMR_{Mo}$ × CF	0.32	HR_{Mo} × CF
Chinese cabbages/pe-tsai	0.26	$STMR_{Mo}$ × CF	1.28	HR_{Mo} × CF
Kales	0.26	$STMR_{Mo}$ × CF	1.28	HR_{Mo} × CF
	0.01*	$STMR_{Mo}$ × CF (fall-back)	0.01*	$STMR_{Mo}$ × CF (fall-back)
Kohlrabies	0.3	EU MRL	0.3	EU MRL
Lamb's lettuces/corn salads Cresses and other sprouts and shoots Land cresses Roman rocket/rucola Red mustards Baby leaf crops (including brassica species)	0.60	$STMR_{Mo}$ × CF	2.47	HR_{Mo} × CF
Escaroles/broad-leaved endives	0.60	$STMR_{Mo}$ × CF	2.47	HR_{Mo} × CF
	0.04	$STMR_{Mo}$ × CF (fall-back)	0.08	$STMR_{Mo}$ × CF (fall-back)
Lettuces	0.68	$STMR_{Mo}$ × CF	1.49	HR_{Mo} × CF
Witloofs/Belgian endives	0.01*	$STMR_{Mo}$ × CF	0.01*	HR_{Mo} × CF
Fresh herbs	0.60	$STMR_{Mo}$ × CF	2.47	HR_{Mo} × CF
Beans (with pods) Peas (with pods)	0.53	$STMR_{Mo}$ × CF (tentative)	3.13	HR_{Mo} × CF (tentative)
Beans (without pods) Peas (without pods)	0.26	$STMR_{Mo}$ × CF (tentative)	0.99	HR_{Mo} × CF (tentative)
Cardoons	0.5	EU MRL	0.5	EU MRL
Globe artichokes	0.17	$STMR_{Mo}$ × CF	0.22	HR_{Mo} × CF
Leeks	0.01*	$STMR_{Mo}$ × CF	0.01*	HR_{Mo} × CF
Beans (dry)	0.49	$STMR_{Mo}$ × CF (tentative)	0.99	HR_{Mo} × CF (tentative)
Peas (dry)	0.33	$STMR_{Mo}$ × CF (tentative)	0.33	HR_{Mo} × CF (tentative)
Peanuts/groundnuts	0.11	$STMR_{Mo}$ × CF (tentative)	0.36	HR_{Mo} × CF (tentative)
Cotton seeds	1	EU MRL	1	EU MRL
Olives for oil production	0.28	$STMR_{Mo}$ × CF	0.92	HR_{Mo} × CF
Barley grains Oat grains Rye grains Wheat grains	0.01*	$STMR_{Mo}$ × CF	0.01*	HR_{Mo} × CF
Coffee beans	0.29	$STMR_{Mo}$ × CF (tentative)	0.47	HR_{Mo} × CF (tentative)
Hops	4.58	$STMR_{Mo}$ × CF (tentative)	4.76	HR_{Mo} × CF (tentative)
Sugar beet roots	0.01*	$STMR_{Mo}$ × CF	0.01*	HR_{Mo} × CF

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement residue definition to risk assessment residue definition; Mo: monitoring; MRL: maximum residue level.
*: Indicates that the input value is proposed at the limit of quantification.

D.4. Indicative consumer risk assessment of the existing CXLs

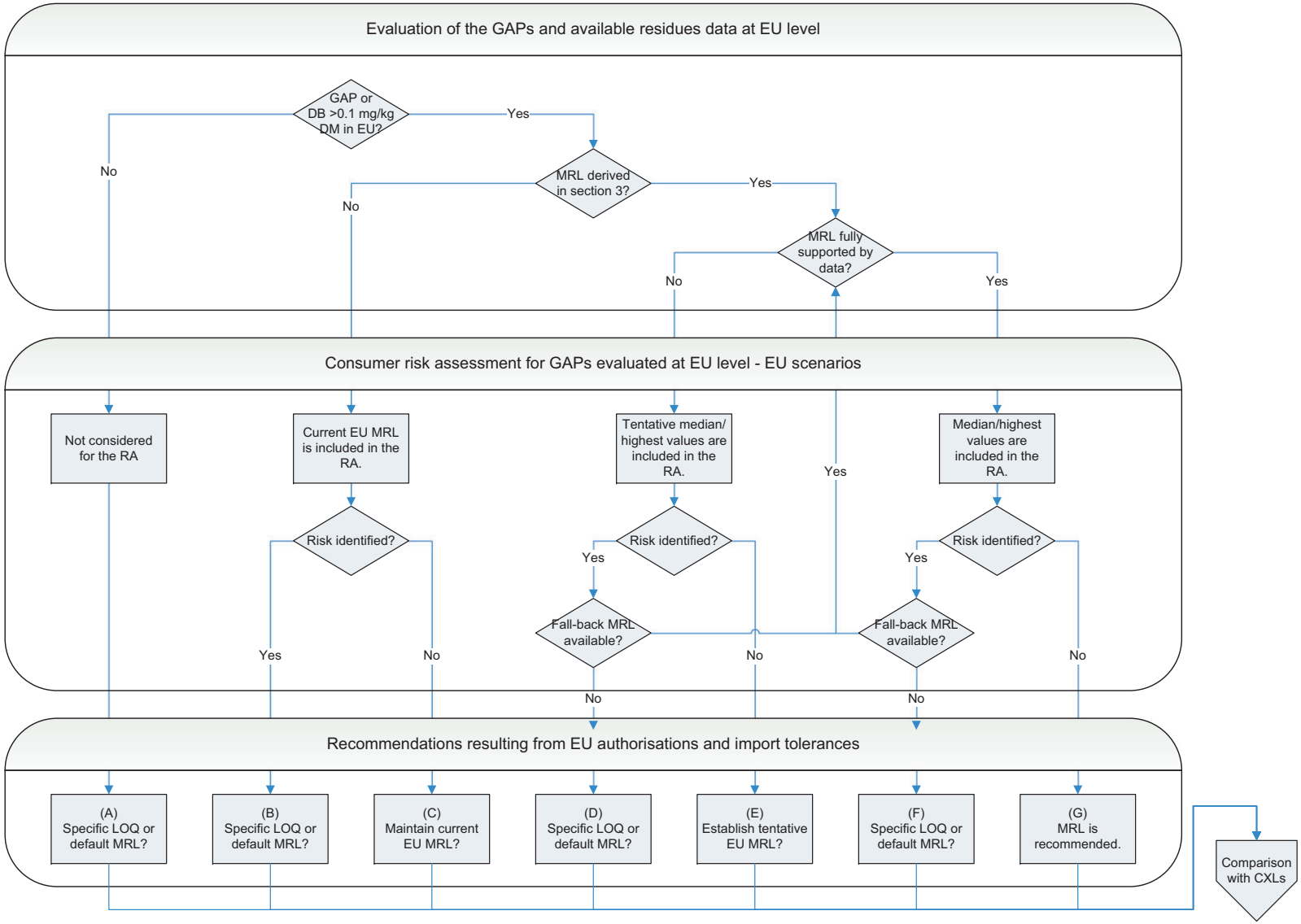
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid				
Commodities for which a risk for consumers was identified are reported in bold				
Citrus fruits	0.07	STMR × PF (CXL)	0.25	HR × PF (CXL)
Tree nuts	0.01	STMR (CXL)	0.01	HR (CXL)
Apples	0.07	STMR (CXL)	0.23	HR (CXL)
Pears	0.38	STMR (CXL)	0.71	HR (CXL)
Apricots	0.36	STMR (CXL)	0.77	HR (CXL)
Cherries	0.55	STMR (CXL)	2.50	HR (CXL)
Peaches	0.36	STMR (CXL)	0.77	HR (CXL)
Plums	0.28	STMR (CXL)	0.70	HR (CXL)
Table grapes	0.11	STMR (CXL)	0.61	HR (CXL)
Wine grapes	0.11	STMR (CXL)	0.61	HR (CXL)
Strawberries	0.17	STMR (CXL)	0.35	HR (CXL)
Blackberries	0.89	STMR (CXL)	2.80	HR (CXL)
Dewberries	0.89	STMR (CXL)	2.80	HR (CXL)
Raspberries	0.89	STMR (CXL)	2.80	HR (CXL)
Blueberries	0.89	STMR (CXL)	2.80	HR (CXL)
Cranberries	0.05*	STMR (CXL)	0.05*	HR (CXL)
Currants (red, black and white)	0.89	STMR (CXL)	2.80	HR (CXL)
Gooseberries	0.89	STMR (CXL)	2.80	HR (CXL)
Rose hips	0.89	STMR (CXL)	2.80	HR (CXL)
Mulberries	0.89	STMR (CXL)	2.80	HR (CXL)
Azarole (Mediterranean medlar)	0.89	STMR (CXL)	2.80	HR (CXL)
Elderberries	0.89	STMR (CXL)	2.80	HR (CXL)
Table olives	0.36	STMR (CXL)	1.10	HR (CXL)
Kumquats	0.26	STMR (CXL)	0.88	HR (CXL)
Bananas	0.01	STMR (CXL)	0.05	HR (CXL)
Mangoes	0.05	STMR (CXL)	0.15	HR (CXL)
Pomegranate	0.43	STMR (CXL)	0.55	HR (CXL)
Potatoes	0.05	STMR (CXL)	0.28	HR (CXL)
Cassava	0.05	STMR (CXL)	0.28	HR (CXL)
Sweet potatoes	0.05	STMR (CXL)	0.28	HR (CXL)
Yams	0.05	STMR (CXL)	0.28	HR (CXL)
Arrowroot	0.05	STMR (CXL)	0.28	HR (CXL)
Beetroot	0.05	STMR (CXL)	0.28	HR (CXL)
Carrots	0.05	STMR (CXL)	0.28	HR (CXL)
Celeriac	0.05	STMR (CXL)	0.28	HR (CXL)
Horseradish	0.05	STMR (CXL)	0.28	HR (CXL)
Jerusalem artichokes	0.05	STMR (CXL)	0.28	HR (CXL)
Parsnips	0.05	STMR (CXL)	0.28	HR (CXL)
Parsley root	0.05	STMR (CXL)	0.28	HR (CXL)
Radishes	0.05	STMR (CXL)	0.28	HR (CXL)
Salsify	0.05	STMR (CXL)	0.28	HR (CXL)
Swedes	0.05	STMR (CXL)	0.28	HR (CXL)
Turnips	0.05	STMR (CXL)	0.28	HR (CXL)

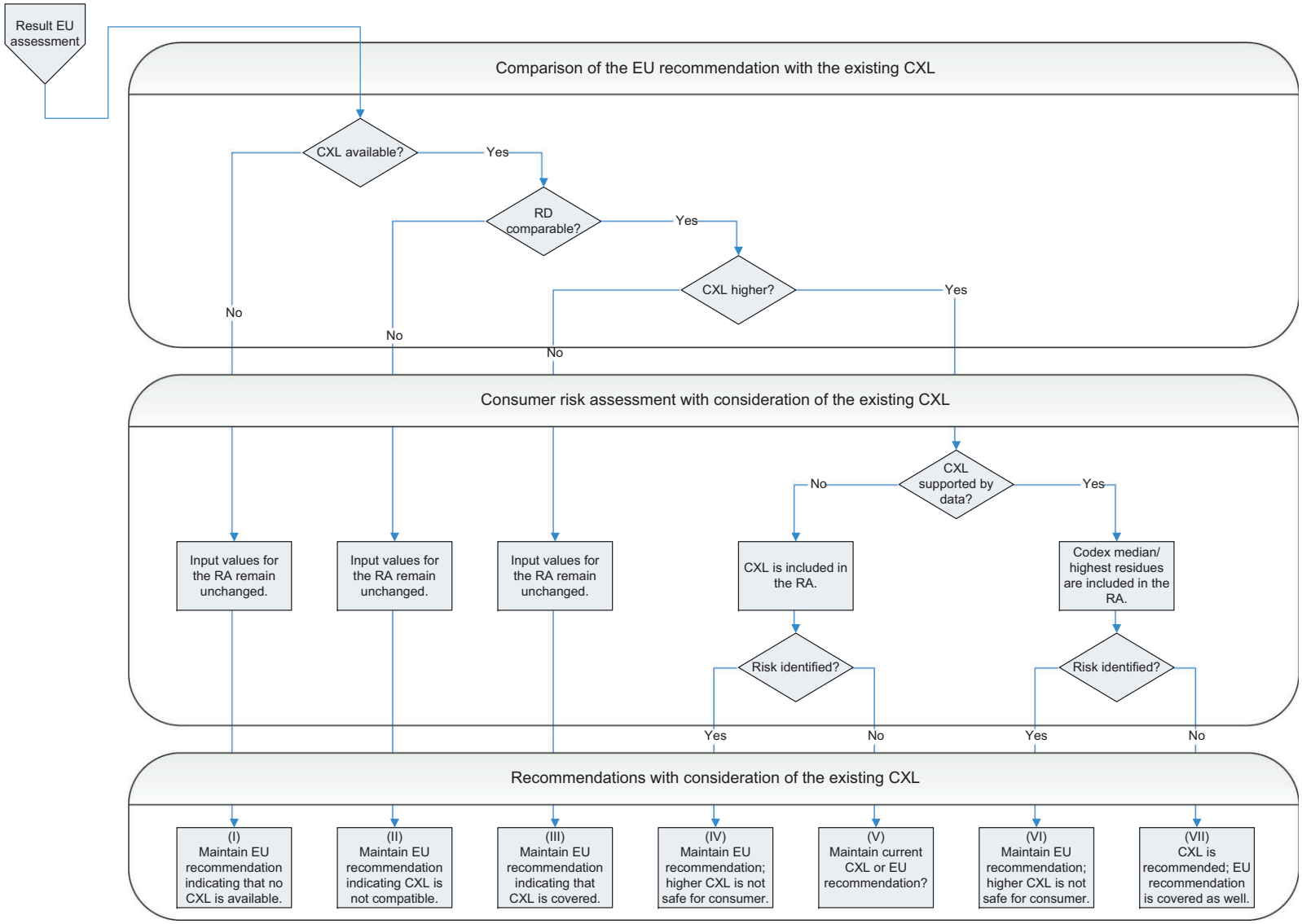
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Onions	0.05	STMR (CXL)	0.06	HR (CXL)
Tomatoes	0.08	STMR (CXL)	0.29	HR (CXL)
Peppers	0.15	STMR (CXL)	0.48	HR (CXL)
Aubergines (egg plants)	0.05	STMR (CXL)	0.14	HR (CXL)
Cucumbers	0.31	STMR (CXL)	0.39	HR (CXL)
Courgettes	0.31	STMR (CXL)	0.39	HR (CXL)
Melons	0.05	STMR (CXL)	0.15	HR (CXL)
Watermelons	0.05	STMR (CXL)	0.10	HR (CXL)
Sweet corn	0.01	STMR (CXL)	0.02	HR (CXL)
Broccoli	0.08	STMR (CXL)	0.32	HR (CXL)
Cauliflower	0.08	STMR (CXL)	0.32	HR (CXL)
Brussels sprouts	0.08	STMR (CXL)	0.32	HR (CXL)
Head cabbage	0.08	STMR (CXL)	0.32	HR (CXL)
Kale	1.30	STMR (CXL)	2.00	HR (CXL)
Lettuce	0.90	STMR (CXL)	1.20	HR (CXL)
Basil	5.00	STMR (CXL)	7.30	HR (CXL)
Beans (fresh, with pods)	0.40	STMR (CXL)	0.88	HR (CXL)
Beans (fresh, without pods)	0.40	STMR (CXL)	0.88	HR (CXL)
Peas (fresh, with pods)	0.60	STMR (CXL)	3.80	HR (CXL)
Peas (fresh, without pods)	0.58	STMR (CXL)	1.10	HR (CXL)
Celery	0.37	STMR (CXL)	3.20	HR (CXL)
Leek	0.05*	STMR (CXL)	0.05*	HR (CXL)
Beans (dry)	0.50	STMR (CXL)	1.00	HR (CXL)
Lentils (dry)	0.50	STMR (CXL)	1.00	HR (CXL)
Peas (dry)	0.50	STMR (CXL)	1.00	HR (CXL)
Lupins (dry)	0.50	STMR (CXL)	1.00	HR (CXL)
Peanuts	0.12	STMR (CXL)	0.40	HR (CXL)
Sunflower seed	0.05*	STMR (CXL)	0.05*	HR (CXL)
Rape seed	0.05*	STMR (CXL)	0.05*	HR (CXL)
Soya bean	0.38	STMR (CXL)	1.50	HR (CXL)
Olives for oil production	0.36	STMR (CXL)	1.10	HR (CXL)
Barley grain	0.05	STMR (CXL)	0.05	HR (CXL)
Buckwheat grain	0.05	STMR (CXL)	0.05	HR (CXL)
Maize grain	0.05	STMR (CXL)	0.05	HR (CXL)
Millet grain	0.05	STMR (CXL)	0.05	HR (CXL)
Oats grain	0.05	STMR (CXL)	0.05	HR (CXL)
Rice grain	0.05	STMR (CXL)	0.05	HR (CXL)
Rye grain	0.05	STMR (CXL)	0.05	HR (CXL)
Sorghum grain	0.05	STMR (CXL)	0.05	HR (CXL)
Wheat grain	0.05	STMR (CXL)	0.05	HR (CXL)
Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	6.40	STMR (CXL)	28	HR (CXL)
Coffee beans	0.35	STMR (CXL)	0.48	HR (CXL)
Hops (dried), including hop pellets and unconcentrated powder	0.70	STMR (CXL)	5.80	HR (CXL)
Sugar beet (root)	0.05	STMR (CXL)	0.28	HR (CXL)
Swine meat	0.01	STMR (CXL)	0.04	HR (CXL)
Swine fat tissue	0.01	STMR (CXL)	0.02	HR (CXL)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine liver	0.06	STMR (CXL)	0.18	HR (CXL)
Swine kidney	0.06	STMR (CXL)	0.18	HR (CXL)
Ruminant meat	0.01	STMR (CXL)	0.04	HR (CXL)
Ruminant fat tissue	0.01	STMR (CXL)	0.02	HR (CXL)
Ruminant liver	0.06	STMR (CXL)	0.18	HR (CXL)
Ruminant kidney	0.06	STMR (CXL)	0.18	HR (CXL)
Poultry meat	0.01	STMR (CXL)	0.01	HR (CXL)
Poultry fat tissue	0.01	STMR (CXL)	0.01	HR (CXL)
Poultry liver	0.01	STMR (CXL)	0.02	HR (CXL)
Ruminant milk	0.02	STMR (CXL)	0.02	HR (CXL)
Birds eggs	0.01	STMR (CXL)	0.01	HR (CXL)

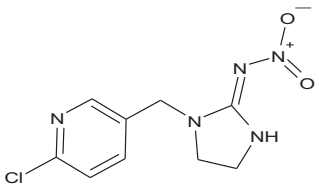
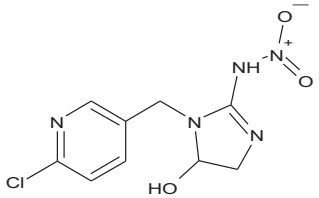
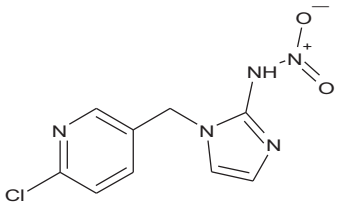
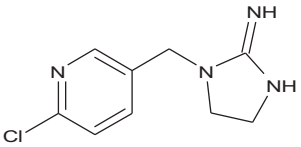
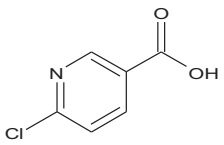
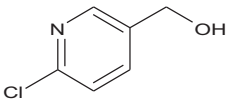
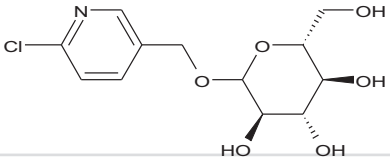
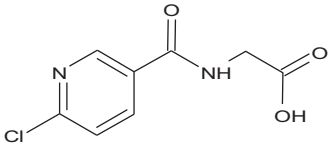
STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CXL: codex maximum residue limit.
*: Indicates that the input value is proposed at the limit of quantification.

Appendix E – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

Appendix F – Used compound codes

Code/trivial name[a]	Chemical name/SMILES notation[b]	Structural formula[c]
Imidacloprid	(*E*)-1-[(6-chloro-3-pyridyl)methyl]-*N*-nitroimidazolidin-2-ylideneamine [O-][N+](=O)/N=C1\NCCN1Cc1cnc(Cl)cc1 YWTYJOPNNQFBPC-DLSJENCCNA-N	
imidacloprid-5-hydroxy (M01)	(5*RS*)-1-[(6-chloropyridin-3-yl)methyl]-2-(nitroamino)-4,5-dihydro-1*H*-imidazol-5-ol [O-][N+](=O)NC1=NCC(O)N1Cc1cnc(Cl)cc1 MATMQDMQFSFQHB-UHFFFAOYSA-N	
imidacloprid olefin (M06)	1-[(6-chloropyridin-3-yl)methyl]-*N*-nitro-1*H*-imidazol-2-amine [O-][N+](=O)Nc1nccn1Cc1cnc(Cl)cc1 TYLCDJYHUVCRBH-UHFFFAOYSA-N	
imidacloprid-desnitro (M09)	1-[(6-chloropyridin-3-yl)methyl]-4,5-dihydro-1*H*-imidazol-2-amine Clc1ncc(CN2CCNC2=N)cc1 UEQZFAGVRGWPDK-UHFFFAOYSA-N	
imidacloprid-6-CNA (M14)	6-chloronicotinic acid OC(=O)c1cnc(Cl)cc1 UAWMVMPAYRWUFX-UHFFFAOYSA-N	
imidacloprid-CHMP (M28)	(6-chloropyridin-3-yl)methanol OCc1cnc(Cl)cc1 GOXYBEXWMJZLJB-UHFFFAOYSA-N	
imidacloprid-CHMP-glucoside (M29)	(6-chloropyridin-3-yl)methyl D-glucopyranoside Clc1ccc(COC2O[C@H](CO)[C@@H](O)[C@H](O)[C@H]2O)cn1 ZRRXFGLNJBNGQI-AZMJIDJFSA-N	
glycine-conjugate of 6-chloropyridine-3-carboxylic acid	*N*-[(6-chloropyridin-3-yl)carbonyl]glycine O=C(NCC(=O)O)c1cnc(Cl)cc1 VGSLNHSCEKVAIM-UHFFFAOYSA-N	

SMILES: simplified molecular-input line-entry system.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).
(c): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).

Appendix G – Alternative MRLs derived considering also the (former) authorised outdoor EU uses

Code number	Commodity	MRL (mg/kg)	Comment
Enforcement residue definition: imidacloprid			
110000	Citrus fruits	0.9	Tentative MRL derived from the current import tolerance. Covers also the critical outdoor use for southern Europe
120010	Almonds	0.02*	MRL derived from the critical outdoor use for southern Europe
120080	Pecans	0.02*	MRL derived from the current import tolerance. No critical outdoor uses were notified for northern and southern Europe
130010	Apples	0.09	MRL derived from the critical outdoor use for southern Europe
130020	Pears	0.15	Tentative MRL derived from the critical outdoor use for southern Europe
130030	Quinces	0.06	MRL derived from the critical outdoor use for northern Europe
140010	Apricots	0.2	Tentative MRL derived from the critical outdoor use for southern Europe
140020	Cherries (sweet)	0.3	MRL derived from the critical outdoor use for southern Europe
140030	Peaches	0.2	MRL derived from the critical outdoor use for southern Europe
140040	Plums	0.07	Tentative MRL derived from the critical outdoor use for southern Europe
151010	Table grapes	0.7	Tentative MRL derived from the current import tolerance. Covers also the critical outdoor uses for northern and southern Europe
151020	Wine grapes	0.7	Tentative MRL derived from the current import tolerance. Covers also the critical outdoor uses for northern and southern Europe
154010	Blueberries	5	Tentative MRL derived from the current import tolerance. No critical outdoor uses were notified for northern and southern Europe
154020	Cranberries	5	Tentative MRL derived from the current import tolerance. No critical outdoor uses were notified for northern and southern Europe
154030	Currants (black, red and white)	5	MRL based on the existing EU MRL (current import tolerance is not supported by residue trials). No critical outdoor uses were notified for northern and southern Europe
154040	Gooseberries (green, red and yellow)	5	MRL based on the existing EU MRL (current import tolerance is not supported by residue trials). No critical outdoor uses were notified for northern and southern Europe
154050	Rose hips	5	MRL based on the existing EU MRL (current import tolerance is not supported by residue trials). No critical outdoor uses were notified for northern and southern Europe
154060	Mulberries (black and white)	5	MRL based on the existing EU MRL (current import tolerance is not supported by residue trials). No critical outdoor uses were notified for northern and southern Europe

Code number	Commodity	MRL (mg/kg)	Comment
154070	Azaroles/Mediterranean medlars	0.05	MRL based on the existing EU MRL (current import tolerance is not supported by residue trials). No critical outdoor uses were notified for northern and southern Europe
154080	Elderberries	5	MRL based on the existing EU MRL (current import tolerance is not supported by residue trials). No critical outdoor uses were notified for northern and southern Europe
161030	Table olives	1	MRL derived from the critical outdoor use for southern Europe
163010	Avocados	1	MRL based on the existing EU MRL (the critical outdoor use for southern Europe is not supported by residue trials)
163020	Bananas	0.01*	MRL derived from the current import tolerance. No critical outdoor uses were notified for northern and southern Europe
163030	Mangoes	0.2	MRL based on the existing EU MRL (the critical outdoor use for southern Europe is not supported by residue trials)
163050	Granate apples/ pomegranates	1	MRL based on the existing EU MRL (current import tolerance is not supported by residue trials). No critical outdoor uses were notified for northern and southern Europe
211000	Potatoes	0.05	Tentative MRL derived from the critical outdoor use for northern Europe
220010	Garlic	0.04	MRL derived from the critical outdoor use for northern Europe.
220020	Onions	0.04	MRL derived from the critical outdoor use for northern Europe
220030	Shallots	0.04	MRL derived from the critical outdoor use for northern Europe
220040	Spring onions/green onions and Welsh onions	0.04	MRL derived from the critical outdoor use for northern Europe
231010	Tomatoes	0.3	MRL derived from the critical indoor use for northern and southern Europe. Covers also the critical outdoor use for southern Europe
231020	Sweet peppers/bell peppers	0.9	MRL derived from the critical indoor use for northern and southern Europe. An exceedance of the ARfD has been identified for the critical outdoor use for southern Europe
231030	Aubergines/eggplants	0.3	MRL derived from the critical indoor use for northern and southern Europe. Covers also the critical outdoor use for southern Europe
231040	Okra/lady's fingers	4	Tentative MRL derived from the critical outdoor use for southern Europe
232010	Cucumbers	0.5	MRL derived from the critical indoor use for northern and southern Europe. Covers also the critical outdoor use for southern Europe
232020	Gherkins	0.4	MRL derived from the critical indoor use for northern and southern Europe. Covers also the critical outdoor use for southern Europe
232030	Courgettes	0.4	MRL derived from the critical indoor use for northern and southern Europe. Covers also the critical outdoor use for southern Europe
233010	Melons	0.15	Tentative MRL derived from the critical indoor use for northern and southern Europe. Covers also the critical outdoor use for southern Europe

Code number	Commodity	MRL (mg/kg)	Comment
233020	Pumpkins	0.15	Tentative MRL derived from the critical indoor use for northern and southern Europe use. Covers also the critical outdoor use for southern Europe
233030	Watermelons	0.15	Tentative MRL derived from the critical indoor use for northern and southern Europe. Covers also the critical outdoor use for southern Europe
241010	Broccoli	0.09	MRL derived from the critical outdoor use for southern Europe
241020	Cauliflowers	0.09	MRL derived from the critical outdoor use for southern Europe
242010	Brussels sprouts	0.15	MRL derived from the critical outdoor use for northern Europe
242020	Head cabbages	0.08	Tentative MRL derived from the critical outdoor use for southern Europe
243010	Chinese cabbages/pe-tsai	0.5	MRL derived from the critical outdoor use for southern Europe
243020	Kales	0.01*	MRL derived from the critical outdoor use for northern Europe. An exceedance of the ARfD has been identified for the critical outdoor use for southern Europe
244000	Kohlrabies	0.3	MRL based on the existing EU MRL (the critical outdoor use for northern Europe is not supported by residue trials)
251010	Lamb's lettuces/corn salads	2	MRL derived from the critical outdoor use for southern Europe
251020	Lettuces	0.6	MRL derived from the critical outdoor use for southern Europe
251030	Escaroles/broad-leaved endives	0.05	MRL derived from the critical outdoor use for northern Europe. An exceedance of the ARfD has been identified for the critical outdoor use for southern Europe.
251040	Cresses and other sprouts and shoots	2	MRL derived from the critical outdoor use for southern Europe
251050	Land cresses	2	MRL derived from the critical outdoor use for southern Europe
251060	Roman rocket/rucola	2	MRL derived from the critical outdoor use for southern Europe
251070	Red mustards	2	MRL derived from the critical outdoor use for southern Europe
251080	Baby leaf crops (including *Brassica* species)	2	MRL derived from the critical outdoor use for southern Europe
255000	Witloofs/Belgian endives	0.01*	MRL derived from the critical outdoor use for northern Europe
256000	Fresh herbs	2	MRL derived from the critical outdoor use for southern Europe
260010	Beans (with pods)	5	Tentative MRL derived from the current import tolerance. Covers also the critical outdoor use for southern Europe and the critical indoor use for northern and southern Europe
260020	Beans (without pods)	2	Tentative MRL derived from the current import tolerance. Covers also the critical outdoor use for southern Europe
260030	Peas (with pods)	5	Tentative MRL derived from the current import tolerance. Covers also the critical outdoor use for southern Europe and the critical indoor use for northern and southern Europe
260040	Peas (without pods)	2	Tentative MRL derived from the current import tolerance. Covers also the critical outdoor use for southern Europe

Code number	Commodity	MRL (mg/kg)	Comment
270020	Cardoons	0.5	MRL based on the existing EU MRL (the critical outdoor use for southern Europe is not supported by residue trials)
270050	Globe artichokes	0.4	MRL derived from the critical outdoor use for southern Europe
270060	Leeks	0.01*	MRL derived from the critical outdoor use for northern Europe
300010	Beans (dry)	2	Tentative MRL derived from the current import tolerance. No critical outdoor uses were notified for northern and southern Europe
300030	Peas (dry)	0.01*	Tentative MRL derived from the critical outdoor use for southern Europe
401020	Peanuts/groundnuts	0.5	Tentative MRL derived from the current import tolerance. No critical outdoor uses were notified for northern and southern Europe
401090	Cotton seeds	1	MRL based on the existing EU MRL (the critical outdoor use for southern Europe is not supported by residue trials)
402010	Olives for oil production	0.7	MRL derived from the critical outdoor use for southern Europe
500010	Barley grains	0.01*	MRL derived from the critical outdoor uses for northern and southern Europe
500050	Oat grains	0.01*	MRL derived from the critical outdoor uses for northern and southern Europe
500070	Rye grains	0.01*	MRL derived from the critical outdoor uses for northern and southern Europe
500090	Wheat grains	0.01*	MRL derived from the critical outdoor uses for northern and southern Europe
620000	Coffee beans	1	Tentative MRL derived from the current import tolerance. No critical outdoor uses were notified for northern and southern Europe
700000	Hops	15	Tentative MRL derived from the current import tolerance. Covers also the critical outdoor use for northern Europe
900010	Sugar beet roots	0.01*	MRL derived from the critical outdoor uses for northern and southern Europe

MRL:: maximum residue level; ARfD: acute reference dose.
*: Indicates that the MRL is set at the limit of quantification.