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

European Food Safety Authority (EFSA), Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, German Giner, Luna Greco, Samira Jarrah, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and Alessia Verani

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 isoxaben. To assess the occurrence of isoxaben residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EC) No 33/2008, as well as the European authorisations reported by Member States and the UK (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. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

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

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Correspondence: pesticides.mrl@efsa.europa.eu
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Summary

Isoxaben was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/32/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 16 October 2020, EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK were invited to submit by 13 November 2020 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, Sweden, to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States and the UK were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 15 February 2021. On the basis of all the data submitted by Member States, the UK and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and the evaluation report were provided by the RMS to EFSA on 17 June 2021. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States, the UK and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008, EFSA prepared in October 2021 a draft reasoned opinion, which was circulated to Member States and the EURLs for consultation via a written procedure. Comments received by 18 November 2021 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of isoxaben in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as parent isoxaben for all crops following soil treatment and early post-emergence applications. The investigation of the nature of residues in processed commodities is not required since residues in all commodities are below 0.1 mg/kg and the total theoretical maximum daily intake is below 10% of the ADI. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all four main plant matrices at the limit of quantification (LOQ) of 0.01 mg/kg. However, analytical methods for hops and herbal infusions are not available. According to the EURLs, the LOQ of 0.01 mg/kg is achievable in the four main matrix groups of plant origin by using the QuEChERS method in routine analyses.

Available residue trials data were considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for clover forage and grass forage.

Isoxaben is authorised for use on crops that might be fed to livestock. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure was calculated for the Dutch toddler, representing 0.7% of the acceptable daily intake (ADI). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.
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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.

Isoxaben was included in Annex I to Council Directive 91/414/EEC by means of Commission Directive 2011/32/EU\(^3\) which has been deemed to be approved under Regulation (EC) No 1107/2009\(^4\), in accordance with Commission Implementing Regulation (EU) No 540/2011\(^5\), as amended by Commission Implementing Regulation (EU) No 541/2011\(^6\). Therefore, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, isoxaben was evaluated by Sweden, designated as rapporteur Member State (RMS) upon resubmission in the framework of Commission Regulation (EC) No 33/2008\(^7\). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2010). The approval of isoxaben is restricted to uses as herbicide. Furthermore, according to the provisions of the approval regulation, confirmatory information was requested, among others, as regards residues in rotational crops, to be submitted by 31 May 2013. Confirmatory data on residues in rotational crops were submitted by the applicant, evaluated by the RMS (Sweden, 2014) and considered by risk managers in a revised review report (European Commission, 2020).

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

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

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

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1 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.
2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991. p. 1-32. Repealed by Regulation (EC) No 1107/2009.
3 Commission Directive 2011/32/EU of 8 March 2011 amending Council Directive 91/414/EEC to include isoxaben as active substance and amending Commission Decision 2008/934/EC. OJ L 62, 9.3.2011, p. 19–22.
4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
5 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
6 Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.
7 Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.

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As the basis for the MRL review, on 16 October 2020, EFSA initiated the collection of data for this active substance. In a first step, Member States and UK\(^8\) were invited to submit by 13 November 2020 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 15 Member States and the UK provided feedback on their national authorisations of isoxaben. Based on the GAP data submitted, the designated RMS, Sweden, was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States and the UK were requested to provide residue data supporting the critical GAPs by 15 February 2021.

On the basis of all the data submitted by Member States, the UK and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked Sweden to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report were submitted to EFSA on 17 June 2021. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, EFSA prepared in October 2021 a draft reasoned opinion, which was circulated to Member States and the EURLs for commenting via a written procedure. All comments received by 18 November 2021 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Sweden, 2021), taking into account also the information provided by Member States and the UK during the collection of data, and the EURLs report on analytical methods (EURLs, 2021) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2021a) and the Member States consultation report (EFSA, 2021b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile as well as the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

## Terms of reference

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

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

## The active substance and its use pattern

Isoxaben is the ISO common name for \(N\)-[3-(1-ethyl-1-methylpropyl)-1,2-oxazol-5-yl]-2,6-dimethoxybenzamide (IUPAC).

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

The EU MRLs for isoxaben are established in Annexes IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for isoxaben are not available. No MRL changes occurred since the entry into force of the Regulation mentioned above.

For the purpose of this MRL review, all the uses of isoxaben currently authorised within the EU as submitted by the Member States and the UK during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for isoxaben are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

\(^8\) The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and with the established transition period, the EU requirements on data reporting also apply to the United Kingdom data collected until 31 December 2020.
Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Sweden, 2021);
- the draft assessment report (DAR), its addendum prepared under Council Directive 91/414/EEC and its revised addendum following the evaluation of confirmatory data (Sweden, 2006, 2010, 2014);
- the additional report (AR) prepared under Commission Regulation (EC) No 33/2008 (Sweden, 2009);
- the conclusion on the peer review of the pesticide risk assessment of the active substance isoxaben (EFSA, 2010).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 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

The metabolism of isoxaben was investigated after soil/foliar treatment in cereals (wheat and barley) and assessed in the framework of the peer review (Sweden, 2006; EFSA, 2010). In addition, studies in fruits (grapes) and leafy vegetables (leeks), after soil and foliar/soil treatment, respectively, were evaluated by the RMS in the framework of this review (Sweden, 2021). In all studies, isoxaben was radiolabelled on the 14C-isoxazole (IS) or on the 14C-phenyl (PH) ring of the molecule. An overview of all available metabolism studies is reported in Appendix B.1.1.1.

The metabolism studies were conducted in wheat and barley with pre- and early post-emergence applications of 1 x 200 or 500 g a.s./ha. In mature straw and grain, the residue consisted of multicomponent polar compounds, mainly conjugates. Isoxaben, hydroxy isoxaben (2-hydroxy isoxaben), 3-hydroxy isoxaben and 1-hydroxy isoxaben were present. Isoxaben residues were not expected to exceed 0.01 mg/kg in grain and 0.10 mg/kg in straw (EFSA, 2010).

Isoxaben was applied to soil surrounding grape vines at the rate of 2008–2204 g a.s./ha (Sweden, 2021). Mature grapes and leaves were collected 165 days after the application. Residues in both the IS- and PH-treated grapes were below the limit of quantification (0.008 mg/kg), indicating limited translocation into the edible portion. The IS- and PH-treated leaf samples contained 0.304 and 0.288 mg/kg isoxaben equivalents, respectively. No quantifiable level of parent isoxaben was observed in the leaves. The extractable radioactive residue in leaves was multicomponent, tentatively identified as hydroxylated on the aliphatic side chain metabolites, limited benzamide bridge cleavage metabolites and multiple, low-level, polar components. One unknown metabolite was observed in the leaf samples of both radiolabels, and was characterised as aqueous-soluble, containing both sides of the benzamide bridge.

Isoxaben was applied with a single foliar application to leeks at BBCH 14 (preharvest interval (PHI) of 119 days) and to the surrounding soil at 250 g a.s./ha (Sweden, 2021). Whole leek plants were sampled at maturity and separated into leaf blade and stem (including root). The phenyl label leaf blade and stem contained 0.001 and 0.004 mg eq/kg, respectively, while the isoxazole label leaf blade and stem contained 0.003 and 0.004 mg eq/kg, respectively. As the total radioactive residues were less than 0.01 mg isoxaben equivalents per kg, no characterisation of the nature of these residues was...
carried out. The results indicate that following application to immature plants and surrounding soil, residues are not translocated into the leaves and the stems/roots.

It is noted that the metabolism study on leeks does not cover all the GAPs reported for leafy crops under this review in terms of PHI. This is the case of the GAPs on celery leaves that have shorter PHIs than the one assessed in the metabolism study. Therefore, a metabolism study on leafy crops performed with a shorter PHI would be in principle still needed to confirm the metabolism of isoxaben in this commodity. Nevertheless, considering the overall data available and the results of the risk assessment (see Section 3), this additional study is considered desirable only.

Furthermore, it is highlighted that for courgettes, pumpkins, beans without pods, herbal infusions from roots and chicory roots, the NEU GAPs are reported for foliar application up to BBCH 16, corresponding to early post-emergence which are in principle not supported by a metabolism study. However, based on the metabolism studies on primary crops and the phenological stage of the plants at treatment (BBCH stage between 13 and 16), limited uptake and translocation to edible parts of crop is expected. In addition, in the confined rotational crop study and in the available residue trials, a limited uptake is observed in all crops tested (see Sections 1.1.2 and 1.2.1). Therefore, it can be concluded that no additional metabolism studies are required to support these uses. Studies on cereals and leafy vegetables following soil and early post-emergence treatment and in fruits following soil treatment show that isoxaben is the only relevant compound in plants.

1.1.2. Nature of residues in rotational crops

Isoxaben is authorised on crops that may be grown in rotation. The field DT₉₀ reported in soil degradation studies evaluated in the framework of the peer review ranged from 219 to 1028 days for isoxaben, while for metabolite 1-hydroxy isoxaben ranged from 258 to 697 days, and for metabolite oxypropyl isoxaben ranged between 285 and 927 days (EFSA, 2010). Therefore, further investigation on the nature of residue in rotational crops was required.

Thus, one confined rotational crop study with isoxaben radiolabelled on the ¹⁴C-isoxazole (IS) or on the ¹⁴C-phenyl (PH) ring of the molecule was submitted as confirmatory data and included in the revised addendum (Sweden, 2014). Isoxaben was applied at a rate of 250 g a.s./ha onto bare soil (sandy loam), and lettuce, radish and wheat were planted at back intervals (PBI) of 30, 120, 189 and 365 days after treatment (DAT). An overview of the study is reported in Appendix B.1.1.1.

The maximum TRR in immature lettuce was observed at 0.028 mg eq./kg 180 DAT. In mature lettuce, the maximum TRR was 0.026 mg eq./kg at 180 DAT while at 365 DAT, the TRR was below 0.01 mg/kg. In radish roots, the maximum TRR was 0.074 mg eq./kg at 30 DAT. At 180 and 365 DAT, the TRR was below 0.01 mg/kg in radish roots. At 30 and 120 DAT, there was slow growth and abnormal development of lettuces and radish roots. In wheat grain, the maximum TRR was 0.027 mg eq./kg at 120 DAT. At 180 DAT, no samples were taken for wheat grain, and at 365 DAT, the TRR was below 0.01 mg/kg. The highest individual levels of isoxaben found in the confined rotational crop were 0.012 mg eq./kg at 30 DAT in radish tops, 0.014 mg eq./kg at 30 DAT in radish root and 0.011 mg eq./kg at 120 DAT in wheat straw (Sweden, 2014). At 180 DAT, isoxaben was found below 0.01 mg/kg in lettuce (mature and immature) and radish roots, while in wheat grain, the TRR was below 0.01 mg eq./kg at 365 DAT. Metabolites were below 0.01 mg eq./kg in all crop fractions, except for hydroxy isoxaben (2-hydroxy isoxaben) found only in wheat straw at 30 and 120 DAT at 0.011 and 0.012 mg eq./kg, respectively.

The metabolism and distribution of isoxaben in rotational crops are similar to the metabolic pathway observed in primary crops.

1.1.3. Nature of residues in processed commodities

There were no studies investigating the nature of residues of isoxaben in processed commodities available for this review. Nevertheless, in all commodities, residues were below 0.1 mg/kg and the total theoretical maximum daily intake is below 10% of the ADI. Therefore, the investigation of the nature of residues in processed commodities is not required.

1.1.4. Methods of analysis in plants

During the peer review, it was concluded that adequate analytical methods are available for the determination of isoxaben residues in high water content commodities (endives, wheat and barley
forage, chicory roots and chicory leaves), dry content commodities (wheat grain, barley grain and in wheat and barley straw) by LC–MS/MS with an LOQ of 0.01 mg/kg (EFSA, 2010).

Additional analytical methods using LC–MS/MS, with confirmatory method and independent laboratory validation (ILV), were provided in the framework of this review for the enforcement of isoxaben in high water content commodities (wheat forage, lettuce leaves), dry commodities (barley grain and straw, wheat straw), high oil content commodities (rape seed, sunflower seed) and high acid content commodities (orange whole fruit, lemon whole fruit) with an LOQ of 0.01 mg/kg (Sweden, 2021).

It can be concluded that isoxaben can be monitored in high water content, high acid content, dry and high oil content commodities with an LOQ of 0.01 mg/kg. However, analytical methods for hops and herbal infusions are missing (data gap). An overview of the available studies is reported in Appendix B.1.1.1.

Based on data available to the EURLs, isoxaben can be monitored in high water content, high acid content, dry and high fat content commodities with an LOQ of 0.01 mg/kg. In high water content, high acid content and dry commodities, lower levels, down to 0.002 mg/kg, were successfully validated (EURLs, 2021).

1.1.5. Stability of residues in plants

The storage stability of isoxaben was investigated in the framework of the peer review (EFSA, 2010) and in new studies submitted under this review (Sweden, 2021). An overview of the available studies is reported in Appendix B.1.1.2.

Residues of isoxaben are stable for at least 12 months in endive (high water content commodities) and for at least 24 months in grapes and cereal grain and straw (high acid and dry/high starch content commodities, respectively) when stored at –20°C (EFSA, 2010). In addition, residues of isoxaben are stable in rapeseed and dry bean seed (high oil and high protein content commodities, respectively), for at least 12 months when stored at –18°C (Sweden, 2021).

It is noted that no specific study is available for the storage stability in herbal infusions from flowers and hops. However, as storage stability was investigated and demonstrated in the four main plant matrices, the most limiting storage stability conditions demonstrated for general matrices are assumed to be applicable to these matrices as well.

1.1.6. Proposed residue definitions

The metabolism of isoxaben was similar following soil and early post-emergence application to cereals and to leafy vegetables and soil application to fruits. The metabolism studies on rotational crops (leafy, cereals and roots) confirmed that parent is the only relevant compound in plants upon soil application. The investigation of the metabolism of isoxaben upon processing is not required.

In some studies, no characterisation of the residues was possible (e.g. leafy vegetables), while in other studies, different compounds were present. However, a significant translocation into the edible parts of the crops after soil and early post-emergence application was not observed in all the studies. Based on the overall data, the residue definition for enforcement and risk assessment in all crops is proposed as isoxaben only, for soil application and early post-emergence applications. It is noted that isoxaben will undergo the renewal process soon, so the residue definition proposed in this review may be re-considered.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all four main plant matrices is available (EFSA, 2010; Sweden, 2021). Analytical methods for hops and herbal infusions are missing. According to the EURLs, the LOQ of 0.01 is achievable in the four main matrix groups of plant origin by using the QuEChERS method in routine analyses (EURL, 2021).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of isoxaben residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Sweden, 2021) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2010). Most residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability...
of residues was demonstrated. Information on the storage stability is missing for the trials performed on melons, leeks and celery leaves, whereas samples from residue trials on courgettes and pumpkins were stored longer than the storage stability period for high water content commodities. However, since overall, according to the metabolism studies and the results of the trials available, isoxaben is not expected to be present at significant levels in fruits/crops/leafy crops, additional information on the storage conditions and storage stability studies are only desirable.

The number of residue trials and extrapolations was evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017). An overview of the available residue trials is reported in Appendix B.1.2.1.

Residue trials are not available to support the authorisations on clover forage and grass forage. Therefore, MRL and risk assessment values could not be derived for these crops and the following data gaps were identified:

- Clover forage, grass forage: four trials on clover forage and grass forage compliant with the northern outdoor GAP are required.

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

- Strawberries: The number of residue trials supporting the indoor GAP is not compliant with the data requirements for this crop. However, significant residues are not expected to occur based on the metabolism in fruits following soil application and since the GAP is for application during dormant stage. Therefore, further residue trials are not required.

- Raspberries (red and yellow) and blackberries: The number of residue trials supporting the northern GAP is not compliant with the data requirements for these crops. However, significant residues are not expected to occur based on the metabolism in fruits following soil application and since the GAP is for application during dormant stage. Therefore, further residue trials are not required.

- Blueberries, gooseberries (green, red and yellow), rose hips: Although MRL and risk assessment values can be derived from the northern data, four trials compliant with the southern GAP would in principle still be required. However, significant residues are not expected to occur based on overdosed trials supporting the NEU GAP and the metabolism study on fruits following soil application. Therefore, further residue trials are not required.

- Currants (black, red and white): Although MRL and risk assessment values can be derived from the northern data, four trials compliant with the southern GAP would in principle still be required. However, significant residues are not expected to occur based on overdosed trials on currants and the metabolism study on fruits following soil application. Therefore, further residue trials are not required.

- Bananas: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop. It is also noted that, although all results were below the LOQ, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and according to the metabolism study, residues in fruits are not expected to occur when isoxaben is applied following soil application (confirmed as well by the available trials on pome and stone fruits). Therefore, further residue trials are not required.

- Carrots: The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. It is also noted that, although all results were below the LOQ, samples from trials were analysed using a method validated at an LOQ of 0.05 mg/kg while the LOQ for enforcement in high water content commodities is 0.01 mg/kg. However, based on the rotational crop metabolism study (performed at 3.3 N rate of the GAP on carrots), residues in carrots are expected to remain below the LOQ of 0.01 mg/kg when isoxaben is applied according to the authorised use. Therefore, MRL and risk assessment values can be derived at the LOQ of 0.01 mg/kg and further residue trials are not required.

- Onions: The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ, the GAP is for an application every 2 years and the metabolism of isoxaben in roots/tuber vegetables following soil application indicates that significant residues are not expected to occur. Therefore, further residue trials are not required.
• Melons: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ, according to the metabolism study residues in fruits are not expected to occur when isoxaben is applied following soil application and the GAP is for a soil application every 2 years. Therefore, further residue trials are not required.

• Celery leaves: The number of residue trials supporting the northern/southern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and according to the metabolism study residues in leafy vegetables are not expected to occur when isoxaben is applied following soil treatment with an application rate up to 250 g a.s./ha. Therefore, further residue trials are not required.

• Sage, rosemary, thyme, basil and edible flowers: There are no residue trials to support the northern GAP for these crops. Since according to the metabolism study residues are not expected to occur following early post-emergence application with isoxaben at up to 250 g a.s./ha, MRL and risk assessment values are tentatively proposed at the LOQ. However, two residue trials are needed to confirm that no significant residues are expected.

• Asparagus: The number of residue trials supporting the northern/southern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and residues in the edible part are not expected to occur when isoxaben is applied according to the authorised use on asparagus (application at pre-emergence or after harvest of the shoots). Therefore, further residue trials are not required.

• Leeks: The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and residues in leafy vegetables are not expected to occur when isoxaben is applied following soil treatment with an application rate up to 250 g a.s./ha. Therefore, further residue trials are not required.

• Spring onions/green onions and Welsh onions: Although MRL and risk assessment values can be derived from the northern data, four trials compliant with the southern GAP would in principle still be required. However, the SEU GAP is for an application every 2 years and residues are not expected based on trials with roots/tuber vegetables and the metabolism of isoxaben in roots following soil application. Therefore, further residue trials are not required.

• Chives: Although MRL and risk assessment values can be derived from the northern data, four trials compliant with the southern GAP would in principle still be required. However, residues were below the LOQ in trials supporting the NEU GAP (that has the same GAP parameters), and residues are not expected to occur when isoxaben is applied to leafy vegetables as soil treatment at early growth stages. Therefore, further residue trials are not required.

• Rapeseeds/canola seed: Although MRL and risk assessment values can be derived from the northern data, eight trials compliant with the southern GAP would in principle still be required. However, residues were below the LOQ in trials supporting the NEU GAP (that has the same GAP parameters), and according to the metabolism studies, residues are not expected to occur when isoxaben is applied as soil treatment. Therefore, further residue trials are not required.

• Cotton seed: There are no residue trials supporting the southern outdoor GAP. Since according to the available studies, residues are not expected to occur when isoxaben is applied as soil treatment, MRL and risk assessment values are tentatively proposed at the LOQ. However, two residue trials are needed to confirm that no significant residues are expected.

• Herbal infusions from flowers: There are no residue trials to support the northern/southern GAP. Since according to the metabolism study, residues are not expected to occur following early post-emergence application with isoxaben at up to 250 g a.s./ha, MRL and risk assessment values are tentatively proposed at the LOQ. However, two residue trials compliant with the northern or with the southern outdoor GAP are needed to confirm that no significant residues are expected.

• Herbal infusions from roots: There are no residue trials to support the northern GAP. Since according to the available studies, residues are not expected to occur when isoxaben is applied as soil treatment or at early post-emergence, MRL and risk assessment values are proposed at the LOQ, based on an extrapolation from trials on carrots. It is noted that a dehydration factor
was not applied because isoxaben was always below the LOQ in carrots and concentration of residues is not expected.

- Hops: The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because residues were all below the LOQ of 0.01 mg/kg and because application is during dormant stage. Therefore, further residue trials are not required.

- Chicory roots: Considering that the trials were performed according to a more critical GAP and residues were below or at the LOQ the MRL is proposed at the LOQ of 0.01 mg/kg and further residue trials are not required.

1.2.2. Magnitude of residues in rotational crops

There were no field rotational crop studies available for this review. Four accumulation soil studies (2 in NEU and 2 in SEU), where isoxaben and metabolites hydroxy isoxaben (2-hydroxy isoxaben) and oxypropyl isoxaben were analysed, were assessed in the framework of the peer review (EFSA, 2010). The soils in the NEU studies were silty clay loam and a sandy clay loam, whereas in the SEU, the soils were clay loam. The studies conducted in the NEU were made with one application of 500 g a.s./ha made every year for 5 years, whereas in the SEU studies were made with one application of 1000 g a.s./ha every year for 5 years. According to the peer review, there was no accumulation of parent or metabolites in the soils tested (EFSA, 2010). It is noted that the longest soil field DT90 reported for isoxaben and metabolites hydroxy isoxaben (2-hydroxy isoxaben) and oxypropyl isoxaben were reported for clay loam soils (EFSA, 2010). Since according to these studies, accumulation in soil is not expected over the years, the confined rotational crop study performed with 250 g a.s./ha on bare soil at 1N rate of the most critical GAPs for a crop that can be rotated reported in this review (e.g. cucurbits), is sufficient to conclude that significant residues of isoxaben and metabolites hydroxy isoxaben (2-hydroxy isoxaben) and oxypropyl isoxaben are not expected to occur in crops grown in rotation (see also Section 1.1.2).

It is noted that some phytotoxicity was observed at earlier sampling intervals in the submitted study, thus a plant back interval of at least 180 days is recommended for some rotational crops (e.g. leafy vegetable, root crops). This information should be considered by risk managers for the adoption of mitigation measures.

1.2.3. Magnitude of residues in processed commodities

Studies on the effect of industrial processing and/or household preparation are not available and are not required (see also Section 1.1.3).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for clover forage and grass forage.

Tentative MRLs were also derived for cereals straw in view of the future need to set MRLs in feed items.

2. Residues in livestock

Isoxaben is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D.

Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

It is however noted that for some feed items (grass and clover forage), no residue data is available, and therefore, the calculated dietary burden might be underestimated.

3. Consumer risk assessment

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). Input values for the exposure calculations
were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix D. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

The exposure values calculated were compared with the toxicological reference values for isoxaben, derived by EFSA (2010). The highest chronic exposure was calculated for the Dutch toddler, representing 0.7% of the acceptable daily intake (ADI). An overview of the consumer risk assessment is reported in Appendix B.3. Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer’s health.

Conclusions

The metabolism of isoxaben in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as parent isoxaben for all crops following soil treatment and early post-emergence applications. The investigation of the nature of residues in processed commodities is not required since residues in all commodities are below 0.1 mg/kg and the total theoretical maximum daily intake is below 10% of the ADI. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all four main plant matrices at the LOQ of 0.01 mg/kg. However, analytical methods for hops and herbal infusions are not available. According to the EURLs, the LOQ of 0.01 mg/kg is achievable in the four main matrix groups of plant origin by using the QuEChERS method in routine analyses.

Available residue trials data were considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for clover forage and grass forage.

Isoxaben is authorised for use on crops that might be fed to livestock. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure was calculated for the Dutch toddler, representing 0.7% of the acceptable daily intake (ADI). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Recommendations

MRL recommendations reported in Table 1 were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion. All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 1 footnotes for details). In particular, some tentative MRLs need to be confirmed by the following data:

1) Analytical methods for the enforcement in hops and herbal infusions;
2) Additional residue trials supporting the GAPs on sage, rosemary, thyme, basil and edible flowers, cotton seeds and herbal infusions from flowers.

Regarding MRLs in animal commodities, it is highlighted, however, that since no residue data is available to support the authorised uses on some animal feed items (grass and clover forage), the calculated livestock exposure might be underestimated. EFSA therefore 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:

- residue trials supporting the northern outdoor GAP on clover forage and grass forage.

If the above-reported data gap is not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.
EFSA also underlines that, according to the information provided by the EURs, the analytical standard for isoxaben is commercially available.

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

- a representative study investigating the storage stability of isoxaben covering the residue trials performed with courgettes, melons, pumpkins, leeks and celery leaves;
- A representative study investigating the metabolism in leafy vegetables at PHI covering the GAP on celery leaves.

Table 1: Summary table

| Code number | Commodity                | Existing EU MRL (mg/kg) | Outcome of the review | Comment |
|-------------|--------------------------|-------------------------|-----------------------|---------|
|             |                          |                         | MRL (mg/kg)           |         |
| 110010      | Grapefruit               | 0.02*                   | 0.01*                 | Recommended* |
| 110020      | Oranges                  | 0.02*                   | 0.01*                 | Recommended* |
| 110030      | Lemons                   | 0.02*                   | 0.01*                 | Recommended* |
| 110040      | Limes                    | 0.02*                   | 0.01*                 | Recommended* |
| 110050      | Mandarins                | 0.02*                   | 0.01*                 | Recommended* |
| 120010      | Almonds                  | 0.05                    | 0.01*                 | Recommended* |
| 120040      | Chestnuts                | 0.05                    | 0.01*                 | Recommended* |
| 120060      | Hazelnuts                | 0.05                    | 0.01*                 | Recommended* |
| 120110      | Walnuts                  | 0.05                    | 0.01*                 | Recommended* |
| 130010      | Apples                   | 0.05                    | 0.01*                 | Recommended* |
| 130020      | Pears                    | 0.05                    | 0.01*                 | Recommended* |
| 130030      | Quinces                  | 0.05                    | 0.01*                 | Recommended* |
| 130040      | Medlar                   | 0.05                    | 0.01*                 | Recommended* |
| 130050      | Loquat                   | 0.05                    | 0.01*                 | Recommended* |
| 140010      | Apricots                 | 0.02*                   | 0.01*                 | Recommended* |
| 140020      | Cherries                 | 0.05                    | 0.01*                 | Recommended* |
| 140030      | Peaches                  | 0.02*                   | 0.01*                 | Recommended* |
| 140040      | Plums                    | 0.05                    | 0.01*                 | Recommended* |
| 151010      | Table grapes             | 0.05                    | 0.01*                 | Recommended* |
| 151020      | Wine grapes              | 0.05                    | 0.01*                 | Recommended* |
| 152000      | Strawberries             | 0.05                    | 0.01                  | Recommended* |
| 153010      | Blackberries            | 0.05                    | 0.01*                 | Recommended* |
| 153020      | Dewberries               | 0.05                    | 0.01                  | Recommended* |
| 153030      | Raspberries             | 0.05                    | 0.01*                 | Recommended* |
| 154010      | Blueberries              | 0.05                    | 0.01*                 | Recommended* |
| 154020      | Cranberries              | 0.05                    | 0.01*                 | Recommended* |
| 154030      | Currants (red, black and white) | 0.05 | 0.01*                 | Recommended* |
| 154040      | Gooseberries            | 0.05                    | 0.01*                 | Recommended* |
| 154050      | Rose hips                | 0.05                    | 0.01*                 | Recommended* |
| 154060      | Mulberries               | 0.05                    | 0.01*                 | Recommended* |
| 154070      | Azarole (mediterranean medlar) | 0.05 | 0.01*                 | Recommended* |
| 154080      | Elderberries            | 0.05                    | 0.01*                 | Recommended* |
| 162010      | Kiwi                     | 0.02*                   | 0.01*                 | Recommended* |
| 163020      | Bananas                  | 0.02*                   | 0.01*                 | Recommended* |
| 213020      | Carrots                  | 0.05                    | 0.01*                 | Recommended* |
| 213040      | Horseradish             | 0.05                    | 0.01*                 | Recommended* |
| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|------------------------|-----------------------|---------|
| 213060      | Parsnips  | 0.05                   | 0.01*                 | Recommended(a) |
| 220010      | Garlic    | 0.02*                  | 0.01*                 | Recommended(a) |
| 220020      | Onions    | 0.02*                  | 0.01*                 | Recommended(a) |
| 220030      | Shallots  | 0.02*                  | 0.01*                 | Recommended(a) |
| 220040      | Spring onions | 0.02* | 0.01* | Recommended(a) |
| 232030      | Courgettes| 0.05                   | 0.05                  | Recommended(a) |
| 233010      | Melons    | 0.05                   | 0.01*                 | Recommended(a) |
| 233020      | Pumpkins  | 0.05                   | 0.01*                 | Recommended(a) |
| 255000      | Witloof   | 0.02*                  | 0.01*                 | Recommended(a) |
| 256020      | Chives    | 0.05                   | 0.01*                 | Recommended(a) |
| 256030      | Shallots  | 0.05                   | 0.01*                 | Recommended(a) |
| 256050      | Sage      | 0.05                   | 0.01*                 | Further consideration needed(b) data gap #2 |
| 256060      | Rosemary  | 0.05                   | 0.01*                 | Further consideration needed(b) data gap #2 |
| 256070      | Thyme     | 0.05                   | 0.01*                 | Further consideration needed(b) data gap #2 |
| 256080      | Basil     | 0.05                   | 0.01*                 | Further consideration needed(b) data gap #2 |
| 260020      | Beans (fresh, without pods) | 0.02* | 0.02 | Recommended(c) |
| 270010      | Asparagus | 0.05                   | 0.01*                 | Recommended(c) |
| 270060      | Leek      | 0.02*                  | 0.01*                 | Recommended(c) |
| 270070      | Rhubarb   | 0.02*                  | 0.01*                 | Recommended(c) |
| 401060      | Rape seed | 0.02*                  | 0.01*                 | Recommended(c) |
| 401090      | Cotton seed | 0.02* | 0.01* | Further consideration needed(b) data gap #2 |
| 500010      | Barley grain | 0.1   | 0.01* | Recommended(c) |
| 500050      | Oats grain | 0.1    | 0.01* | Recommended(c) |
| 500070      | Rye grain | 0.1    | 0.01* | Recommended(c) |
| 500090      | Wheat grain | 0.1   | 0.01* | Recommended(c) |
| 631000      | Herbal infusions (dried, flowers) | 0.02* | 0.01* | Further consideration needed(b) data gaps #1 and #2 |
| 633000      | Herbal infusions (dried, roots) | 0.02* | 0.01* | Further consideration needed(b) data gap #1 |
| 700000      | Hops (dried), including hop pellets and unconcentrated powder | 0.05 | 0.01* | Further consideration needed(b) data gap #1 |
| 900030      | Chicory roots | 0.02* | 0.01* | Recommended(a) |
|             | Other commodities of plant and/or animal origin | See Reg. 149/2008 | – | Further consideration needed(c) |

MRL: maximum residue level.
*: Indicates that the MRL is set at the limit of quantification.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).
(b): 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 F–I in Appendix E).
(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A–I in Appendix E).

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Abbreviations

- a.i. active ingredient
- a.s. active substance
- ADI acceptable daily intake
- AR applied radioactivity
- ARfD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- BVL Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany
- bw body weight
- CAC Codex Alimentarius Commission
- CAS Chemical Abstract Service
- CCPR Codex Committee on Pesticide Residues
- CEN European Committee for Standardization (Comité Européen de Normalisation)
- 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
- DM dry matter
- DT₉₀ period required for 90% dissipation (define method of estimation)
- EC emulsifiable concentrate
- eq residue expressed as a.s. equivalent
- EURLs European Union Reference Laboratories for Pesticide Residues (former CRLs)
- FAO Food and Agriculture Organization of the United Nations
- GAP Good Agricultural Practice
- GC gas chromatography
- HR highest residue
- IEDI international estimated daily intake
- ILV independent laboratory validation
- ISO International Organisation for Standardization
- IUPAC International Union of Pure and Applied Chemistry
- Kₒc organic carbon adsorption coefficient
- LC liquid chromatography
- LC–MS/MS liquid chromatography with tandem mass spectrometry
- LOQ limit of quantification
- Mo Monitoring
- MRL maximum residue level
- MS Member States
- MS mass spectrometry detector
- MS/MS tandem mass spectrometry detector
- MW molecular weight
- NEDI national estimated daily intake
- NTMDI national theoretical maximum daily intake
- OECD Organisation for Economic Co-operation and Development
PBI  plant back interval
PHI  preharvest interval
\( P_{ow} \)  partition coefficient between \textit{n}-octanol and water
ppm  parts per million \((10^{-6})\)
PRIMo  (EFSA) Pesticide Residues Intake Model
PROFile  (EFSA) Pesticide Residues Overview File
QuEChERS  Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA  risk assessment
RAC  raw agricultural commodity
RD  residue definition
RMS  rapporteur Member State
RSD  relative standard deviation
SANCO  Directorate-General for Health and Consumers
SBI  sterol biosynthesis inhibitors
SC  suspension concentrate
SCPAFF  Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)
SEU  southern European Union
SG  water soluble granule
SL  soluble concentrate
SMILES  simplified molecular-input line-entry system
SP  water soluble powder
STMR  supervised trials median residue
TAR  total applied radioactivity
TMDI  theoretical maximum daily intake
TRR  total radioactive residue
UV  ultraviolet (detector)
WG  water dispersible granule
WHO  World Health Organization
### Appendix A – Summary of authorised uses considered for the review of MRLs

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

| Crop and/or situation | MS or country | F or G or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|--------------|-------------|-----------------------------|-----------|---------|
|                       |               |             |                                   |              | Method kind | Range of growth stages & season | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit |          |
| **Almonds**           | UK            | F           | Weeds                             | SC           | Soil treatment – general (see also comment field) | 00 1 | – – | 250 g a.i./ha | n.a. | Dormant stage |
| **Chestnuts**         | UK            | F           | Weeds                             | SC           | Soil treatment – general (see also comment field) | 00 1 | – – | 250 g a.i./ha | n.a. | Dormant stage |
| **Hazelnuts**         | UK            | F           | Weeds                             | SC           | Soil treatment – general (see also comment field) | 00 1 | – – | 250 g a.i./ha | n.a. | Dormant stage |
| **Walnuts**           | UK            | F           | Weeds                             | SC           | Soil treatment – general (see also comment field) | 00 1 | – – | 250 g a.i./ha | n.a. | Dormant stage |
| **Apples**            | FR            | F           | Weeds                             | SC           | Soil treatment – general (see also comment field) | 0-60 1 | – – | 600 g a.i./ha | n.a. |          |
| **Pears**             | FR            | F           | Weeds                             | SC           | Soil treatment – general (see also comment field) | 0-60 1 | – – | 600 g a.i./ha | n.a. |          |
| **Quinces**           | FR            | F           | Weeds                             | SC           | Soil treatment – general (see also comment field) | 0-60 1 | – – | 600 g a.i./ha | n.a. |          |
| Crop and/or situation | MS or country | FG or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|---------|-----------------------------------|-------------|-------------|-------------------------------|-----------|---------|
| Medlars               | FR           | F       | Weeds                             | SC          | 125 g/L     | Soil treatment general (see also comment field) | 0-60      | 1       | 600 g a.i./ha | n.a. |
| Loquats               | FR           | F       | Weeds                             | SC          | 125 g/L     | Soil treatment general (see also comment field) | 0-60      | 1       | 600 g a.i./ha | n.a. |
| Apricots              | AT, BE, DE   | F       | Weeds                             | SC          | 500 g/L     | Soil treatment general (see also comment field) | 0-59      | 1       | 500 g a.i./ha | n.a. |
| Cherries              | AT, BE, DE   | F       | Weeds                             | SC          | 500 g/L     | Soil treatment general (see also comment field) | 0-59      | 1       | 500 g a.i./ha | n.a. |
| Peaches               | AT, BE, DE   | F       | Weeds                             | SC          | 500 g/L     | Soil treatment general (see also comment field) | 0-59      | 1       | 500 g a.i./ha | n.a. |
| Plums                 | AT, BE, DE   | F       | Weeds                             | SC          | 500 g/L     | Soil treatment general (see also comment field) | 0-59      | 1       | 500 g a.i./ha | n.a. |
| Table grapes          | BE           | F       | Weeds                             | SC          | 500 g/L     | Soil treatment spraying | 0-59      | 1       | 500 g a.i./ha | n.a. |
| Wine grapes           | FR           | F       | Weeds                             | SC          | 125 g/L     | Soil treatment spraying | 0-3       | 1       | 750 g a.i./ha | n.a. |

Do not apply on more than 30% of the surface of the plot

Review of the existing MRLs for isoxaben

www.efsa.europa.eu/efsajournal 20 EFSA Journal 2022;20(1):7062
| Crop and/or situation | MS or country | F G or T(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|------------|----------------------------------|-------------|-------------|-------------------------------|--------------|---------|
| Strawberries          | DE, BE, NL    | F          | Birdseed, shepherd’s purse, charlock, common chickweed | SC 500 g/L | Soil treatment – general (see also comment field) | 41 1 | – – | 200 g a.i./ha | n.a. | Application at beginning of vegetation, before emergence of weeds, not in planting year |
| Blackberries          | BE, AT, DE    | F          | Annual dicots                    | SC 500 g/L | Soil treatment – general (see also comment field) | 0–59 1 | – – | 250 g a.i./ha | Up to 30% of the crops field can be treated. From November to beginning of March (dormant stage before flowering) |
| Dewberries            | AT, DE        | F          | Annual dicotyledonous weeds      | SC 500 g/L | Soil treatment – spraying | 59 1 | – – | 250 g a.i./ha | n.a. | In spring, before flowering, pre-emergence of the weeds/ Application from planting year, up to first bloom, pre-emergence of the weeds, row treatment |
| Raspberries           | IE, UK        | F          | SC 500 g/L                       | Soil treatment – general (see also comment field) | 0 1 | – – | 250 g a.i./ha | n.a. | Dormant stage |

(a) F, G or T refer to the specific group of crops or pests controlled.
(b) Type (e.g., SC, WDG) indicates the formulation type.
(c) Range of growth stages and season involves specific growth stages and season information.
(d) PHI refers to the Pre-Application Interval, which is crucial for crop safety and efficacy.
## Review of the existing MRLs for isoxaben

| Crop and/or situation | MS or country | F G or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|----------|------------------------------------|-------------|------------|-------------------------------|------------|---------|
|                       |              |          |                                    |             |            |                               |            |         |
| Blueberries           | BE; AT, DE   | F        | Birdseed, common chickweed         | SC          | 500 g/L    | Soil treatment – spraying     | 59 1       | 500 g a.i./ha n.a. Aronia berries, Before flowering, pre-emergence of weeds |
| Cranberries           | BE; AT, DE   | F        | Annual dicots                      | SC          | 500 g/L    | Soil treatment – general (see also comment field) | 0-59 1     | 250 g a.i./ha up to 30% of the crops field can be treated. From November to beginning of March (dormant stage before flowering). |
| Currants              | FR           | F        | Weeds                              | SC          | 125 g/L    | Soil treatment – spraying     | 0-3 1      | 600 g a.i./ha n.a. Only on Black currants Extrapolated from strawberries and grapes trials |
| Gooseberries          | BE           | F        | Annual dicots                      | SC          | 500 g/L    | Soil treatment – general (see also comment field) | 0-59 1     | 250 g a.i./ha Up to 30% of the crops field can be treated. From November to beginning of March (dormant stage before flowering) |
| Rose hips             | AT, DE       | F        | Annual dicotyledonous weeds        | SC          | 500 g/L    | Soil treatment – spraying     | 59 1       | 250 g a.i./ha n.a. In spring, before flowering, pre-emergence of the weeds |
| Crop and/or situation | MS or country | F | G | T(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|---|---|------|------------------------------------|-------------|-------------|-------------------------------|--------------|---------|
| Mulberries AT, DE F   | Annual dicotyledonous weeds | SC | 500 g/L | Soil treatment – spraying | 59 | 1 | | 250 g a.i./ha | n.a. | in spring, before flowering, pre-emergence of the weeds |
| Azaroles AT F         | Annual dicotyledonous weeds | SC | 500 g/L | Soil treatment – spraying | 59 | 1 | | 250 g a.i./ha | n.a. | In spring, before flowering, pre-emergence of the weeds |
| Elderberries AT, DE F | Annual dicotyledonous weeds | SC | 500 g/L | Soil treatment – spraying | 59 | 1 | | 250 g a.i./ha | n.a. | In spring, before flowering, pre-emergence of the weeds |
| Carrots UK F          | Annual dicotyledonous weeds | SC | 500 g/L | Foliar treatment – general (see also comment field) | 0-9 | 1 | | 75 g a.i./ha | n.a. | Pre-emergence Since application is done at early growth stage (up to BBCH 09), it is assumed that this represents a soil treatment and that the foliar treatment refers to the weed and not the crop |
| Horseradishes IE, UK F| SC | 500 g/L | Foliar treatment – general (see also comment field) | 0-9 | 1 | | 75 g a.i./ha | n.a. | Pre-emergence Since application is done at early growth stage (up to BBCH 09), it is |
| Crop and/or situation | MS or country | F OR G | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|--------|-----------------------------------|-------------|------------|--------------------------------|------------|---------|
|                       |               |        |                                   |             | Range of growth stages & season | Number | Interval between application | a.s./hL | Rate and unit |          |
|                       |               |        |                                   |             | season | min-max | (min) | min-max | g a.i./ha |          |          |
| Parsnips IE, UK F     |               |        |                                   | SC          | 500 g/L | 0-9     | 1    | –       | 75 g | n.a. Pre-emergence |
|                       |               |        |                                   |             |         |         |      |         | a.i./ha |          |          |
| Garlic BE, IE, NL F   | Annual dicots |        |                                   | SC          | 500 g/L | 11-12   | 1    | –       | 100 g | n.a. > BBCH11 or after planting |
|                       |               |        |                                   |             |         |         |      |         | a.i./ha |          |          |
| Onions FR F Weeds     |               |        |                                   | SC          | 125 g/L | 0-0     | 1    | –       | 250 g | n.a. One application every 2 years. Since application is done at BBCH 00, it is |
|                       |               |        |                                   |             |         |         |      |         | a.i./ha |          |          |
| Crop and/or situation | MS or country | F or T<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|----------------------|--------------|----------------|----------------------------------|-------------|------------|-------------------------------|----------------|---------|
|                      |              |                |                                  | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit | |
| Shallots             | BE, IE, NL, UK | F               | Annual dicots                    | SC          | 500 g/L    | Foliar treatment – general (see also comment field) | 11–13 | 1 | – | – | 100 g a.i./ha | > BBCH11 or after planting |
| Spring onions       | NL           | F               | Weeds                            | SC          | 500 g/L    | Foliar treatment – broadcast spraying | 9–12 | 1 | – | – | 100 g a.i./ha | n.a. | – |
| Courgettes          | UK           | F               | SC                               | 500 g/L    | 13 | Foliar treatment – general (see also comment field) | 1 | – | – | 250 g a.i./ha | n.a. | 3 true leaf stage |
| Pumpkins            | UK           | F               | SC                               | 500 g/L    | 13 | Foliar treatment – general (see also comment field) | 1 | – | – | 250 g a.i./ha | n.a. | 3 true leaf stage |
| Witloofs            | BE           | F               | Annual dicots                    | SC          | 500 g/L    | Foliar treatment – general (see also comment field) | 10–16 | 1 | – | – | 100 g a.i./ha | Dose splitting authorised |
| Chives              | FR           | F               | Weeds                            | SC          | 125 g/L    | Soil treatment – general (see also comment field) | 12–14 | 1 | – | – | 250 g a.i./ha | 90 | |

<sup>(a)</sup> Crop and/or situation, MS or country, F or T.<br>
<sup>(b)</sup> Type of preparation, Conc. a.s., Method kind.<br>
<sup>(c)</sup> Range of growth stages & season, Number min-max, Interval between application (min).<br>
<sup>(d)</sup> PHI (days).<br>

Assumed that this represents a soil treatment and that the foliar treatment refers to the weed and not the crop.
| Crop and/or situation | MS or country | FG or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|----------------------|--------------|---------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Celery leaves        | FR           | F       | Weeds                             | SC 125 g/L  | Soil treatment – general (see also comment field) | 125 g a.i./ha | 30  | Only on Sorrel (Rumex spp.) |
| Sage                 | BE           | F       | Annual dicots                     | SC 500 g/L  | Foliar treatment – general (see also comment field) | 187.5 g a.i./ha |      | After planting |
| Rosemary             | BE           | F       | Annual dicots                     | SC 500 g/L  | Foliar treatment – general (see also comment field) | 187.5 g a.i./ha |      | After planting |
| Thyme                | BE           | F       | Annual dicots                     | SC 500 g/L  | Foliar treatment – general (see also comment field) | 187.5 g a.i./ha |      | Including hyssop, oregano and lemon savoury. After planting |
| Basil                | BE           | F       | Annual dicots                     | SC 500 g/L  | Foliar treatment – general (see also comment field) | 187.5 g a.i./ha |      | Including lemon balm and min. After planting |
| Beans (without pods) | BE           | F       | Annual dicots                     | SC 500 g/L  | Foliar treatment – general (see also comment field) | 50 g a.i./ha |      | |
| Asparagus            | FR           | F       | Weeds                             | SC 107 g/L  | Foliar treatment – broadcast spraying | 267.5 g a.i./ha | n.a. | Application at BBCH 00 stage (pre-emergence) or after harvest of shoots. – Do not apply on |
| Crop and/or situation | MS or country | F or G or T<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|-----------------------------|-----------------------------------|-------------|-----------|-----------------------------|---------------------|---------|
| Leeks                 | FR            | F                           | Weeds                             | SC          | 125 g/L   | Foliar treatment – broadcast spraying | 12–14               | 1       | 250 g a.i./ha | 90     | One application every 2 years |
| Rhubarbs              | BE, NL, IE, UK| Annual dicots               | SC 500 g/L                        | Foliar treatment – general (see also comment field) | 0          | 1                                      | – –                 | 200 g a.i./ha | During dormancy Since application is done at BBCH 00, it is assumed that this represents a soil treatment and that the foliar application refers to the weed and not the crop |
| Rapeseeds             | FR            | F                           | Weeds                             | SC 125 g/L  | Soil treatment – general (see also comment field) | 14–20               | 1       | 50 g a.i./ha | n.a.  |
| Barley                | NL, BE        | F                           | Weeds                             | 500 g/L     | Foliar treatment – broadcast spraying | 11–13               | 1       | 100 g a.i./ha | n.a.  |
| Oat                   | UK            | F                           | SC 500 g/L                        | Foliar treatment – general (see also comment field) | 13         | 1                                      | – –                 | 100 g a.i./ha | BBCH 13 or Before 31st January in year of harvest whichever is soonest |
| Crop and/or situation | MS or country | FG or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|---------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| **Rye**               | UK           | F       |                                   | SC          | 500 g/L    | Foliar treatment – general (see also comment field) | 13 1      | – – 100 g a.i./ha n.a. BBCH 13 or Before 31st January in year of harvest whichever is soonest |
| **Wheat**             | UK           | F       |                                   | SC          | 500 g/L    | Foliar treatment – general (see also comment field) | 13 1      | – – 100 g a.i./ha n.a. BBCH 13 or Before 31st January in year of harvest whichever is soonest |
| **Herbal infusions from flowers** | FR | F | Weeds | SC | 125 g/L | Soil treatment – general (see also comment field) | 1 | – – 125 g a.i./ha 90 Only on Roman chamomile |
| **Herbal infusions from roots** | BE | F | Annual dicots | SC | 500 g/L | Foliar treatment – general (see also comment field) | 13 1 | – – 100 g a.i./ha n.a. Valerian, after prickings |
| **Hops**              | BE, IE, UK   | F       | Annual dicots                     | SC          | 500 g/L    | Foliar treatment – general (see also comment field) | 0–8 1      | – – 250 g a.i./ha During dormancy. Up to 30% of the crops field can be treated |
| **Chicory roots**     | BE, IE, NL, FR | F | Annual dicots                     | SC          | 500 g/L    | Foliar treatment – general (see also comment field) | 10–16 1    | – – 100 g a.i./ha Including yacon roots. Dose splitting authorised |
| Crop and/or situation | MS or country | F G or T(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-------------|------------------------------|---------------|---------|
| Clover (for forage)   | BE            | F           | Annual dicots                     | SC          | Foliar treatment - general (see also comment field) | from 10 1     | –      | 50 g a.i./ha | n.a.    |
| Grass (for forage)    | NL, BE        | F           | Weeds                             | 500 g/L     | Foliar treatment - broadcast spraying | 0–13 1        | –      | 50 g a.i./ha | n.a.    |

**Notes:**

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI – minimum preharvest interval.

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

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): MS: Member State.

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## A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|------------------------------------|-------------|-------------|--------------------------------|------------|---------|
|                       |               |                                    |             |             |                                |            |         |
| **Grapefruits**       | ES            | Dicotyledonous weeds                | SC          | 500 g/L     | Soil treatment – general       | 0          | 1       |
|                       |               |                                    |             |             | (see also comment field)       |            |         |
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| Crop and/or situation | MS or country | F G or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|----------------------|---------------|---------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
|                      |               |         |                                   | Type(b) Conc. a.s. Method kind Range of growth stages & season(e) Number min–max Interval between application (min) a.s./hL min–max Water L/ha min–max Rate and unit |           |          |                               |
| Limes                | ES            | F       | Dicotyledonous weeds              | SC 500 g/L Soil treatment – general (see also comment field) 0 1 | – – | 450 g a.i./ha | n.a. 100–400 L/ha | Application rate refers to the rate of use in the treated band (30% of the total crop area). Volume: 100–400 L/ha |
| Mandarins            | ES            | F       | Dicotyledonous weeds              | SC 500 g/L Soil treatment – general (see also comment field) 0 1 | – – | 450 g a.i./ha | n.a. 100–400 L/ha | Application rate refers to the rate of use in the treated band (30% of the total crop area). Volume: 100–400 L/ha |
| Almonds              | FR            | F       | Weeds                             | SC 125 g/L Soil treatment – general (see also comment field) 0–60 1 | – – | 600 g a.i./ha | n.a. 100–400 L/ha | |
| Chestnuts            | FR            | F       | Weeds                             | SC 125 g/L Soil treatment – general (see also comment field) 0–60 1 | – – | 600 g a.i./ha | n.a. 100–400 L/ha | |
| Crop and/or situation | MS or country | FG or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|------------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| **Hazelnuts**          | FR            | F          | Weeds                             | SC          | 125 g/L    | Soil treatment – general (see also comment field) | 0–60       | 1       | –       | –        | 600 g a.i./ha | n.a. |
| **Walnuts**            | FR            | F          | Weeds                             | SC          | 125 g/L    | Soil treatment – general (see also comment field) | 0–60       | 1       | –       | –        | 600 g a.i./ha | n.a. |
| **Apples**             | ES            | F          | Dicotyledonous weeds              | SC          | 125 g/L    | Soil treatment – spraying          | 0–69       | 1       | –       | –        | 600 g a.i./ha | n.a. |
| **Pears**              | ES, PT        | F          | Dicotyledonous weeds              | SC          | 125 g/L    | Soil treatment – general (see also comment field) | 0–69       | 1       | –       | –        | 600 g a.i./ha | n.a. |
| **Quinces**            | ES            | F          | Dicotyledonous weeds              | SC          | 125 g/L    | Soil treatment – general (see also comment field) | 0–69       | 1       | –       | –        | 600 g a.i./ha | n.a. |
| **Medlars**            | IT            | F          | Bidens bipinnata                  | SC          | 500 g/L    | Soil treatment – spraying           | 0–69       | 1       | –       | –        | 600 g a.i./ha | n.a. |

*Note: Volume: from dormancy to flowering (winter–spring).*

Volume: 100–400 L/ha

Volume: 100–400 L/ha

Volume: 400–800 L/ha

Application timing: from dormancy to flowering (winter–spring)
| Crop and/or situation | MS or country | F G or T (b) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------------|--------------|-----------------------------------|-------------|-------------|--------------------------------|---------------|---------|
|                       |               |              |                                   | Type (b)    | Concentration | Method kind | Range of growth stages & season (c) | Number min-max | Interval between application (min) | Water L/ha min-max | Rate and unit |                   |
| Loquats               | ES F          |              | Dicotyledonous weeds              | SC 125 g/L | Soil treatment general (see also comment field) | 0-69 1 | – – | 600 g a.i./ha | n.a. |
| Apricots              | ES F          |              | Dicotyledonous weeds              | SC 125 g/L | Soil treatment general (see also comment field) | 0-69 1 | – – | 600 g a.i./ha | n.a. |
| Cherries              | ES, IT F      |              | Dicotyledonous weeds              | SC 125 g/L | Soil treatment general (see also comment field) | 0-69 1 | – – | 600 g a.i./ha | n.a. |
| Peaches               | ES, IT F      |              | Dicotyledonous weeds              | SC 125 g/L | Soil treatment general (see also comment field) | 0-69 1 | – – | 600 g a.i./ha | n.a. |
| Plums                 | ES, IT F      |              | Dicotyledonous weeds              | SC 125 g/L | Soil treatment general (see also comment field) | 0-69 1 | – – | 600 g a.i./ha | n.a. |

Application rate refers to the rate of use in the treated band (30% of the total crop area).
| Crop and/or situation | MS or country | F G or T\(^{(a)}\) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI \((\text{days})\) | Remarks |
|-----------------------|--------------|-------------------|----------------------------------|------------|-------------|-------------------------------|----------------|---------|
| Table grapes          | IT           | F                 | Weeds                            | SC         | 500 g/L     | Soil treatment – spraying     | 0–14           | 1       | 750 g a.i./ha | n.a.  |
|                       |              |                   |                                  |            |             |                               |                |         | Application timing: from dormancy to leaf development Application rate refers to the rate of use in the treated band (30% of the total crop area) |
| Wine grapes           | IT           | F                 | Weeds                            | SC         | 500 g/L     | Soil treatment – spraying     | 0–14           | 1       | 750 g a.i./ha | n.a.  |
|                       |              |                   |                                  |            |             |                               |                |         | Application timing: from dormancy to leaf development Application rate refers to the rate of use in the treated band (30% of the total crop area) |
| Blueberries           | IT           | F                 | Weeds                            | SC         | 107 g/L     | Soil treatment – spraying     | 0–3            | 1       | 535 g a.i./ha | n.a.  |
|                       |              |                   |                                  |            |             |                               |                |         | mixture of isoxaben + oryzalin 429 g/L established crops. |

\(a\): Crop and/or situation; MS or country; F G or T: F: fruit, G: grain, T: tobacco; F G or T: F: fruit, G: grain, T: tobacco; Pests or group of pests controlled; Preparation: Type(b), Conc. a.s.; Method kind; Application: Range of growth stages & season(c), Number min–max, Interval between application (min); Application rate per treatment: a.s./hL min–max, Water L/ha min–max, Rate and unit; PHI: \((\text{days})\).
| Crop and/or situation | MS or country | F G or T<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|------------------------|-----------------------------------|-------------|-------------|-------------------------------|----------------|---------|
|                       |               |                        |                                   |             | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit |                       |
| Currants              | IT            | F                      | Weeds                             | SC          | 107 g/L     | Soil treatment – spraying     | 0–3            | 1                    | –              | –                  | 535 g a.i./ha | n.a. mixture of isoxaben + oryzalin 429 g/L established crops. Strip application (no more than 30% of the plot area) tractor-mounted or hand sprayer |
| Gooseberries          | IT            | F                      | Weeds                             | SC          | 107 g/L     | Soil treatment – spraying     | 0–3            | 1                    | –              | –                  | 535 g a.i./ha | n.a. mixture of isoxaben + oryzalin 429 g/L established crops. Strip application |

<sup>(a)</sup> Crop or group of pests controlled

<sup>(b)</sup> Type of preparation

<sup>(c)</sup> Method kind

<sup>(d)</sup> PHI (days)
| Crop and/or situation | MS or country | F G or T<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|-------------------------|-----------------------------------|-------------|-----------------|-----------------------------|-----------------|---------|
|                       |               |                         |                                   |             | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit | Remarks |
| Rose hips             | IT            | F                       | Weeds                             | SC          | 107 g/L         | Soil treatment – spraying   | 0–3            | 1                | –                  | –               | 535 g a.i./ha | n.a.          | mixture of isoxaben + oryzalin 429 g/L established crops. Strip application (no more than 30% of the plot area) tractor-mounted or hand sprayer |
| Kiwi fruits           | ES, FR        | F                       | Dicotyledonous weeds              | SC          | 125 g/L         | Soil treatment – general (see also comment field) | 0–14           | 1                | –                  | –               | 750 g a.i./ha | n.a.          | ES: Volume: 100–200 L/ha, FR: Do not apply on more than 30% of the surface. |
| Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|-----------------------------------|-------------|-------------|-------------------------------|-----------|---------|
|                       |              |                                   |             |             |                               |           |         |
| Bananas               | FR           | F                                 | SC          | 107 g/L     | Soil treatment general (see also comment field) | 1         | 481.5 g a.i./ha n.a. Row application only with a boom sprayer Do not apply on more than 30% of the surface of the plot |
| Garlic                | FR           | F                                 | SC          | 125 g/L     | Soil treatment general (see also comment field) | 1         | 250 g a.i./ha n.a. |
| Spring onions         | FR           | F                                 | SC          | 125 g/L     | Soil treatment general (see also comment field) | 1         | 250 g a.i./ha 90 One application every 2 years |
| Melons                | FR           | F                                 | SC          | 125 g/L     | Soil treatment general (see also comment field) | 1         | 250 g a.i./ha 45 One application every 2 years. Do not apply on more than 50% of the surface. Stage of application: early post-planting. |
| Crop and/or situation | MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-------------|-------------------------------|----------------|---------|
| **Type(b)** | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | a.s./hl min-max | Water L/ha min-max | Rate and unit |
| Chives | FR | F | Weeds | SC | 125 g/L | Soil treatment – general (see also comment field) | 12-14 | 1 | – | – | 250 g a.i./ha | 90 |
| Celery leaves | FR | F | Weeds | SC | 125 g/L | Soil treatment – general (see also comment field) | 1 | – | – | 125 g a.i./ha | 30 |
| Only on Sorrel (Rumex spp.) |
| Asparagus | FR, IT | F | Weeds | SC | 107 g/L | Foliar treatment – broadcast spraying | 0 | 1 | – | – | 267.5 g a.i./ha | n.a. |
| Application at BBCH 00 stage (pre-emergence) or after harvest of shoots. Do not apply on more than 75% of the surface in pre-emergence. Since application is done at BBCH 00, it is assumed that this represents a soil treatment |
| Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|------------------------------|------------|---------|
|                       |               |                                   | Type(b) Conc. a.s. Method kind Range of growth stages & season(c) Number min-max Interval between application (min) a.s./hL min-max Water L/ha min-max Rate and unit |                         |               |                     | |
| Rapeseeds             | FR            | Weeds                             | SC 125 g/L  | Soil treatment – general (see also comment field) | 14–20 1 | – | – | 50 g a.i./ha | n.a. |
| Cotton seeds          | ES            | Dicotyledonous weeds              | SC 500 g/L  | Foliar treatment – broadcast spraying | 0 1 | – | – | 150 g a.i./ha | n.a. |
| Barley                | ES, IT, PT    | Dicotyledonous weeds              | SC 125 g/L  | Foliar treatment – broadcast spraying | 0–13 1 | – | – | 125 g a.i./ha | n.a. |
| Oat                   | ES, IT, PT    | Dicotyledonous weeds              | SC 125 g/L  | Foliar treatment – broadcast spraying | 0–13 1 | – | – | 125 g a.i./ha | n.a. |
| Rye                   | ES, IT, PT    | Dicotyledonous weeds              | SC 125 g/L  | Foliar treatment – broadcast spraying | 0–13 1 | – | – | 125 g a.i./ha | n.a. |
### A.3. Authorised indoor uses in EU

| Crop and/or situation | MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|------------|-----------------------------------|-------------|------------|--------------------------------|---------------|---------|
| Wheat                 | ES, IT, PT    | F          | Dicotyledonous weeds              | SC 125 g/L  | Foliar treatment - broadcast spraying 0-13 1 | 125 g a.i./ha | n.a. | Volume: 100-400 L/ha |
| Herbal infusions from flowers | FR | F | Weeds | SC 125 g/L | Soil treatment – general (see also comment field) | 1 | – | – | 125 g a.i./ha | 90 | Only on Roman chamomile |
| Strawberries          | IE            | I          | Dicotyledonous weeds              | SC 500 g/L  | Soil treatment – general (see also comment field) 0 1 | 0 | – | – | 200 g a.i./ha | n.a. | Dormant stage |

**MS:** Member State.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system. Growth stage ranges from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(c): PHI – minimum preharvest interval.
(d): PHI – minimum preharvest interval.
## Appendix B – List of end points

### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Grapes      | Soil treatment, 1 × 2,008–2,204 g a.s./ha | At maturity | Radiolabelled isoxaben: U-phenyl-14C radiolabel and isoxazole-5-14C radiolabel (Sweden, 2021) |
| Leafy crops                       | Leeks       | Soil/Foliar treatment, 1 × 250 g a.s./ha | 119 (BBCH 49) | Radiolabelled isoxaben: U-phenyl-14C radiolabel and isoxazole-5-14C radiolabel (Sweden, 2021). Treatment was done as foliar spray to the immature leek plants (growth stage BBCH 14) and the surrounding soil |
| Cereals/grass                     | Barley      | Soil/Foliar treatment, 1 × 200 g a.s./ha | 7, 14, 28 and 87 days | Radiolabelled isoxaben: U-phenyl-14C radiolabel and isoxazole-5-14C radiolabel (Sweden, 2006). Treatments were done at pre-emergence to early post-emergence stage |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Radish      | Bare soil, 250 g a.s./ha | 30, 120, 189, 365 | Radiolabelled isoxaben: U-phenyl-14C radiolabel and isoxazole-5-14C radiolabel (Sweden, 2014). Phytotoxicity observed at 120 DAT |
| Leafy crops                         | Lettuce     | Bare soil, 250 g a.s./ha | 30, 120, 189, 365 | Radiolabelled isoxaben: U-phenyl-14C radiolabel and isoxazole-5-14C radiolabel (Sweden, 2014). Phytotoxicity observed at 30 DAT and 120 DAT. |
| Cereal (small grain)                | Wheat       | Bare soil, 250 g a.s./ha | 30, 120, 365 | Radiolabelled isoxaben: U-phenyl-14C radiolabel and isoxazole-5-14C radiolabel (Sweden, 2014) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Not triggered | – |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered | – |
| Sterilisation (20 min, 120°C, pH 6)      | Not triggered | – |
Can a general residue definition be proposed for primary crops? | Yes | Based on the overall evidence from metabolism studies in primary crops (soil treatment of fruits and leafy vegetables and foliar treatment of leafy vegetables at early post-emergence and cereals at pre-emergence and early post-emergence) and the metabolism in rotational crops (soil treatment of leafy vegetables, cereals and roots).

Since translocation to edible parts is not expected to occur when application is done at early stages, the available studies cover also early post-emergence applications on fruits, roots crops and pulses and oilseeds.

Rotational crop and primary crop metabolism similar? | Yes | Residue pattern in processed commodities similar to residue pattern in raw commodities?

not applicable | In all commodities residues were below 0.1 mg/kg and the total theoretical maximum daily intake is below 10% of the ADI. Therefore, the investigation of the nature of residues in processed commodities is not required.

Plant residue definition for monitoring (RD-Mo) | Soil applications and early post-emergence application: isoxaben

Plant residue definition for risk assessment (RD-RA) | Soil applications and early post-emergence application: isoxaben

Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) | Matrices with high water, high acid content and dry matrices: LC–MS/MS, LOQ 0.01 mg/kg Confirmatory method and ILV available.

(ERFSA, 2010, Sweden, 2021)

Matrices with high oil content matrices: LC–MS/MS, LOQ 0.01 mg/kg Confirmatory method and ILV available.

(Sweden, 2021)

Analytical methods for hops and herbal infusions is missing (data gap).

Based on data available to the EURLs, isoxaben can be monitored in high water content, high acid content, dry and high fat content commodities with an LOQ of 0.01 mg/kg

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

| Plant products (available studies) | Category           | Commodity      | $T$ (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|--------------------|----------------|----------|------------------|-------------------|----------------|
|                                   | High water content | Endives        | –20      | 12 Months        | Isoxaben          | EFSA (2010)    |
|                                   | High oil content   | Rapeseed       | –18      | 12 Months        | Isoxaben          | Sweden (2021)  |
|                                   | High protein content | Dry bean      | –18      | 12 Months        | Isoxaben          | Sweden (2021)  |
|                                   | High starch content | Cereal grain   | –20      | 24 Months        | Isoxaben          | EFSA (2010)    |
|                                   | High acid content  | Grapes         | –20      | 24 Months        | Isoxaben          | EFSA (2010)    |
|                                   | Others             | Straw          | –20      | 24 Months        | Isoxaben          | EFSA (2010)    |
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|-----------|-----------|---------------------------------------------------------------|-----------------|------------------------|---------------|-----------------|
| Pome fruits, Citrus fruits, Almonds, Chestnuts, Hazelnuts/cobnuts, Walnuts, Stone fruits, Kiwi | NEU | 11 × < 0.01 | Combined data set of trials on pome fruits (6 apples, 1 pear) and 4 trials on plums compliant with GAP (Sweden, 2021). Extrapolation to pome fruits, stone fruits and tree nuts is applicable. Not authorised for use on citrus fruits and kiwi in NEU. MRL\_OECD = 0.01 | 0.01* | 0.01 | 0.01 |
| | SEU | 8 × < 0.01 | Combined data set of 4 trials on apples and 4 trials on peaches compliant with GAP (Sweden, 2021). Extrapolation to citrus fruits, pome fruits, stone fruits, tree nuts and kiwi is applicable. MRL\_OECD = 0.01 | 0.01* | 0.01 | 0.01 |
| Table/Wine grapes | NEU | 8 × < 0.01 | Trials on wine and table grapes compliant with GAP (Sweden, 2021). MRL\_OECD = 0.01 | 0.01* | 0.01 | 0.01 |
| | SEU | 8 × < 0.01 | Trials on wine and table grapes compliant with GAP (Sweden, 2021). MRL\_OECD = 0.01 | 0.01* | 0.01 | 0.01 |
| Strawberries | NEU | 7 × < 0.01; 0.01 | Trials on strawberries compliant with GAP (Sweden, 2021). MRL\_OECD = 0.01 | 0.01 | 0.01 | 0.01 |
| | EU | 3 × < 0.01 | Trials on strawberries compliant with GAP (Sweden, 2021). Residues not expected to occur based on the metabolism in fruits following soil application and since the GAP is for application during dormant stage. MRL\_OECD = 0.01 | 0.01* | 0.01 | 0.01 |
| Dewberries | NEU | 10 × < 0.01; 0.01 | Extrapolation from combined data set of trials on strawberries and raspberries (Sweden, 2021) to dewberries is applicable. MRL\_OECD = 0.01 | 0.01 | 0.01 | 0.01 |
| Raspberries (red and yellow), Blackberries | NEU | 3 × < 0.01 | Trials on raspberries compliant with GAP (Sweden, 2021). Extrapolation to blackberries is applicable. Residues not expected to occur based on the metabolism in fruits following soil application and since the GAP is for application during dormant stage. MRL\_OECD = 0.01 | 0.01* | 0.01 | 0.01 |
| Commodity | Region\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) |
|-----------|-----------------|---------------------------------------------------------------|----------------|------------------------|-------------------|-------------------|
| Cranberries, Mulberries (black and white), Azaroles/Mediterranean medlars, Elderberries | NEU | 11 × < 0.01 | Extrapolation from combined data set of trials on grapes performed with 700 g a.s./ha (8) and currants (3) performed with 500–2,000 g a.s./ha to cranberries, mulberries, azaroles/Mediterranean medlars and elderberries is applicable. Overdosed trials acceptable since residues were always below the LOQ. MRL\(_{OECD} = 0.01\) | 0.01* | 0.01 | 0.01 |
| Blueberries, Gooseberries (green, red and yellow), Rose hips | NEU | 11 × < 0.01 | Extrapolation from combined data set of trials on grapes performed with 700 g a.s./ha (8) and currants (3) performed with 500–2,000 g a.s./ha to blueberries, gooseberries, rose hips, is applicable. Overdosed trials acceptable because results were always below the LOQ. MRL\(_{OECD} = 0.01\) | 0.01* | 0.01 | 0.01 |
| Currants (black, red and white) | NEU | 3 × < 0.01 | Trials on currants with application rates between 500 g a.s./ha to 2,000 g a.s./ha (Sweden, 2021), considered acceptable because results were always below the LOQ. Residues are not expected to occur based on overdosed trials and the metabolism study on fruits following soil application. MRL\(_{OECD} = 0.01\) | 0.01* | 0.01 | 0.01 |
| Bananas | SEU | < 0.01 | Trial on bananas compliant with GAP (Sweden, 2021). Reduced number of trials sufficient considering that the application is done on the soil under the tree and the results from trials on pome and stone fruits | 0.01* | 0.01 | 0.01 |
| Carrots, Horse radishes, Parsnips | NEU | 4 × < 0.05 | Trials on carrots compliant with GAP (Sweden, 2021). Extrapolation to horseradishes and parsnips is applicable. The reduced number of residue trials is considered acceptable since all trials were below the LOQ. Moreover, based on the rotational crop metabolism study, residues in these root crops are expected to remain below the LOQ of 0.01 mg/kg when isoxaben is applied according to the authorised use. Therefore, MRL and risk assessment values are proposed at 0.01 mg/kg | 0.01* | 0.01 | 0.01 |
## Commodity Region(a) Residue levels observed in the supervised residue trials (mg/kg) Comments/Source Calculated MRL (mg/kg) HR(b) (mg/kg) STMR(c) (mg/kg)

### Garlic, Onions, Shallots

**NEU**

4 × < 0.01 Residue trials performed on onions with 2 × 100 g a.s./ha (Sweden, 2021), but at a later growth stage with residues below the LOQ considered acceptable. The reduced number of residue trials is considered acceptable since all trials were below the LOQ the GAP is for an application every 2 years and the metabolism of isoxaben in roots/tuber vegetables following soil application indicates that significant residues are not expected to occur. Extrapolation to garlic and shallots is applicable.

MRL<sub>OECD</sub> = 0.01

0.01* 0.01 0.01

**SEU**

4 × < 0.01 Residue trials performed on onions with 2 × 100 g a.s./ha (Sweden, 2021) at a later growth stage, considered acceptable. Extrapolation to garlic is applicable. No authorised use on onions and shallots in the SEU.

MRL<sub>OECD</sub> = 0.01

0.01* 0.01 0.01

### Courgettes

**NEU**

4 × < 0.05 Trials on courgettes compliant with GAP (Sweden, 2021). Samples were stored up to 427 days, which is longer than the demonstrated storage stability period in high water content commodities (12 months). However, since, overall, according to the metabolism studies and the results of the trials available, isoxaben is not expected to be present at significant levels in fruits crops, an additional storage stability study is only desirable.

MRL<sub>OECD</sub> = 0.05

0.05 0.05 0.05

### Melons pumpkins

**NEU**

4 × < 0.01 Trials on pumpkins compliant with GAP (Sweden, 2021). Samples were stored for 383 days, which is slightly more than storage stability for high water commodities (12 months). However, since, overall, according to the metabolism studies and the results of the trials available, isoxaben is not expected to be present at significant levels in fruits crops, an additional storage stability study is only desirable.

MRL<sub>OECD</sub> = 0.01

0.01* 0.01 0.01

**SEU**

2 × < 0.01 Trials on melons compliant with GAP (Sweden, 2021). Information on storage stability was not reported. The reduced number of residue trials is considered acceptable in this case because results were always below the LOQ and residues in fruits are not expected to occur when

0.01* 0.01 0.01
### Commodity Region | Region<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg)
--- | --- | --- | --- | --- | --- | ---
Witloofs/Belgian endives | NEU | $5 \times < 0.01$ | isoxaben is applied following soil application. No authorised for use on pumpkins in SEU. MRL<sub>OECD</sub> = – | 0.01* | 0.01 | 0.01
Celery leaves | NEU | $2 \times < 0.01$ | Residue trials on witloofs leaves (after forcing), performed with 1.5N ($1 \times 150$ g a.s./ha) and 2N ($2 \times 100$ g a.s./ha), considered acceptable because results were always below the LOQ (Sweden, 2021). MRL<sub>OECD</sub> = 0.01 | 0.01* | 0.01 | 0.01
SEU | $2 \times < 0.01$ | The authorised use is on sorrel, and the residue trials were performed on sorrel (Sweden, 2021). The reduced number of residue trials is considered acceptable in this case because results were always below the LOQ and residues are not expected to occur in leafy crops when isoxaben is applied following soil application. The storage period was not reported (indicated as $> 30$ days). However, since, overall, according to the metabolism studies and the results of the trials available, isoxaben is not expected to be present at significant levels in leafy crops, additional information on the storage conditions are only desirable. MRL<sub>OECD</sub> = – | 0.01* | 0.01 | 0.01
Sage, Rosemary, Thyme, Basil and edible flowers | NEU | – | No residue trials available. Residues in leafy vegetables are not expected to occur when isoxaben is applied following foliar/soil treatment at early growth stages with an application up to 250 g a.s./ha. However, two residue trials are needed to confirm that no significant residues are expected. | 0.01* (tentative)<sup>(d)</sup> | 0.01 | 0.01

<sup>(a)</sup> Region: NEU = Northern Europe, SEU = Southern Europe.

<sup>(b)</sup> HR: Hazard Ratio

<sup>(c)</sup> STMR: Short-term MRL

<sup>(d)</sup> Tentative value.
| Commodity            | Region(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|----------------------|-----------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|---------------|----------------|
| Beans (without pods) | NEU       | 4 × < 0.02                                                      | Trials on beans without pods, compliant with GAP (Sweden, 2021). MRL\(_{\text{OECD}}\) = 0.02 | 0.02                   | 0.02          | 0.02           |
| Asparagus            | NEU       | 2 × < 0.01                                                      | Trials on asparagus compliant with GAP (Sweden, 2021). The reduced number of residues trials is acceptable because all results were below the LOQ and residues in the edible part are not expected to occur when isoxaben is applied according to the authorised use on asparagus. MRL\(_{\text{OECD}}\) = – | 0.01*                 | 0.01          | 0.01           |
| SEU                  | 2 × < 0.01 | Trials on asparagus compliant with GAP (Sweden, 2021). The reduced number of residues trials is acceptable because all results were below the LOQ and residues in the edible part are not expected to occur when isoxaben is applied according to the authorised use on asparagus. MRL\(_{\text{OECD}}\) = – | 0.01*                 | 0.01          | 0.01           |
| Leeks                | NEU       | 2 × < 0.01                                                      | Trials on leeks compliant with GAP (Sweden, 2021). The reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and residues in leafy vegetables and roots crops are not expected to occur when isoxaben is applied following soil treatment at early growth stages with an application rate up to 250 g a.s./ha. Extrapolation to spring onions and chives is applicable. MRL\(_{\text{OECD}}\) = – | 0.01*                 | 0.01          | 0.01           |
| SEU                  | –         | No residue trials available. No authorised for use on leeks in SEU. | –                                                                              | –                      | –             | –              |
| Rhubarbs             | NEU       | 5 × < 0.01                                                      | Trials on rhubarbs compliant with GAP (4) or overdosed (1) (500 g a.s./ha) acceptable because results were always below the LOQ (Sweden, 2021). MRL\(_{\text{OECD}}\) = 0.01 | 0.01*                 | 0.01          | 0.01           |
### Commodity Region (a) Residue levels observed in the supervised residue trials (mg/kg) Comments/Source Calculated MRL (mg/kg) HR(b) (mg/kg) STMR(c) (mg/kg)

| Commodity                  | Region | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|----------------------------|--------|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|-----------------|
| Rapeseeds/canola seeds     | NEU    | $4 \times < 0.01$                                               | Trials on oilseed rape compliant with GAP (Sweden, 2021). The reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and residues are not expected to occur based on the metabolism of isoxaben following soil application. MRL\textsubscript{OECD} = 0.01 | 0.01*                  | 0.01         | 0.01            |
|                            | SEU    | –                                                                | No residue trials available. Residues are not expected to occur based on the metabolism of isoxaben following soil application.                                                                                                                                 | –                      | –            | –              |
| Cotton seeds               | SEU    | –                                                                | No residue trials available. Residues are not expected to occur when isoxaben is applied following soil treatment. However, two residue trials are needed to confirm that no significant residues are expected. | 0.01* (tentative)      | 0.01         | 0.01            |
| Barley grains, Oat grains  | NEU    | $8 \times < 0.01$                                               | Trials on barley grain compliant with GAP (EFSA, 2010). Extrapolation to oat grains is applicable. MRL\textsubscript{OECD} = 0.01                                                                                     | 0.01*                  | 0.01         | 0.01            |
|                            | SEU    | $8 \times < 0.01$                                               | Trials on barley grain compliant with GAP (EFSA, 2010). Extrapolation to oat grains is applicable. MRL\textsubscript{OECD} = 0.01                                                                                     | 0.01*                  | 0.01         | 0.01            |
| Wheat grains, Rye grains   | NEU    | $8 \times < 0.01$                                               | Trials on wheat grain compliant with GAP (EFSA, 2010). Extrapolation to rye grain is applicable. MRL\textsubscript{OECD} = 0.01                                                                                   | 0.01*                  | 0.01         | 0.01            |
|                            | SEU    | $8 \times < 0.01$                                               | Trials on wheat grain compliant with GAP (EFSA, 2010). Extrapolation to rye grain is applicable. MRL\textsubscript{OECD} = 0.01                                                                                   | 0.01*                  | 0.01         | 0.01            |
| Herbal infusions from flowers | NEU   | –                                                                | No residue trials available. Residues are not expected to occur when isoxaben is applied following soil treatment at early growth stages with an application rate up to 250 g a.s./ha. However, two residue trials are needed to confirm that no significant residues are expected | 0.01* (tentative)      | 0.01         | 0.01            |
|                            | SEU    | –                                                                | No residue trials available. Residues are not expected to occur when isoxaben is applied following soil treatment at early growth stages with an application rate up to 250 g a.s./ha. However, two residue trials are needed to confirm that no significant residues are expected | 0.01* (tentative)      | 0.01         | 0.01            |
| Herbal infusions from roots | NEU    | $4 \times < 0.05$                                               | Extrapolated from carrots. It is noted that a dehydration factor was not applied because isoxaben was always below the LOQ and concentration of residues is not expected. | 0.01* (tentative)      | 0.01         | 0.01            |
| Commodity | Region<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|-----------|---------------------|---------------------------------------------------------------|-----------------|------------------------|-------------------|-------------------|
| Hops      | NEU                 | 3 × < 0.01                                                    | Trials on hops compliant with GAP (Sweden, 2021). Reduced number of residue trials is considered acceptable in this case because residues were all below the LOQ of 0.01 mg/kg and because the application is done during dormant stage. MRL<sub>OECD</sub> = 0.01 | 0.01* (tentative)<sup>(e)</sup> | 0.01 | 0.01 |
| Chicory roots | NEU          | 3 × < 0.01; 2 × 0.01                                            | Trials on chicory roots performed with 1.5N (1 × 150 g a.s./ha) and 2N (2 × 100 g a.s./ha) (Sweden, 2021). Considering that the trials were performed according to a more critical GAP and residues were below or at the LOQ the MRL is proposed at the LOQ of 0.01 mg/kg | 0.01* | 0.01 | 0.01 |
| Clover forage | NEU           | –                                                            | No residue trials are available | – | – | – |
| Grass forage | NEU           | –                                                            | No residue trials are available | – | – | – |
| Barley straw, Oat straw | NEU | 6 × < 0.01; 0.02; 0.03                                        | Trials on barley straw compliant with GAP (EFSA, 2010). Extrapolation to oat straw is applicable. MRL<sub>OECD</sub> = 0.04 | 0.04 (tentative)<sup>(f)</sup> | 0.03 | 0.01 |
|          | SEU               | 3 × < 0.01; 0.01; 4 × 0.02                                     | Trials on barley straw compliant with GAP (EFSA, 2010). Extrapolation to oat straw is applicable. MRL<sub>OECD</sub> = 0.04 | 0.04 (tentative)<sup>(f)</sup> | 0.02 | 0.02 |
| Wheat straw, Rye straw | NEU        | 6 × < 0.01                                                    | Trials on wheat straw compliant with GAP (EFSA, 2010). Extrapolation to rye straw is applicable. MRL<sub>OECD</sub> = 0.01 | 0.01* (tentative)<sup>(f)</sup> | 0.01 | 0.01 |
|          | SEU               | 7 × < 0.01; 0.02                                              | Trials on wheat straw compliant with GAP (EFSA, 2010). Extrapolation to rye straw is applicable. MRL<sub>OECD</sub> = 0.03 | 0.03 (tentative)<sup>(f)</sup> | 0.02 | 0.01 |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

*: 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, Country code: if non-EU trials.
(b): Highest residue.
(c): Supervised trials median residue.
(d): MRL is tentative because additional trials are needed to confirm that no significant residues are expected.
(e): MRL is tentative because analytical methods are missing.
(f): MRL for feed items are proposed on a tentative basis.
B.1.2.2. Residues in rotational crops

(a) Overall summary

|                  |                  |
|------------------|------------------|
| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No |
| Based on the results of the confined rotational crop study and soil accumulation studies, residues uptake of isoxaben and metabolites is not expected. |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered |
| –                |

B.1.2.3. Processing factors

Studies are not available and are not required.
### B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup<sup>(a)</sup> | Most critical commodity<sup>(b)</sup> | Trigger exceeded (Y/N) | Comments |
|-----------------------------|---------------------------------------------|-------------------------------------|------------------------------------|-----------------------|---------|
|                             | Median | Maximum | Median | Maximum                      |                      |         |
| Cattle (all)                | 0.001  | 0.001   | 0.03   | 0.03                         | Dairy cattle         | Carrot, culls | N   | – |
| Cattle (dairy only)         | 0.001  | 0.001   | 0.03   | 0.03                         | Dairy cattle         | Carrot, culls | N   | – |
| Sheep (all)                 | 0.001  | 0.002   | 0.03   | 0.04                         | Lamb                 | Carrot, culls | N   | – |
| Sheep (ewe only)            | 0.001  | 0.001   | 0.03   | 0.04                         | Ram/Ewe              | Carrot, culls | N   | – |
| Swine (all)                 | 0.001  | 0.001   | 0.03   | 0.03                         | Swine (finishing)    | Carrot, culls | N   | – |
| Poultry (all)               | 0.001  | 0.001   | 0.02   | 0.02                         | Poultry layer        | Carrot, culls | N   | – |
| Poultry (layer only)        | 0.001  | 0.001   | 0.02   | 0.02                         | Poultry layer        | Carrot, culls | N   | – |

<sup>(a)</sup>: When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

<sup>(b)</sup>: The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.
### B.2.1. Nature of residues and methods of analysis in livestock

Studies on livestock are not available and are not required since MRLs for livestock commodities are not needed.

### B.3. Consumer risk assessment

#### B.3.1. Consumer risk assessment

Acute risk assessment not relevant since no ARfD has been considered necessary.

| Parameter                                      | Value                                      |
|------------------------------------------------|--------------------------------------------|
| **ADI** (mg/kg bw per day)                     | 0.05 mg/kg bw per day (EFSA, 2010)         |
| **TMDI according to EFSA PRIMo**               | Not assessed in this review.               |
| **NTMDI, according to (to be specified)**      | Not assessed in this review.               |
| **Highest IEDI, according to EFSA PRIMo (rev.3.1)** | 0.7% ADI (NL, toddler)                     |
| **Main contributor:**                          | Apples: 0.2% of ADI                        |
| **NEDI (% ADI)**                               | Not assessed in this review.               |

Assumptions made for the calculations:
The calculation is based on the median residue levels derived for raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

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

| Parameter                                      | Value                                      |
|------------------------------------------------|--------------------------------------------|
| **Metabolite(s)**                              | Not assessed in this review.               |
| **ADI (mg/kg bw per day)**                     | Not assessed in this review.               |
| **Intake of groundwater metabolites (% ADI)**  | Not assessed in this review.               |

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

| Code number | Commodity            | Existing EU MRL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment        |
|-------------|----------------------|-------------------------|----------------------------------|----------------|
| 110010      | Grapefruit           | 0.02*                   | 0.01*                            | Recommended (a) |
| 110020      | Oranges              | 0.02*                   | 0.01*                            | Recommended (a) |
| 110030      | Lemons               | 0.02*                   | 0.01*                            | Recommended (a) |
| 110040      | Limes                | 0.02*                   | 0.01*                            | Recommended (a) |
| 110050      | Mandarins            | 0.02*                   | 0.01*                            | Recommended (a) |
| 120010      | Almonds              | 0.05                    | 0.01*                            | Recommended (a) |
| 120040      | Chestnuts            | 0.05                    | 0.01*                            | Recommended (a) |
| 120060      | Hazelnuts            | 0.05                    | 0.01*                            | Recommended (a) |
| 120110      | Walnuts              | 0.05                    | 0.01*                            | Recommended (a) |
| 130010      | Apples               | 0.05                    | 0.01*                            | Recommended (a) |
| 130020      | Pears                | 0.05                    | 0.01*                            | Recommended (a) |
| 130030      | Quinces              | 0.05                    | 0.01*                            | Recommended (a) |
| 130040      | Medlar               | 0.05                    | 0.01*                            | Recommended (a) |
| 130050      | Loquat               | 0.05                    | 0.01*                            | Recommended (a) |
| 140010      | Apricots             | 0.02*                   | 0.01*                            | Recommended (a) |
| 140020      | Cherries             | 0.05                    | 0.01*                            | Recommended (a) |
| 140030      | Peaches              | 0.02*                   | 0.01*                            | Recommended (a) |
| 140040      | Plums                | 0.05                    | 0.01*                            | Recommended (a) |
| 151010      | Table grapes         | 0.05                    | 0.01*                            | Recommended (a) |
| 151020      | Wine grapes          | 0.05                    | 0.01*                            | Recommended (a) |
| 152000      | Strawberries         | 0.05                    | 0.01                             | Recommended (a) |
| 153010      | Blackberries         | 0.05                    | 0.01*                            | Recommended (a) |
| 153020      | Dewberries           | 0.05                    | 0.01                             | Recommended (a) |
| 153030      | Raspberries          | 0.05                    | 0.01*                            | Recommended (a) |
| 154010      | Blueberries          | 0.05                    | 0.01*                            | Recommended (a) |
| 154020      | Cranberries          | 0.05                    | 0.01*                            | Recommended (a) |
| 154030      | Currants (red, black and white) | 0.05 | 0.01* | Recommended (a) |
| 154040      | Gooseberries         | 0.05                    | 0.01*                            | Recommended (a) |
| 154050      | Rose hips            | 0.05                    | 0.01*                            | Recommended (a) |
| 154060      | Mulberries           | 0.05                    | 0.01*                            | Recommended (a) |
| 154070      | Azarole (mediterranean medlar) | 0.05 | 0.01* | Recommended (a) |
| 154080      | Elderberries         | 0.05                    | 0.01*                            | Recommended (a) |
| 162010      | Kiwi                 | 0.02*                   | 0.01*                            | Recommended (a) |
| 163020      | Bananas              | 0.02*                   | 0.01*                            | Recommended (a) |
| 213020      | Carrots              | 0.05                    | 0.01*                            | Recommended (a) |
| 213040      | Horseradish          | 0.05                    | 0.01*                            | Recommended (a) |
| 213060      | Parsnips             | 0.05                    | 0.01*                            | Recommended (a) |
| 220010      | Garlic               | 0.02*                   | 0.01*                            | Recommended (a) |
| 220020      | Onions               | 0.02*                   | 0.01*                            | Recommended (a) |
| 220030      | Shallots             | 0.02*                   | 0.01*                            | Recommended (a) |
| 220040      | Spring onions        | 0.02*                   | 0.01*                            | Recommended (a) |
| 232030      | Courgettes           | 0.05                    | 0.05                             | Recommended (a) |
| 233010      | Melons               | 0.05                    | 0.01*                            | Recommended (a) |
| Code number | Commodity                                           | Existing EU MRL (mg/kg) | Outcome of the review |
|-------------|-----------------------------------------------------|-------------------------|----------------------|
| 233020      | Pumpkins                                           | 0.05                    | Recommended\(^{(a)}\) |
| 255000      | Witloof                                             | 0.02\(^{*}\)           | Recommended\(^{(a)}\) |
| 256020      | Chives                                              | 0.05                    | Recommended\(^{(a)}\) |
| 256030      | Celery leaves                                       | 0.05                    | Recommended\(^{(a)}\) |
| 256050      | Sage                                                | 0.05                    | Further consideration needed\(^{(b)}\) data gap #2 |
| 256060      | Rosemary                                            | 0.05                    | Further consideration needed\(^{(b)}\) data gap #2 |
| 256070      | Thyme                                               | 0.05                    | Further consideration needed\(^{(b)}\) data gap #2 |
| 256080      | Basil                                               | 0.05                    | Further consideration needed\(^{(b)}\) data gap #2 |
| 260020      | Beans (fresh, without pods)                        | 0.02\(^{*}\)           | Recommended\(^{(c)}\) |
| 270010      | Asparagus                                           | 0.05                    | Recommended\(^{(c)}\) |
| 270060      | Leek                                                | 0.02\(^{*}\)           | Recommended\(^{(c)}\) |
| 270070      | Rhubarb                                             | 0.02\(^{*}\)           | Recommended\(^{(c)}\) |
| 401060      | Rape seed                                           | 0.02\(^{*}\)           | Recommended\(^{(c)}\) |
| 401090      | Cotton seed                                         | 0.02\(^{*}\)           | Further consideration needed\(^{(b)}\) data gap #2 |
| 500010      | Barley grain                                        | 0.1                     | Recommended\(^{(c)}\) |
| 500050      | Oats grain                                          | 0.1                     | Recommended\(^{(c)}\) |
| 500070      | Rye grain                                           | 0.1                     | Recommended\(^{(c)}\) |
| 500090      | Wheat grain                                         | 0.1                     | Recommended\(^{(c)}\) |
| 631000      | Herbal infusions (dried, flowers)                   | 0.02\(^{*}\)           | Further consideration needed\(^{(b)}\) data gaps #1 and #2 |
| 633000      | Herbal infusions (dried, roots)                     | 0.02\(^{*}\)           | Further consideration needed\(^{(b)}\) data gap #1 |
| 700000      | Hops (dried), including hop pellets and unconcentrated powder | 0.05 | Further consideration needed\(^{(b)}\) data gap #1 |
| 900030      | Chicory roots                                       | 0.02\(^{*}\)           | Recommended\(^{(a)}\) |
| –           | Other commodities of plant and/or animal origin     | See Reg. 149/2008       | –                    | Further consideration needed\(^{(c)}\) |

MRL: maximum residue level

\(^{*}\): Indicates that the MRL is set at the limit of quantification.

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

\(^{(b)}\): 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 F-I in Appendix E).

\(^{(c)}\): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
**Appendix C – Pesticide Residue Intake Model (PRIMo)**

**PRIMo(EU)**

- **LOQs (mg/kg)** range from: 0.01 to: 0.01
- **ADI (mg/kg bw per day):** 0.05
- **ARfD (mg/kg bw):** Not necessary
- **Source of ADI:** EFSA
- **Source of ARfD:** EFSA

**EFSA PRIMo revision 3.1; 2019/03/19**

**Year of evaluation:** 2010

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
|--------------------------------|-----------------------------------|-----------------------------------------------|
| Pears                          | 0.7%                              | 0.6%                                           |
| Oranges                        | 0.6%                              | 0.5%                                           |
| Bananas                        | 0.4%                              | 0.3%                                           |
| Apples                         | 0.3%                              | 0.2%                                           |
| Oranges                        | 0.3%                              | 0.2%                                           |
| Apples                         | 0.3%                              | 0.2%                                           |
| Oranges                        | 0.3%                              | 0.2%                                           |
| Wine grapes                    | 0.3%                              | 0.2%                                           |
| Wine grapes                    | 0.3%                              | 0.2%                                           |
| Apples                         | 0.2%                              | 0.2%                                           |
| Wine grapes                    | 0.2%                              | 0.2%                                           |
| Apples                         | 0.2%                              | 0.2%                                           |
| Wine grapes                    | 0.2%                              | 0.2%                                           |
| Apples                         | 0.2%                              | 0.2%                                           |
| Wine grapes                    | 0.2%                              | 0.2%                                           |
| Apples                         | 0.2%                              | 0.2%                                           |
| Wine grapes                    | 0.2%                              | 0.2%                                           |

**Comments:**

- **PL general:** Apples
- **UK toddler:** Apples
- **Wheat**
- **Courgettes**
- **Apples**
- **Wine grapes**

**Conclusion:**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of isoxaben is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

## Show results for all crops

### Unprocessed commodities

| Results for children | Results for adults |
|----------------------|--------------------|
| No. of commodities for which ARfD/ADI is exceeded (ESTI): | No. of commodities for which ARfD/ADI is exceeded (ESTI): |

| Highest % of ARfD/ADI | Commodities | MRL/input for RA | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input for RA | Exposure (µg/kg bw) |
|-----------------------|-------------|------------------|---------------------|-----------------------|-------------|------------------|---------------------|

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (ESTI calculation)

### Processed commodities

| Results for children | Results for adults |
|----------------------|--------------------|
| No. of processed commodities for which ARfD/ADI is exceeded (ESTI): | No. of processed commodities for which ARfD/ADI is exceeded (ESTI): |

| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL/input for RA | Exposure (µg/kg bw) |
|-----------------------|-----------------------|------------------|---------------------|-----------------------|-----------------------|------------------|---------------------|

Expand/collapse list

Conclusion:
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: isoxaben** |                       |                        |                       |         |
| Barley straw         | 0.02                  | STMR                   | 0.03                 | HR      |
| Oat straw            | 0.02                  | STMR                   | 0.03                 | HR      |
| Rye straw            | 0.01                  | STMR                   | 0.02                 | HR      |
| Triticale straw      | 0.01                  | STMR                   | 0.02                 | HR      |
| Wheat straw          | 0.01                  | STMR                   | 0.02                 | HR      |
| Carrot culls         | 0.01*                 | STMR                   | 0.01*                | HR      |
| Barley grain         | 0.01*                 | STMR                   | 0.01*                | STMR    |
| Oat grain            | 0.01*                 | STMR                   | 0.01*                | STMR    |
| Rye grain            | 0.01*                 | STMR                   | 0.01*                | STMR    |
| Triticale grain      | 0.01*                 | STMR                   | 0.01*                | STMR    |
| Wheat grain          | 0.01*                 | STMR                   | 0.01*                | STMR    |
| Apple pomace, wet    | 0.01*                 | STMR<sup>(a)</sup>     | 0.01*                | STMR<sup>(a)</sup> |
| Brewer’s grain dried | 0.01*                 | STMR<sup>(a)</sup>     | 0.01*                | STMR<sup>(a)</sup> |
| Canola (Rape seed) meal | 0.01*               | STMR<sup>(a)</sup>     | 0.01*                | STMR<sup>(a)</sup> |
| Citrus dried pulp    | 0.01*                 | STMR<sup>(a)</sup>     | 0.01*                | STMR<sup>(a)</sup> |
| Distiller’s grain dried | 0.01*              | STMR<sup>(a)</sup>     | 0.01*                | STMR<sup>(a)</sup> |
| Rape meal            | 0.01*                 | STMR<sup>(a)</sup>     | 0.01*                | STMR<sup>(a)</sup> |
| Wheat gluten meal    | 0.01*                 | STMR<sup>(a)</sup>     | 0.01*                | STMR<sup>(a)</sup> |
| Wheat milled by-products | 0.01*              | STMR<sup>(a)</sup>     | 0.01*                | STMR<sup>(a)</sup> |

STMR: supervised trials median residue; HR: highest residue.
*: Indicates that the input value is proposed at the limit of quantification.
(a): For fruit pomace, cereal bran and/or oilseed meals, no default processing factor was applied because isoxaben is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

D.2. Consumer risk assessment

| Commodity              | Chronic risk assessment |
|------------------------|-------------------------|
|                       | Input value (mg/kg)     | Comment |
| **Risk assessment residue definition: isoxaben** |                       |         |
| Grapefruits            | 0.01*                   | STMR    |
| Oranges                | 0.01*                   | STMR    |
| Lemons                 | 0.01*                   | STMR    |
| Limes                  | 0.01*                   | STMR    |
| Mandarins              | 0.01*                   | STMR    |
| Almonds                | 0.01*                   | STMR    |
| Chestnuts              | 0.01*                   | STMR    |
| Hazelnuts/cobnuts      | 0.01*                   | STMR    |
| Walnuts                | 0.01*                   | STMR    |
| Apples                 | 0.01*                   | STMR    |
| Pears                  | 0.01*                   | STMR    |
| Quinces                | 0.01*                   | STMR    |
| Medlars                | 0.01*                   | STMR    |
| Loquats/Japanese medlars | 0.01*              | STMR    |
| Apricots               | 0.01*                   | STMR    |
| Commodity                                      | Chronic risk assessment | Input value (mg/kg) | Comment  |
|------------------------------------------------|-------------------------|---------------------|----------|
| Cherries (sweet)                               |                         | 0.01*               | STMR     |
| Peaches                                        |                         | 0.01*               | STMR     |
| Plums                                          |                         | 0.01*               | STMR     |
| Table grapes                                   |                         | 0.01*               | STMR     |
| Wine grapes                                    |                         | 0.01*               | STMR     |
| Strawberries                                   |                         | 0.01*               | STMR     |
| Blackberries                                   |                         | 0.01*               | STMR     |
| Dewberries                                     |                         | 0.01*               | STMR     |
| Raspberries (red and yellow)                   |                         | 0.01*               | STMR     |
| Blueberries                                    |                         | 0.01*               | STMR     |
| Cranberries                                    |                         | 0.01*               | STMR     |
| Currants (black, red and white)                |                         | 0.01*               | STMR     |
| Gooseberries (green, red and yellow)           |                         | 0.01*               | STMR     |
| Rose hips                                      |                         | 0.01*               | STMR     |
| Mulberries (black and white)                   |                         | 0.01*               | STMR     |
| Azaroles/Mediterranean medlars                 |                         | 0.01*               | STMR     |
| Elderberries                                   |                         | 0.01*               | STMR     |
| Kiwi fruits (green, red, yellow)               |                         | 0.01*               | STMR     |
| Bananas                                        |                         | 0.01*               | STMR     |
| Carrots                                        |                         | 0.01*               | STMR     |
| Horseradishes                                  |                         | 0.01*               | STMR     |
| Parsnips                                       |                         | 0.01*               | STMR     |
| Garlic                                         |                         | 0.01*               | STMR     |
| Onions                                         |                         | 0.01*               | STMR     |
| Shallots                                       |                         | 0.01*               | STMR     |
| Spring onions/green onions and Welsh onions    |                         | 0.01*               | STMR     |
| Courgettes                                     |                         | 0.05                | STMR     |
| Melons                                         |                         | 0.01*               | STMR     |
| Pumpkins                                       |                         | 0.01*               | STMR     |
| Witloofs/Belgian endives                       |                         | 0.01*               | STMR     |
| Chives                                         |                         | 0.01*               | STMR     |
| Celery leaves                                  |                         | 0.01*               | STMR     |
| Sage                                           |                         | 0.01*               | STMR     |
| Rosemary                                       |                         | 0.01*               | STMR     |
| Thyme                                          |                         | 0.01*               | STMR (tentative) |
| Basil and edible flowers                       |                         | 0.01*               | STMR (tentative) |
| Beans (without pods)                           |                         | 0.02                | STMR     |
| Asparagus                                      |                         | 0.01*               | STMR     |
| Leeks                                          |                         | 0.01*               | STMR     |
| Rhubarbs                                       |                         | 0.01*               | STMR     |
| Rapeseeds/canola seeds                         |                         | 0.01*               | STMR     |
| Cotton seeds                                   |                         | 0.01*               | STMR (tentative) |
| Barley grains                                  |                         | 0.01*               | STMR     |
| Oat grains                                     |                         | 0.01*               | STMR     |
| Rye grains                                     |                         | 0.01*               | STMR     |
| Wheat grains                                   |                         | 0.01*               | STMR     |
| Herbal infusions from flowers                  |                         | 0.01*               | STMR (tentative) |
| Herbal infusions from roots                    |                         | 0.01*               | STMR (tentative) |
### Commodity

| Commodity       | Chronic risk assessment | Input value (mg/kg) | Comment          |
|-----------------|-------------------------|---------------------|------------------|
| Hops            |                         | 0.01*               | STMR (tentative) |
| Chicory roots   |                         | 0.01                | STMR             |

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

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg GM in EU?
  - Yes
    - MRL And RA derived in Section 3?
      - No
        - Is RD RA derived for this commodity?
          - No
            - MRL fully supported by data?
              - Yes
                - Median/highest values are included in the RA.
              - No
                - Risk identified?
                  - Yes
                    - Tentative median/highest values are included in the RA.
                  - No
                    - Fail-back MRL available?
                      - Yes
                        - Median/highest values are included in the RA.
                      - No
                        - Fail-back MRL available?
                          - Yes
                            - Median/highest values are included in the RA.
                          - No
                            - Tentative median/highest values are included in the RA.
  - No
    - Not considered for the RA.

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

- Current EU MRL is included in the RA.
  - Tentative median/highest values are included in the RA.
    - Risk identified?
      - Yes
        - Median/highest values are included in the RA.
      - No
        - Fail-back MRL available?
          - Yes
            - Median/highest values are included in the RA.
          - No
            - Fail-back MRL available?
              - Yes
                - Median/highest values are included in the RA.
              - No
                - Tentative median/highest values are included in the RA.
- Not considered for the RA.
  - Fail-back MRL available?
    - Yes
      - Median/highest values are included in the RA.
    - No
      - Tentative median/highest values are included in the RA.

Recommendations resulting from EU authorisations and import tolerances

- Fail-back MRL available?
  - Yes
    - Median/highest values are included in the RA.
  - No
    - Tentative median/highest values are included in the RA.

(A) Specific LOQ or default MRL?
(B) Specific LOQ or default MRL?
(C) Specific LOQ or default MRL?
(D) Maintain current EU MRL?
(E) Specific LOQ or default MRL?
(F) Establish tentative EU MRL?
(G) Specific LOQ or default MRL?
(H) MRL is recommended.
Review of the existing MRLs for isoxaben

Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes
  - RD comparable?
    - Yes
    - CXL higher?
      - Yes
      - Maintain EU recommendation indicating that CXL is available.
    - No
    - CXL higher?
      - No
      - Maintain current CXL or EU recommendation?
        - Yes
        - CXL is recommended; EU recommendation is covered as well.
        - No
        - CXL higher?
          - No
          - Risk identified?
            - Yes
            - Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
            - No
            - Input values for the RA remain unchanged.
              - No
              - CXL supported by data?
                - Yes
                - Codex median/highest residues are included in the RA.
                - No
                - CXL higher?
                  - No
                  - Input values for the RA remain unchanged.
                    - No
                    - RD comparable?
                      - Yes
                      - CXL higher?
                        - Yes
                        - Maintain EU recommendation indicating CXL is not compatible.
                      - No
                      - Input values for the RA remain unchanged.
                        - No
                        - Risk identified?
                          - Yes
                          - Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
                          - No
                          - Input values for the RA remain unchanged.
                            - No
                            - Result EU assessment
                              - Review of the existing MRLs for isoxaben

Consumer risk assessment with consideration of the existing CXL

- Input values for the RA remain unchanged.
- CXL is included in the RA.
- Codex median/highest residues are included in the RA.
- Risk identified?
  - Yes
  - Input values for the RA remain unchanged.
    - No
    - Result EU assessment
      - Review of the existing MRLs for isoxaben

Recommendations with consideration of the existing CXL

- Maintain EU recommendation indicating that no CXL is available.
- Maintain EU recommendation indicating CXL is not compatible.
- Maintain EU recommendation indicating that CXL is covered.
- Maintain current CXL or EU recommendation?
  - Yes
  - CXL is recommended; EU recommendation is covered as well.
  - No
  - Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
### Appendix F – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|--------------------------------|-------------------------------------------------|---------------------------------|
| isoxaben                      | \(N\{3\{1\text{-ethyl}-1\text{-methylpropyl}\text{isoxazol-5-yl}\}\}2,6\text{-dimethoxybenzamide}\)  
PMHURSZHKJGBM-UHFFFAOYSA-N  
CCC(C)(CC)c1cc(NC(=O)c2c(OC)cccc2OC)on1 | ![Structural formula for isoxaben](image) |
| hydroxy isoxaben or 2-hydroxy isoxaben | \(N\{3\{[(2RS)-2\text{-hydroxybutan-2-yl]}\}1,2\text{-oxazol-5-yl}\}2,6\text{-dimethoxybenzamide}\) | ![Structural formula for hydroxy isoxaben](image) |
| 1-hydroxy isoxaben            | \(N\{3\{[(2RS)-1\text{-hydroxybutan-2-yl]}\}1,2\text{-oxazol-5-yl}\}2,6\text{-dimethoxybenzamide}\) | ![Structural formula for 1-hydroxy isoxaben](image) |
| 3-hydroxy isoxaben            | \(N\{3\{[(2RS,3RS)-3\text{-hydroxybutan-2-yl]}\}1,2\text{-oxazol-5-yl}\}2,6\text{-dimethoxybenzamide}\) | ![Structural formula for 3-hydroxy isoxaben](image) |
| oxypropyl isoxaben            | 2,6-dimethoxy-\(N\{3\{[(3RS)-3\text{-methyl-2-oxopentan-3-yl]}\}1,2\text{-oxazol-5-yl}\}benzamide\) | ![Structural formula for oxypropyl isoxaben](image) |

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

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

<sup>(b)</sup> ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).

<sup>(c)</sup> ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).