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

European Food Safety Authority (EFSA), Maria Anastassiadou, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Maqrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Marianna Raczyk, Hermine Reich, Silvia Ruocco, Angela Sacchi, Miguel Santos, Alois Stanek, 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 bupirimate. To assess the occurrence of bupirimate 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 (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.

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

Requestor: European Commission

Question number: EFSA-Q-2009-00034

Correspondence: pesticides.mrl@efs.europa.eu
Acknowledgement: EFSA wishes to thank the rapporteur Member State the Netherlands for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2019. Reasoned opinion on the review of the existing maximum residue levels for bupirimate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(7):5757, 57 pp. https://doi.org/10.2903/j.efsa.2019.5757

ISSN: 1831-4732

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Summary

Bupirimate was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/25/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 17 July 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 17 August 2017 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS) the Netherlands to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 22 February 2018. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report were provided by the RMS to EFSA on 3 July 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURL, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008, EFSA prepared in March 2019 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 4 April 2019 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of bupirimate was investigated in primary crops (fruits only) and rotational crops. According to the results of the metabolism studies, the residue definition for risk assessment can be proposed as sum of bupirimate, ethirimol and de-ethyl ethirimol, expressed as bupirimate. For enforcement, two residue definitions are proposed: (1) bupirimate and (2) ethirimol (to cover the presence of this active substance, not approved in the European Union (EU)), from the use of bupirimate. The residue definition applies to fruit crops only. These residue definitions are also applicable to processed commodities and rotational crops. Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water and high acid content matrices at the limit of quantification (LOQ) of 0.01 mg/kg. The EURLs reported that bupirimate and ethirimol can be monitored in all four main plant matrices.

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities belonging to the fruit crops, except for table/wine grapes and aubergines for which only tentative MRL proposals and risk assessment values were derived and for ethirimol in aubergines for which data was not sufficient to derive MRLs and risk assessment values. For all other crops, data were not sufficient to derive MRLs and risk assessment values.

Bupirimate 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. The calculated dietary burden for cattle (all) was found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Further investigation of residues as well as the setting of MRLs in bovine/equine products (muscle, fat, liver and kidney) was necessary.

The metabolism of bupirimate residues in livestock was investigated in lactating goats at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, no residues are expected to be transferred in the different tissues. The residue definition for enforcement and risk assessment in bovine/equine tissues was proposed as de-ethyl ethirimol. It was noted that no analytical methods for the enforcement of the proposed residue definition were available.

The above-mentioned metabolism study was sufficient to conclude that MRLs and risk assessment values in all ruminants tissues could be established at the LOQ level. However, in the absence of analytical methods for enforcement of de-ethyl ethirimol in animal matrices, tentative MRLs were proposed at an indicative LOQ of 0.01 mg/kg.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo).
commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 36% acceptable daily intake (ADI) (UK toddler). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for bupirimate and ethirimol.
# Table of contents

Abstract................................................................................................................................................... 1  
Summary................................................................................................................................................. 3  
Background ............................................................................................................................................. 6  
The active substance and its use pattern ................................................................................................. 7  
The active substance and its use pattern ................................................................................................. 7  
Terms of Reference .................................................................................................................................. 7  
Assessment.............................................................................................................................................. 8  
1. Residues in plants .......................................................................................................................... 8  
1.1. Nature of residues and methods of analysis in plants ................................................................. 8  
1.1.1. Nature of residues in primary crops .......................................................................................... 8  
1.1.2. Nature of residues in rotational crops ..................................................................................... 9  
1.1.3. Nature of residues in processed commodities ......................................................................... 9  
1.1.4. Methods of analysis in plants ................................................................................................. 9  
1.1.5. Stability of residues in plants .................................................................................................. 9  
1.1.6. Proposed residue definitions.................................................................................................. 10  
1.2. Magnitude of residues in plants .................................................................................................. 10  
1.2.1. Magnitude of residues in primary crops ............................................................................... 10  
1.2.2. Magnitude of residues in rotational crops ........................................................................... 10  
1.2.3. Magnitude of residues in processed commodities ............................................................... 11  
1.2.4. Proposed MRLs ................................................................................................................... 11  
2. Residues in livestock ....................................................................................................................... 12  
2.1. Nature of residues and methods of analysis in livestock ........................................................... 12  
2.2. Magnitude of residues in livestock ........................................................................................... 12  
3. Consumer risk assessment .............................................................................................................. 13  
Conclusions.............................................................................................................................................. 13  
Recommendations.................................................................................................................................... 14  
References............................................................................................................................................... 16  
Abbreviations ........................................................................................................................................... 17  
Appendix A – Summary of authorised uses considered for the review of MRLs ..................................... 19  
Appendix B – List of end points ....................................................................................................... 30  
Appendix C – Pesticide Residue Intake Model (PRIMo) ........................................................................ 51  
Appendix D – Input values for the exposure calculations .................................................................. 53  
Appendix E – Decision tree for deriving MRL recommendations ...................................................... 55  
Appendix F – Used compound codes ............................................................................................... 57
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.

Bupirimate was included in Annex I to Council Directive 91/414/EEC on 1 June 2011 by means of Commission Directive 2011/25/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, in the framework of Commission Regulation (EC) No 33/2008\(^7\) Bupirimate was evaluated by the Netherlands, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2010). The approval of Bupirimate is restricted to uses as fungicide.

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

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

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

As the basis for the MRL review, on 17 July 2017, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 17 August 2017 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation 12 Member States provided feedback on their national authorisations of bupirimate. Based on the GAP data submitted, the designated RMS the Netherlands was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the critical GAPs by 22 February 2018.

---

\(^1\) 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 2011/25/EU of 3 March 2011 amending Council Directive 91/414/EEC to include bupirimate as active substance and amending Commission Decision 2008/934/EC. OJ L No 59, 4.3.2011, p. 32–36.

\(^4\) 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.
On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked the Netherlands to complete the PROF ile and to prepare a supporting evaluation report. The PROF ile and the supporting evaluation report, were submitted to EFSA on 3 July 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, EFSA prepared in March 2019 a draft reasoned opinion, which was circulated to Member States for commenting via a written procedure. All comments received by 4 April 2019 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Netherlands, 2018), taking into account also the information provided by Member States during the collection of data, and the EURL report on analytical methods (EURL, 2018) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2019a) and the Member States consultation report (EFSA, 2019b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROF ile 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**

Bupirimate is the ISO common name for 5-butyl-2-ethylamino-6-methylpyrimidine-4-yl dimethylsulfamate (IUPAC).

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

The EU MRLs for bupirimate are established in Annexes IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for bupirimate are not available. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

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

| Procedure      | Legal implementation | Remarks                                      |
|----------------|----------------------|----------------------------------------------|
| MRL application| Regulation (EC) No 2015/846<sup>(a)</sup> | Modification of the existing MRLs for bupirimate in several crops |

MRL: maximum residue level.

(a): Commission Regulation (EU) 2015/846 of 28 May 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, ametocradin, amisulbrom, bupirimate, clofentezine, ethophon, ethirimol, fluopicolide, imazapic, propamocarb, pyraclostrobin and taufluvinate in or on certain products. OJ L 140, 5.06.2015, p. 1-49.

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

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Netherlands, 2018);
- the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (Netherlands, 2007);
- the additional report (AR) and the final addendum to the additional report prepared under Commission Regulation (EC) No 33/2008 (Netherlands, 2009, 2010);
- the conclusion on the peer review of the pesticide risk assessment of the active substance bupirimate (EFSA, 2010);
- the previous reasoned opinion on bupirimate (EFSA, 2014).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; 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 bupirimate was investigated on apple using topical application and in melons and strawberries following foliar application (Netherlands, 2010), and assessed in the framework of the peer review (EFSA, 2010). New metabolism studies using foliar application on apples, strawberries and melons are available (Netherlands, 2018), but these studies were not peer-reviewed. In all studies bupirimate was radiolabelled in the pyrimidine ring of the molecule.

After four foliar applications of 250–280 g a.s./ha on strawberries and melons, bupirimate was extensively metabolised in plants and only detected shortly after application (27–46% total radioactive residue (TRR) at 3-day preharvest interval (PHI)), while after 14 days, no compound represents more than ca 10% of TRR (EFSA, 2010). In strawberry fruit, 14 days after the last treatment, the main identified metabolites were bupirimate (0.027 mg eq/kg) ethirimol (0.031 mg eq/kg), hydroxylethirimol (0.044 mg eq/kg) and de-ethylated ethirimol (0.012 mg eq/kg). In melon flesh, 3 days after the last treatment, the main identified metabolites were ethirimol (0.012 mg eq/kg), hydroxylethirimol (0.022 mg eq/kg) and de-ethylated ethirimol (0.011 mg eq/kg), whereas bupirimate was not detected.

After four foliar applications of 225 g a.s./ha on apples, the major identified compounds were parent bupirimate at 18% TRR (0.043 mg eq/kg), ethirimol at 9.3% TRR (0.022 mg eq/kg), de-ethylated ethirimol at 3.5% TRR (0.008 mg eq/kg) (Netherlands, 2018). Unidentified compounds did not exceed 5.9% of TRR. Metabolite MF10B (hydroxylethirimol) was not present in any of the extracts. In apple flesh 14 days after last treatment, no compound was present at relevant levels, whereas in apple peel, bupirimate was present at 10.3% TRR (0.024 mg eq/kg) and ethirimol at 6.6%TRR (0.061 mg eq/kg).

After four foliar applications of 375 g a.s./ha on melons, the major identified compounds were parent bupirimate at 36% TRR (0.084 mg eq/kg), ethirimol at 3.6% TRR (0.008 mg eq/kg), de-ethylated ethirimol at 5.8% TRR (0.014 mg eq/kg) and ethyl guanidine at 1.6% TRR (0.004 mg eq/kg) (Netherlands, 2018). Unidentified compounds did not exceed 3.1% of TRR (0.007 mg eq/kg). Metabolite hydroxylethirimol was not present in any of the extracts. The only compounds present at relevant levels 1 day after the last treatment were bupirimate in melon peel (29.7% TRR, 0.07 mg eq/kg) and de-ethylated ethirimol in melon flesh (5.8% TRR, 0.014 mg eq/kg).

After four foliar applications of 250 g a.s./ha on strawberries, unchanged bupirimate accounted for 44.3% TRR (0.703 mg eq/kg), whereas de-ethylated bupirimate was present at 4.9% TRR

---

8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127–175.
(0.077 mg eq/kg) and ethirimol at 8.1% TRR (0.128 mg eq/kg) (Netherlands, 2018). Metabolite hydroxyl-ethirimol was not present in any of the extracts. The only compounds present at relevant levels 3 days after last treatment were bupirimate, de-ethylated ethirimol and ethirimol, present in the fruit at 0.56, 0.024 and 0.0118 mg eq/kg, respectively.

The metabolism studies on fruits were sufficient to depict the metabolic pathway of bupirimate in this crop group. Metabolism studies on leafy vegetables, roots and pulses and oilseeds were not available. Therefore, GAPs belonging to those crop categories are not supported by a primary crop metabolism study. Consequently, a data gap is identified regarding the nature of residues in primary crops for leafy vegetables, roots and pulses and oilseeds.

1.1.2. Nature of residues in rotational crops

Bupirimate is authorised on crops that may be grown in rotation. The worst-case DT$_{90}$ field is 396 days for bupirimate (EFSA, 2010). For ethirimol the maximum field DT$_{90}$ is 27 days so accumulation from use over the years would not be expected.

One confined rotational crop study with bupirimate radiolabelled on the pyrimidine ring was available for this review (Netherlands, 2007, 2010; EFSA, 2010). Bupirimate was applied at a rate of 1.04 kg a.s./ha onto bare soil. Wheat forage, spinach and turnip were planted at nominal plant-back intervals (PBI) of 30, 120 and 365 days after treatment (DAT). Bupirimate and ethirimol were present at concentrations between ~0.001 and 0.015 mg/kg (~0.4-7.6% TRR). Metabolite de-ethylated ethirimol was found in some samples and its concentration was highest in wheat straw at 0.015–0.081 mg/kg (EFSA, 2010). The metabolism was also seen to be very extensive in rotational crops, with a large number of fractions characterised, the only identified compounds being bupirimate, ethirimol and de-ethylated ethirimol. The metabolism and distribution of bupirimate in rotational crops is similar to the metabolic pathway observed in primary crops.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities are available (Netherlands, 2007; EFSA, 2010). Studies were conducted with radiolabelled bupirimate on the pyrimidine ring simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). Breakdown of parent bupirimate was less than 10% under all three conditions with the formation of ethirimol (less than 4%) and other metabolites at less than 2% (EFSA, 2010). The same residue pattern as for raw commodities was proposed for processed commodities (EFSA, 2010).

1.1.4. Methods of analysis in plants

During the peer-review, a method based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) was available to monitor bupirimate and ethirimol residues in high water content commodities (EFSA, 2010) and in high acid commodities (Netherlands, 2010) with a limit of quantification (LOQ) validated at 0.01 mg/kg for each compound. In addition, during the peer review it was concluded that bupirimate and ethirimol can be incorporated in the multi-residue method DFG S19, extended version (EFSA, 2010).

The EURLs reported that bupirimate and ethirimol can be monitored in high water content and high acid content commodities with a LOQ of 0.005 mg/kg and in high oil content and dry commodities with a LOQ of 0.01 mg/kg using a multi-residue QuEChERS (LC-MS/MS) (EURL, 2018).

Since analytical methods are missing for matrices which are difficult to analyse such as hops, a data gap is set for this crop.

1.1.5. Stability of residues in plants

The storage stability of bupirimate and metabolite ethirimol was investigated in the framework of the peer review (EFSA, 2010) and in new studies submitted under this review (Netherlands, 2018). In the framework of the peer-review, storage stability studies showed that bupirimate and ethirimol are stable in high water content matrices for up to 24 and 17 months, respectively (EFSA, 2010).

The new studies reported by the RMS demonstrated the storage stability of bupirimate, ethirimol and de-ethylated ethirimol (separately) for up to 12 months in high water content (apple), high acid content (strawberry), high oil content (sunflower seed), dry commodities (wheat grain, dry bean), and processed commodities (strawberry jam) (Netherlands, 2018).
The above results demonstrate that bupirimate, ethirimol and de-ethyl ethirimol are stable for a period of at least 12 months in all four main plant matrices. It is noted that no specific study is available for the storage stability in 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 is considered applicable to hops.

1.1.6. Proposed residue definitions

The metabolism of bupirimate was assessed in fruits only. The metabolism in rotational crops is similar to the metabolism observed in primary crops and the processing of bupirimate is not expected to modify the nature of residues. In the framework of the peer-review a residue definition for risk assessment was defined as the sum of bupirimate, ethirimol, hydroxy-ethirimol and de-ethyl ethirimol expressed as bupirimate (EFSA, 2010). According to new metabolism studies and residue trials (Netherlands, 2018), the inclusion of metabolite hydroxyl ethirimol seems to be no longer justified as this compound was not detected in the new metabolism studies and is not present in the residue trials where it was analysed for. Therefore, the residue definition for risk assessment is proposed as follows: Sum of bupirimate, ethirimol and de-ethyl ethirimol, expressed as bupirimate.

As the parent compound was found to be a sufficient marker, the residue definition for enforcement is proposed as bupirimate. Ethirimol is also an active substance, although not approved for use as a pesticide in the EU. Consequently, a separate residue definition for enforcement to cover the residues of ethirimol resulting from the application of bupirimate is needed. Therefore, two residue definitions for enforcement are proposed: (1) bupirimate and (2) ethirimol. These residue definitions for enforcement and risk assessment apply to fruits only.

An analytical method for the enforcement of the proposed residue definitions at the LOQ of 0.01 mg/kg in high water content matrices (EFSA, 2010) and in high acid content matrices (Netherlands, 2014, 2018) is available. The EURLs reported that bupirimate and ethirimol can both be monitored in all four plant matrices (EURL, 2018).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of bupirimate residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Netherlands, 2018) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2010) or in the framework of a previous MRL application (EFSA, 2014). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Residue trials are not available to support the authorisations on radishes, peas (without pods), hops and sugar beet (roots and tops). Residue trials on globe artichokes were reported, however since there is no metabolism study on leafy vegetables these trials cannot be used to derive MRL and risk assessment values for globe artichokes. For aubergines, underdosed residue trials on tomatoes could not be used to derive an MRL for ethirimol and a conversion factor for risk assessment, since in these trials there were no quantifiable residues of ethirimol and the data could not be upscaled using the proportional approach. Therefore, MRL and risk assessment values for bupirimate and/or ethirimol could not be derived for all the above-mentioned crops and the following data gaps were identified:

- Radishes: Four trials on radishes compliant with the southern outdoor GAP are required.
- Peas (without pods): Eight trials on peas (without pods) compliant with the southern outdoor GAP are required.
- Hops: Four trials on hops compliant with the southern outdoor GAP are required.
- Sugar beet (roots and tops): Eight trials on sugar beet roots compliant with the southern outdoor GAP are required.
- Aubergines: Four trials on aubergines compliant with the southern and indoor GAPs are required (data gap relevant for deriving an MRL for ethirimol and a robust conversion factor for risk assessment).
• Globe artichokes: Four trials on globe artichokes compliant with the southern outdoor GAP are required.

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

• Table/wine grapes: in the available southern residue trials, samples were only analysed for bupirimate and ethirimol. Although tentative MRL and risk assessment values can be derived from these data, eight trials analysed for all the components in the residue definition for risk assessment are still required.

• Strawberries: only a limited number of trials were analysed for all components of the residue definition for risk assessment. However, this is acceptable considering the overall data which allowed deriving a conversion factor. Therefore, no additional trials are required.

1.2.2. Magnitude of residues in rotational crops

There were no studies investigating the magnitude of residues in rotational crops.

Considering the most critical GAP currently authorised on crops that can be rotated (GAP for aubergines, SEU and indoor uses: 4 × 750 g a.s./ha at BBCH 13-87 with 10-day application interval) the total soil concentration of bupirimate (predicted environmental concentration (PEC) soil total) resulting from the multiannual use of bupirimate at the critical GAP (PEC plateau background) plus from the maximal seasonal application rate is calculated as 0.8398 mg/kg immediately after the last application decreasing to 0.8036 4 days later and 0.7791 mg/kg 7 days later.

These results suggest that the confined rotational crops study where the measured soil concentrations ranged from 0.07 to 0.50 mg eq/kg soil, immediately after application, was under dosed when compared to the predicted concentration in the soil from the use over the years.

From the confined rotational crops study residues are not expected at significant levels in rotated crops except for wheat straw (see Section 1.1.3). However, since the study was under dosed, it cannot be excluded that there is uptake of residues by crops grown in rotation.

Therefore, studies on the magnitude of residues in rotational crops, covering the calculated plateau in soil, are needed to confirm if residue levels in rotated crops are expected to occur at significant levels (data gap).

Pending the submission of these studies, Member States granting national authorisations for bupirimate should take the appropriate risk mitigation measures in order to avoid the presence of significant residues of bupirimate in rotational crops.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on apples, peaches, apricots, grapes, strawberries, melons, currants, tomatoes and parsley (Netherlands, 2007, 2009, 2010, 2018; EFSA, 2010, 2014). An overview of all available processing studies is available in Appendix B.1.2.4. Robust processing factors (fully supported by data) could be derived for apple (wet pomace, juice, sauce), peach (juice, puree, canned), apricot (jam, dried), grapes (must, red wine, juice, wet pomace, raisins), strawberries (canned, jam), melons (pulp, peel), while indicative processing factors (not fully supported by studies, since a minimum of three processing studies is normally required) were derived for apples (dry pomace), grapes (white wine, dry pomace), currants (juice, jam, canned), tomato (juice, puree, paste, canned, dried, ketchup) and parsley (dried leaves).

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

1.2.4. Proposed MRLs

The available data are considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities belonging to the fruit crops, except for ethirimol in aubergines. For all other crops, data were not sufficient to derive MRLs and risk assessment values.

---

9 Assuming a soil density of 1.5 g/cm³, a soil depth of 20 cm, crop interception of 25% and considering the DT values in soil (FOMC (DT₅₀/DT₉₀ 49.9/396 days), alpha = 1.12227, beta = 58.3988.

---
2. Residues in livestock

Bupirimate is authorised for use on apple and sugar beet 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. 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) except for cattle (all). Therefore, further investigation of residues as well as the setting of MRLs in commodities of bovine/equine origin is necessary.

It is highlighted that for several feed items, no residue data were available (e.g. sugar beet). The animal intake of bupirimate residues via these commodities has therefore not been assessed and may have been underestimated. If residue trials on this feed item are made available in the future, the dietary burden may need to be reconsidered.

2.1. Nature of residues and methods of analysis in livestock

A metabolism study in lactating goat was already evaluated during the peer review, however this study was regarded as not appropriate to propose a residue definition for ruminant products (EFSA, 2010), since information on the residue composition in edible tissues and milk was not available (Netherlands, 2010).

A new study investigating the metabolism of bupirimate in lactating goats at a dose rate covering the maximum dietary burdens calculated was made available in the framework of this review (Netherlands, 2018). Lactating goats were dosed twice a day with an oral administration of bupirimate labelled on the pyrimidine ring for six consecutive days at dose levels of 0.0066 mg/kg body weight (bw) day (0.46 mg/kg DM; low-dose level) and 0.33 mg/kg bw per day (13.0 mg/kg DM; high-dose level).

For the low dose-level (corresponding to a 2.7N rate), total radioactive residues were highest in bile (0.150 mg/kg), kidneys (0.015 mg/kg) and liver (0.008 mg/kg). Total radioactive residues in all other tissues were below the limit of detection (< 0.001 mg/kg). For the high dose level (corresponding to a 76N rate), total radioactive residues were highest in bile (5.78 mg/kg), liver (0.315 mg/kg) and kidney (0.337 mg/kg). Total radioactive residues in all other tissues each accounted for ≤ 0.015 mg/kg.

In the high-dose level, bupirimate was not detected in any consumable matrices (muscle, kidney, liver and milk), while ethirimol was not detected in muscle and kidney and appeared at only very low levels in liver and milk (0.001–0.005 mg eq/kg). The metabolite de-ethylated ethirimol was the major component in muscle (17.5% TRR, 0.002 mg eq/kg), liver (26.4% TRR, 0.083 mg eq/kg) and kidney (23.3% TRR, 0.079 mg eq/kg) and it is also present in milk (5.7% TRR, 0.005 mg eq/kg), whereas the metabolite hydroxyl-ethirimol was detected only at significant levels in milk (15.8% TRR, 0.015 mg eq/kg). The parent bupirimate and metabolite ethirimol are not good markers as they are not identified or only appear at very low levels in animal matrices. Metabolite de-ethyl ethirimol is the major metabolite in kidney, liver and muscle, and it is also detected in milk at significant levels (Netherlands, 2018). The RMS proposed a residue definition for enforcement and risk assessment as de-ethyl ethirimol (Netherlands, 2018).

The storage stability of bupirimate in animal commodities was not investigated. However, considering that feeding studies are not necessary to derive MRLs and risk assessment values (see Section 2.2), this is not deemed as a data gap in the framework of the present review.

Analytical methods for the enforcement of de-ethyl ethirimol in animal tissues were not submitted by the applicant and are not available to the EURs (EFSA, 2019b). Since MRLs are to be proposed for cattle/equine tissues (see Section 2.2), this is deemed a data gap. The EURs informed EFSA that an analytical standard for the metabolite de-ethyl ethirimol is commercially available (EFSA, 2019b).

2.2. Magnitude of residues in livestock

There are no feeding studies performed with bupirimate. However, the metabolism study (performed at 2.7N–76N rate compared to the maximum dietary burden calculated) is sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.01 mg/kg in muscle, fat, liver and kidney. Hence, no livestock feeding study is needed and MRLs and risk assessment values for the relevant commodities in different categories of ruminants can be established at the LOQ level. However, in the absence of analytical methods for enforcement of bupirimate in animal matrices, tentative MRLs were proposed at an indicative LOQ of 0.01 mg/kg.
It is noted that MRLs for poultry, swine and sheep products are not required because these categories of livestock are not expected to be exposed to significant levels of bupirimate residues.

3. **Consumer risk assessment**

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. The highest conversion factor (CF = 3.62 from currants) was applied to table/wine grapes and aubergines. No conversion factor was applied to commodities belonging to crop groups not supported by a metabolism study. 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 bupirimate or ethirimol.

The acceptable daily intake (ADI) for bupirimate is 0.05 mg/kg bw per day while for ethirimol an ADI of 0.035 mg/kg bw per day was derived (EFSA, 2010). Considering that bupirimate is nearly completely converted to ethirimol in rat, and that both compounds denote a number of joint toxicological actions, in the framework of the peer review, as worst case, the risk assessment was performed using the lowest ADI value derived for ethirimol (EFSA, 2010). The same approach was carried out in this review. Therefore, the exposure values calculated were compared with the toxicological reference value for ethirimol derived by EFSA (2010). The highest chronic exposure was calculated for the UK toddlers, representing 36% of the ADI. 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 bupirimate was investigated in primary crops (fruits only) and rotational crops. According to the results of the metabolism studies, the residue definition for risk assessment can be proposed as sum of bupirimate, ethirimol and de-ethyl ethirimol, expressed as bupirimate. For enforcement, two residue definitions are proposed: (1) bupirimate and (2) ethirimol (to cover the presence of this active substance, not approved in the EU), from the use of bupirimate. The residue definition applies to fruit crops only. These residue definitions are also applicable to processed commodities and rotational crops. Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water and high acid content matrices at the LOQ of 0.01 mg/kg. The EURRLs reported that bupirimate and ethirimol can be monitored in all four main plant matrices.

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities belonging to the fruit crops, except for table/wine grapes and aubergines for which only tentative MRL proposals and risk assessment values were derived and for ethirimol in aubergines for which data was not sufficient to derive MRLs and risk assessment values. For all other crops, data were not sufficient to derive MRLs and risk assessment values.

Bupirimate 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. The calculated dietary burden for cattle (all) was found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues as well as the setting of MRLs in bovine/equine products (muscle, fat, liver and kidney) was necessary.

The metabolism of bupirimate residues in livestock was investigated in lactating goats at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, no residues are expected to be transferred in the different tissues. The residue definition for enforcement and risk assessment in bovine/equine tissues was proposed as de-ethyl ethirimol. It was noted that no analytical methods for the enforcement of the proposed residue definition were available.

The above-mentioned metabolism study was sufficient to conclude that MRLs and risk assessment values in all ruminants tissues could be established at the LOQ level. However, in the absence of analytical methods for enforcement of de-ethyl ethirimol in animal matrices, tentative MRLs were proposed at an indicative LOQ of 0.01 mg/kg.
Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 36% ADI (UK toddler). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for bupirimate and ethirimol.

**Recommendations**

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

- a representative study investigating primary crop metabolism in leafy vegetables;
- a representative study investigating primary crop metabolism in pulses and oilseeds;
- a representative study investigating primary crop metabolism in root crops;
- residue trials on radishes, peas (without pods), globe artichokes, hops and sugar beets (roots and tops) compliant with the southern outdoor GAP (data gap relevant for bupirimate and ethirimol);
- residue trials on aubergines on the southern and indoor GAPs (data gap relevant for deriving an MRL for ethirimol and to derive a conversion factor for risk assessment);
- residue trials on table/wine grapes analysed for all the components in the residue definition for risk assessment;
- a fully validated analytical method for enforcement in hops;
- a fully validated analytical method for animal products;

If the above-reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

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

- a representative field study, covering the calculated plateau in soil, investigating the residues in rotational crops.

Pending the submission of the rotational crops field studies, Member States granting national authorisations for bupirimate, if needed, should take the appropriate risk mitigation measures in order to avoid the presence of significant residues of bupirimate in rotational crops.

**Table 2: Summary table**

| Code number | Commodity            | Existing EU MRL (mg/kg) | MRL (mg/kg) | Outcome of the review          | Comment            |
|-------------|----------------------|-------------------------|-------------|--------------------------------|--------------------|
| 130010      | Apples               | 0.3                     | 0.3         | Recommended<sup>a</sup>        |                    |
| 130020      | Pears                | 0.2                     | 0.3         | Recommended<sup>a</sup>        |                    |
| 140010      | Apricots             | 0.3                     | 0.3         | Recommended<sup>a</sup>        |                    |
| 140030      | Peaches              | 0.3                     | 0.3         | Recommended<sup>a</sup>        |                    |
| 151010      | Table grapes         | 1.5                     | 1.5         | Further consideration needed<sup>b</sup> |                    |
| 151020      | Wine grapes          | 1.5                     | 1.5         | Further consideration needed<sup>b</sup> |                    |
| 152000      | Strawberries         | 2.0                     | 1.5         | Recommended<sup>a</sup>        |                    |
| 153010      | Blackberries         | 1.5                     | 0.7         | Recommended<sup>a</sup>        |                    |
| 153020      | Dewberries           | 1.5                     | 0.7         | Recommended<sup>a</sup>        |                    |
| 153030      | Raspberries (red and yellow) | 1.5     | 1.5         | Recommended<sup>a</sup>        |                    |
| 154010      | Blueberries          | 0.05                    | 1.5         | Recommended<sup>a</sup>        |                    |
| 154020      | Cranberries          | 0.05                    | 1.5         | Recommended<sup>a</sup>        |                    |
| Code number | Commodity | Existing EU MRL (mg/kg) | MRL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|------------------------|-------------|-----------------------|---------|
| 154030      | Currants (black, red and white) | 5 | 1.5 | Recommended<sup>a</sup> |
| 154040      | Gooseberries (green, red and yellow) | 5 | 1.5 | Recommended<sup>a</sup> |
| 154050      | Rose hips | 0.05 | 1.5 | Recommended<sup>a</sup> |
| 154060      | Mulberries (black and white) | 0.05 | 1.5 | Recommended<sup>a</sup> |
| 154070      | Azaroles/Mediterranean medlars | 0.05 | 1.5 | Recommended<sup>a</sup> |
| 154080      | Elderberries | 0.05 | 1.5 | Recommended<sup>a</sup> |
| 213080      | Radishes | 0.05 | 0.05 | Further consideration needed<sup>c</sup> |
| 231010      | Tomatoes | 2 | 0.8 | Recommended<sup>b</sup> |
| 231020      | Sweet peppers/bell peppers | 2 | 1.5 | Recommended<sup>a</sup> |
| 231030      | Aubergines/eggplants | 2 | 1.5 | Further consideration needed<sup>b</sup> |
| 232010      | Cucumbers | 1 | 2 | Recommended<sup>a</sup> |
| 232020      | Gherkins | 1 | 2 | Recommended<sup>a</sup> |
| 232030      | Courgettes | 3 | 2 | Recommended<sup>a</sup> |
| 233010      | Melons | 0.3 | 0.3 | Recommended<sup>a</sup> |
| 233020      | Pumpkins | 0.3 | 0.3 | Recommended<sup>a</sup> |
| 233030      | Watermelons | 0.3 | 0.3 | Recommended<sup>a</sup> |
| 260040      | Peas (without pods) | 0.5 | 0.5 | Further consideration needed<sup>c</sup> |
| 270050      | Globe artichokes | 0.05 | 0.05 | Further consideration needed<sup>c</sup> |
| 700000      | Hops | 10 | 10 | Further consideration needed<sup>c</sup> |
| 900010      | Sugar beet roots | 0.5 | 0.5 | Further consideration needed<sup>c</sup> |
| –          | Other commodities of plant origin | See Reg. 2015/846 | – | Further consideration needed<sup>d</sup> |

**Enforcement residue definition 2:** ethirimol

| Code number | Commodity | Existing EU MRL (mg/kg) | MRL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|------------------------|-------------|-----------------------|---------|
| 130010      | Apples | 0.1 | 0.06 | Recommended<sup>a</sup> |
| 130020      | Pears | 0.1 | 0.06 | Recommended<sup>a</sup> |
| 140010      | Apricots | 0.05 | 0.04 | Recommended<sup>a</sup> |
| 140030      | Peaches | 0.05 | 0.04 | Recommended<sup>a</sup> |
| 151010      | Table grapes | 0.5 | 0.4 | Further consideration needed<sup>b</sup> |
| 151020      | Wine grapes | 0.5 | 0.4 | Further consideration needed<sup>b</sup> |
| 152000      | Strawberries | 0.2 | 0.3 | Recommended<sup>a</sup> |
| 153010      | Blackberries | 0.1 | 0.07 | Recommended<sup>a</sup> |
| 153020      | Dewberries | 0.1 | 0.07 | Recommended<sup>a</sup> |
| 153030      | Raspberries (red and yellow) | 0.1 | 0.15 | Recommended<sup>a</sup> |
| 154010      | Blueberries | 0.05 | 2 | Recommended<sup>a</sup> |
| 154020      | Cranberries | 0.05 | 2 | Recommended<sup>a</sup> |
| 154030      | Currants (black, red and white) | 2 | 2 | Recommended<sup>a</sup> |
| 154040      | Gooseberries (green, red and yellow) | 2 | 2 | Recommended<sup>a</sup> |
| 154050      | Rose hips | 0.05 | 2 | Recommended<sup>a</sup> |
| 154060      | Mulberries (black and white) | 0.05 | 2 | Recommended<sup>a</sup> |
| 154070      | Azaroles/Mediterranean medlars | 0.05 | 2 | Recommended<sup>a</sup> |
| 154080      | Elderberries | 0.05 | 2 | Recommended<sup>a</sup> |
| 213080      | Radishes | 0.05 | 0.05 | Further consideration needed<sup>c</sup> |
## References

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. [https://doi.org/10.2903/j.efsa.2007.32r](https://doi.org/10.2903/j.efsa.2007.32r)

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance bupirimate. EFSA Journal 2010;8(10):1786, 82 pp. [https://doi.org/10.2903/j.efsa.2010.1786](https://doi.org/10.2903/j.efsa.2010.1786)

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the modification of the existing MRL(s) for bupirimate in several crops. EFSA Journal 2014;12(7):3804, 35 pp. [https://doi.org/10.2903/j.efsa.2014.3804](https://doi.org/10.2903/j.efsa.2014.3804)

EFSA (European Food Safety Authority), 2019a. Completeness check report on the review of the existing MRLs of bupirimate prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 8 March 2019. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

EFSA (European Food Safety Authority), 2019b. Member States consultation report on the review of the existing MRLs of bupirimate prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 17 April 2019. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

---

### Table: Review of the existing MRLs for bupirimate

| Code number | Commodity | Existing EU MRL (mg/kg) | MRL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|-------------------------|-------------|-----------------------|---------|
| 231010      | Tomatoes  | 0.1                     | 0.01*       | Recommended (a)       |         |
| 231020      | Sweet peppers/bell peppers | 0.1 | 0.09 | Recommended (a)       |         |
| 231030      | Aubergines/eggplants   | 0.1 | 0.1 | Further consideration needed (c) |         |
| 232010      | Cucumbers           | 0.2 | 0.05 | Recommended (a)       |         |
| 232020      | Gherkins            | 0.2 | 0.05 | Recommended (a)       |         |
| 232030      | Courgettes          | 0.2 | 0.05 | Recommended (a)       |         |
| 233010      | Melons              | 0.08 | 0.15 | Recommended (a)       |         |
| 233020      | Pumpkins            | 0.08 | 0.15 | Recommended (a)       |         |
| 233030      | Watermelons         | 0.08 | 0.15 | Recommended (a)       |         |
| 260040      | Peas (without pods) | 0.5 | 0.5 | Further consideration needed (c) |         |
| 270050      | Globe artichokes    | 0.05 | 0.05 | Further consideration needed (c) |         |
| 700000      | Hops                | 10 | 10 | Further consideration needed (c) |         |
| 900010      | Sugar beet roots    | 0.05 | 0.05 | Further consideration needed (c) |         |
|             | Other commodities of plant origin | See Reg. 2015/846 | – | Further consideration needed (d) |         |
| 1012010     | Bovine muscle       | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1012020     | Bovine fat tissue   | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1012030     | Bovine liver        | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1012040     | Bovine kidney       | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1015010     | Equine muscle       | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1015020     | Equine fat tissue   | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1015030     | Equine liver        | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1015040     | Equine kidney       | 0.05 | 0.01* | Further consideration needed (b) |         |
|             | Other commodities of animal origin | See Reg. 2015/846 | – | Further consideration needed (d) |         |

**Enforcement residue definition 3:** de-ethyl ethirimol

| Code number | Commodity | Existing EU MRL (mg/kg) | MRL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|-------------------------|-------------|-----------------------|---------|
| 1012010     | Bovine muscle       | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1012020     | Bovine fat tissue   | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1012030     | Bovine liver        | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1012040     | Bovine kidney       | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1015010     | Equine muscle       | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1015020     | Equine fat tissue   | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1015030     | Equine liver        | 0.05 | 0.01* | Further consideration needed (b) |         |
| 1015040     | Equine kidney       | 0.05 | 0.01* | Further consideration needed (b) |         |
|             | Other commodities of animal origin | See Reg. 2015/846 | – | Further consideration needed (d) |         |

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

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

(F): The residue definition is fat soluble.

(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): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).

(d): 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).
EUROPEAN UNION REFERENCE LABORATORIES FOR PESTICIDE RESIDUES (EURL), 2018. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for bupirimate. March 2018. Available online: www.efsa.europa.eu

EUROPEAN COMMISSION, 1997a. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

EUROPEAN COMMISSION, 1997b. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

EUROPEAN COMMISSION, 1997c. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

EUROPEAN COMMISSION, 1997d. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

EUROPEAN COMMISSION, 1997e. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

EUROPEAN COMMISSION, 1997f. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

EUROPEAN COMMISSION, 1997g. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

EUROPEAN COMMISSION, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414/EEC. SANCO 3029/99-rev. 4.

EUROPEAN COMMISSION, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

EUROPEAN COMMISSION, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

EUROPEAN COMMISSION, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.3, June 2017.

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

Netherlands, 2007. Draft assessment report on the active substance bupirimate prepared by the rapporteur Member State the Netherlands in the framework of Council Directive 91/414/EEC, April 2007. Available online: www.efsa.europa.eu

Netherlands, 2009. Additional report to the draft assessment report on the active substance bupirimate prepared by the rapporteur Member State the Netherlands in the framework of Commission Regulation (EC) No 33/2008, November 2009. Available online: www.efsa.europa.eu

Netherlands, 2010. Final addendum to the additional report on the active substance bupirimate prepared by the rapporteur Member State the Netherlands in the framework of Commission Regulation (EC) No 33/2008, August 2010. Available online: www.efsa.europa.eu

Netherlands, 2014. Evaluation report on the modification of MRLs for bupirimate and ethirimol in several commodities prepared by the evaluating Member State The Netherlands under Article 8 of Regulation (EC) No 396/2005, January 2014, 212 pp.

Netherlands, 2018. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for bupirimate, June 2018 updated on 5 April 2019. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.

**Abbreviations**

- a.i. active ingredient
- a.s. active substance
- ADI acceptable daily intake
- ARfD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- 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

www.efsa.europa.eu/efsajournal 17 EFSA Journal 2019;17(7):5757
Review of the existing MRLs for bupirimate
## 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 GT (a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|----------|-----------------------------------|-------------|-------------|-------------------------------|-----------|---------|
|                       |               |          |                                   | Type(b)     | Conc. a.s.  | Method kind                    | Range of growth stages & season(c) | Number min–max | Interval between application (min) | a.s./hL min–max | Water L/ha min–max | Rate and unit | |
| Apples                | UK            | F        | Powdery mildew/ *Podosphaera leucotricha* | EC 250 g/L | Foliar treatment – broadcast spraying | 11–35 | 4 | 10 | – | – | 225 g a.i./ha | 14 | A more critical GAP is approved in Ireland, but it is not supported by data |
| Pears                 | UK            | F        | Powdery mildew/ *Podosphaera leucotricha* | EC 250 g/L | Foliar treatment – broadcast spraying | 11–35 | 4 | 10 | – | – | 225 g a.i./ha | 14 |
| Strawberries          | UK            | F        | Powdery mildew/ *Sphaeroteca macularis* | EC 250 g/L | Foliar treatment – broadcast spraying | 11 | 4 | 10 | – | – | 250 g a.i./ha | 3 |
| Blackberries          | NL            | F        | Powdery mildew | EC 250 g/L | Foliar treatment – broadcast spraying | 4 | 12 | – | – | 250 g a.i./ha | 7 |
| Dewberries            | NL            | F        | Powdery mildew | EC 250 g/L | Foliar treatment – broadcast spraying | 4 | 12 | – | – | 250 g a.i./ha | 7 |
| Raspberries           | FR            | F        | Powdery mildew | EC 250 g/L | Foliar treatment – broadcast spraying | 59–79 | 4 | 12 | – | – | 375 g a.i./ha | 7 |
| 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                    | Number min-max | Interval between application (min) | Rate and unit |         |
| Curants               | UK           | F          | Powdery mildew/Sphaerotheca mors-uvae | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 59–79          | 4                         | –             | 375 g a.i./ha | 7       |
| Gooseberries          | FR           | F          |                                   | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 59–79          | 4                         | –             | 375 g a.i./ha | 7       |

MS: Member State; EC: emulsifiable concentrate; a.s.: active substance; a.i.: active ingredient; GAP: Good Agricultural Practice.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
### A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F or F G or F G or F | 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 | Remarks |
| Apples                | IT            | F                      | Powdery mildew/ Podosphaera leucotricha | EW 250 g/L | Foliar treatment – broadcast spraying | 51–85 | 1–4 | 10 | – | – | 225 g a.i./ha | 14 |
| Pears                 | FR            | F                      | Powdery mildew/ Podosphaera leucotricha | EC 250 g/L | Foliar treatment – broadcast spraying | 53–79 | 1–4 | 10 | – | – | 150 g a.i./ha | 14 |
| Apricots              | IT            | F                      | Powdery mildew/ Sphaerotheca pannosa var. persicae | EW 250 g/L | Foliar treatment – broadcast spraying | 65–91 | 1–4 | 10 | – | – | 250 g a.i./ha | 7 |
| Peaches               | IT            | F                      | Powdery mildew/ Sphaerotheca pannosa var. Persicae | EW 250 g/L | Foliar treatment – broadcast spraying | 65–91 | 1–4 | 10 | – | – | 250 g a.i./ha | 7 |
| Table grapes          | IT            | F                      | Powdery mildew/ Erysiphe necator | EW 250 g/l | Foliar treatment – broadcast spraying | 15–87 | 1–4 | 10 | – | – | 375 g a.i./ha | 14 |
| Wine grapes           | IT            | F                      | Powdery mildew/ Erysiphe necator | EW 250 g/l | Foliar treatment – broadcast spraying | 15–87 | 1–4 | 10 | – | – | 375 g a.i./ha | 14 |
| Strawberries          | IT            | F                      | Powdery mildew/ Sphaerotheca macularis | EW 250 g/L | Foliar treatment – broadcast spraying | 11–89 | 1–4 | 10 | – | – | 250 g a.i./ha | 3 |

**Remarks**

- **Application at the beginning of the first outbreaks**
| 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 |
|-----------------------|--------------|----------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
|                       |              |          |                                    |             |            |                               |            |         |
|                       |              |          |                                    |             |            |                               |            |         |
| Raspberries           | FR           | F        | Powdery mildew                    | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 59–79      | 4       | 12    | 375 g a.i./ha | 7 |
| Blueberries           | ES           | F        | Powdery mildew                    | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 59–79      | 1–4     | 12    | 375 g a.i./ha | 7 |
| Cranberries           | ES           | F        | Powdery mildew                    | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 59–79      | 1–4     | 12    | 375 g a.i./ha | 7 |
| Currants              | FR, ES       | F        | Powdery mildew/ Sphaerotheca mors-uvae | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 59–79      | 1–4     | 12    | 375 g a.i./ha | 7 |
| Gooseberries          | FR, ES       | F        | Powdery mildew/ Sphaerotheca mors-uvae | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 59–79      | 1–4     | 12    | 375 g a.i./ha | 7 |
| Rose hips             | ES           | F        | Powdery mildew                    | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 59–79      | 1–4     | 12    | 375 g a.i./ha | 7 |
| Mulberries            | ES           | F        | Powdery mildew                    | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 59–79      | 1–4     | 12    | 375 g a.i./ha | 7 |
| Crop and/or situation | MS or country | F G or T | Type(b) Conc. a.s. | Method kind | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|----------|-------------------|-------------|-------------|------------|-------------------------------|------------|---------|
| Azaroles              | ES           | F        | Powdery mildew    | EC 250 g/L  | Foliar treatment – broadcast spraying | 59–79      | 1–4                           | 12        | –       | 375 g a.i./ha | 7        |
| Elderberries          | ES           | F        | Powdery mildew    | EC 250 g/L  | Foliar treatment – broadcast spraying | 59–79      | 1–4                           | 12        | –       | 375 g a.i./ha | 7        |
| Radishes              | IT           | F        | Powdery mildew/ Erysiphe cichoracearum Golovynomices cichoracearum | EW 250 g/L  | Foliar treatment – broadcast spraying | 12–45      | 1–2                           | 10        | –       | 312.5 g a.i./ha | 7        |
| Tomatoes              | IT           | F        | Powdery mildew/ Leveillula taurica | EW 250 g/l  | Foliar treatment – broadcast spraying | 12–89      | 1–4                           | 10        | –       | 500 g a.i./ha | 3        |
| Sweet peppers         | IT           | F        | Powdery mildew/ Leveillula taurica | EW 250 g/l  | Foliar treatment – broadcast spraying | 12–89      | 1–4                           | 10        | –       | 500 g a.i./ha | 3        |
| Aubergines            | ES           | F        | Powdery mildew    | EC 250 g/L  | Foliar treatment – broadcast spraying | 13–87      | 1–4                           | 10        | –       | 750 g a.i./ha | 3        |
| Cucumbers             | EL           | F        | Powdery mildew    | EC 250 g/L  | Foliar treatment – broadcast spraying | 12–87      | 1–4                           | 10        | –       | 300 g a.i./ha | 1        |
| Crop and/or situation | MS or country | F or T(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|--------------|-----------|-----------------------------------|-------------|------------|-------------------------------|----------------|---------|
| Gherkins              | ES           | F         | Powdery mildew                    | EC 250 g/L | Foliar treatment – broadcast spraying | 13–87 1–4 10 | 375 g a.i./ha | 1       |
| Courgettes            | EL           | F         | Powdery mildew                    | EC 250 g/L | Foliar treatment – broadcast spraying | 12 1–4 10 | 375 g a.i./ha | 1       |
| Melons                | FR           | F         | Powdery mildew Sphaerotheca fuliginea | EC 250 g/L | Foliar treatment – broadcast spraying | 12 4 10 | 375 g a.i./ha | 3       |
| Pumpkins              | IT           | F         | Powdery mildew/ Podosphaera fusca, Erysiphe cichoracearum | EW 250 g/l | Foliar treatment – broadcast spraying | 12–89 1–4 10 | 250 g a.i./ha | 1       |
| Watermelons           | IT           | F         | Powdery mildew/ Podosphaera fusca, Erysiphe cichoracearum | EW 250 g/l | Foliar treatment – broadcast spraying | 12–89 1–4 10 | 250 g a.i./ha | 1       |
| Peas (without pods)   | ES           | F         | Powdery mildew                    | EC 250 g/L | Foliar treatment – broadcast spraying | 15–89 1–4 10 | 375 g a.i./ha | 15 Apply diluted in 200–400 L of water |
| Globe artichokes      | EL           | F         | Powdery mildew/ Podosphaera pannosa | EC 250 g/L | Foliar treatment – broadcast spraying | 1–1 | 375 g a.i./ha | 7       |
| 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 |                  |
| Hops                  | EL            | F           | Powdery mildew                     | EC          | 250 g/L Foliar treatment – broadcast spraying | 20 | 1–4 | 7 | – | – | 375 g a.i./ha | 7 |
| Sugar beets           | ES            | F           | Powdery mildew                     | EC          | 250 g/L Foliar treatment – broadcast spraying | 15–89 | 1–4 | 7 | – | – | 375 g a.i./ha | 15 |

MS: Member State; EC: emulsifiable concentrate; EW: oil-in-water emulsion; a.s.: active substance; a.i.: active ingredient.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
## A.3. Authorised indoor uses in the EU

| Crop and/or situation | MS or country | FG or Y(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------------|------------|-----------------------------------|-------------|-------------|--------------------------------|----------------|---------|
| Strawberries          | IT, MT        | I          | Powdery mildew/ *Sphaerotheca macularis* | EW 250 g/L  | Foliar treatment – broadcast spraying | 11–89 1–4 10 | –  – | 250 g a.i./ha | 3 |
| Blackberries          | NL            | I          | Powdery mildew                     | EC 250.0 g/L | Foliar treatment – broadcast spraying | 4 10 | –  – | 250 g a.i./ha | 7 |
| Dewberries            | NL            | I          | Powdery mildew                     | EC 250.0 g/L | Foliar treatment – broadcast spraying | 4 10 | –  – | 250 g a.i./ha | 7 |
| Raspberries           | FR            | I          | Powdery mildew                     | EC 250 g/L  | Foliar treatment – broadcast spraying | 59–79 4 12 | –  – | 375 g a.i./ha | 7 |
| Blueberries           | ES            | I          | Powdery mildew                     | EC 250 g/L  | Foliar treatment – broadcast spraying | 59–79 1–4 12 | –  – | 375 g a.i./ha | 7 |
| 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(c) | Number min-max | Interval between application (min) | Rate and unit |         |
| Cranberries            | ES I         | Powdery mildew | EC 250 g/L | Foliar treatment – broadcast spraying | 59–79       | 1–4       | 12                             | –          | 375 g a.i./ha | 7       |
| Currants               | FR ES I      | Powdery mildew/Sphaerotheca mors-uvae | EC 250 g/L | Foliar treatment – broadcast spraying | 59–79       | 1–4       | 12                             | –          | 375 g a.i./ha | 7       |
| Gooseberries           | FR ES I      | Powdery mildew/Sphaerotheca mors-uvae | EC 250 g/L | Foliar treatment – broadcast spraying | 59–79       | 1–4       | 12                             | –          | 375 g a.i./ha | 7       |
| Rose hips              | ES I         | Powdery mildew | EC 250 g/L | Foliar treatment – broadcast spraying | 59–79       | 1–4       | 12                             | –          | 375 g a.i./ha | 7       |
| Mulberries             | ES I         | Powdery mildew | EC 250 g/L | Foliar treatment – broadcast spraying | 59–79       | 1–4       | 12                             | –          | 375 g a.i./ha | 7       |
| Azaroles               | ES I         | Powdery mildew | EC 250 g/L | Foliar treatment – broadcast spraying | 59–79       | 1–4       | 12                             | –          | 375 g a.i./ha | 7       |
| Elderberries           | ES I         | Powdery mildew | EC 250 g/L | Foliar treatment – broadcast spraying | 59–79       | 1–4       | 12                             | –          | 375 g a.i./ha | 7       |
| 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) | 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 |          |         |
| Tomatoes              | IT I         |            | Powdery mildew/Leveillula taurica | EW          | 250 g/l   | Foliar treatment – broadcast spraying | 12-89 | 1-4 | 10 | – | – | 500 g a.i./ha | 3 |
| Sweet peppers        | IT I         |            | Powdery mildew/Leveillula taurica | EW          | 250 g/l   | Foliar treatment – broadcast spraying | 12-89 | 1-4 | 10 | – | – | 500 g a.i./ha | 3 |
| Aubergines            | ES I         |            | Powdery mildew            | EC          | 250 g/L   | Foliar treatment – broadcast spraying | 13-87 | 1-4 | 10 | – | – | 750 g a.i./ha | 3 | 75 g a.i./hL. Max 3 l/ha per application |
| Cucumbers             | ES I         |            | Powdery mildew            | EC          | 250 g/L   | Foliar treatment – broadcast spraying | 13-87 | 1-4 | 10 | – | – | 375 g a.i./ha | 1 | Max 1,5 L product/ha |
| Gherkins              | ES I         |            | Powdery mildew            | EC          | 250 g/L   | Foliar treatment – broadcast spraying | 13-87 | 1-4 | 10 | – | – | 375 g a.i./ha | 1 | Max 1,5 L product/ha |
| Courgettes            | ES I         |            | Powdery mildew            | EC          | 250 g/L   | Foliar treatment – broadcast spraying | 13-87 | 1-4 | 10 | – | – | 375 g a.i./ha | 1 | Max 1,5 L product/ha |
| Melons                | ES I         |            | Powdery mildew            | EC          | 250 g/L   | Foliar treatment – broadcast spraying | 13-87 | 1-3 | 10 | – | – | 375 g a.i./ha | 1 |        |
| 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 |          |
| Pumpkins              | ES I         |              | Powdery mildew                    | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 13-87          | 1-3     | 10            | –             | –           | 375 g a.i./ha | 1          |          |
| Watermelons           | ES I         |              | Powdery mildew                    | EC          | 250 g/L    | Foliar treatment – broadcast spraying | 13-87          | 1-3     | 10            | –             | –           | 375 g a.i./ha | 1          |          |

MS: Member State; EC: emulsifiable concentrate; EW: oil-in-water emulsion; a.s.: active substance; a.i.: active ingredient; GAP: Good Agricultural Practice.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
**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                      | Apple       | Topical, drops onto the leaf | 1, 3, 9, 15, 22 | Radiolabelled bupirimate: pyrimidine ring (EFSA, 2010) |
|                                  | Melon       | Foliar: 4 x 250 g a.s./ha, interval 10-11 days | 3, 14 (fruit); 14 (leaf) |
|                                  | Strawberries| Foliar, 4 x 260-280 g a.s./ha, interval 10-11 days | 14 |
|                                  | Apple       | Foliar, 4 x 225 g a.s./ha, interval 10 days | 14 |
|                                  | Melon       | Foliar, 4 x 375 g a.s./ha, interval 10 days | 1 |
|                                  | Strawberries| Foliar, 4 x 250 g a.s./ha, interval 10 days | 3 |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Turnips     | 1.04 kg a.s. onto bare soil | 30, 120, 365 | Radiolabelled bupirimate: pyrimidine ring (EFSA, 2010) |
| Leafy crops                         | Spinach     | 1.04 kg a.s. onto bare soil | 30, 120, 365 |
| Cereal (small grain)                | Spring wheat| 1.04 kg a.s. onto bare soil | 30, 120, 365 |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Yes        |         | Radiolabelled bupirimate: pyrimidine ring (EFSA, 2010) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | |
| Sterilisation (20 min, 120°C, pH 6)      | Yes        |         | |
**Review of the existing MRLs for bupirimate**

| Question                                                                 | No                                                            | Metabolism studies are available in fruit crops only (EFSA, 2010; Netherlands, 2018) |
|--------------------------------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Rotational crop and primary crop metabolism similar?                     | Yes                                                           | EFSA (2010)                                                                          |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes                                                           | EFSA (2010)                                                                          |

Two separate residue definitions are needed:

**RD 1 – bupirimate:**

Fruit crops only: bupirimate

**RD 2 – ethirimol** (in order to cover the residues of ethirimol resulting from the use of bupirimate):

Fruit crops only: ethirimol

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

Fruit crops: sum of bupirimate, ethirimol and de-ethyl ethirimol, expressed as bupirimate

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

| Matrices with high water content and high acid content matrices: HPLC, LOQ 0.01 mg/kg
| Confirmatory method available
| ILV available for high water and high acid content matrices
| EFRL reported that bupirimate and ethirimol can be enforced in all four main plant matrices with at least a LOQ 0.01 mg/kg (EFSA, 2010; Netherlands, 2010, 2018; EURL, 2018)

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; HPLC: high-performance liquid chromatography; 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      | Apple        | −18    | 24 Months        | Bupirimate, ethirimol                      | EFSA (2010)                 |
|                                   | High oil content        | Sunflower seed| −18    | 12 Months        | Bupirimate, ethirimol, de-ethyl ethirimol  | Netherlands (2018)          |
|                                   | High protein content    | Dry bean     | −18    | 12 Months        | Bupirimate, ethirimol, de-ethyl ethirimol  | Netherlands (2018)          |
|                                   | High starch content     | Wheat grain  | −18    | 12 Months        | Bupirimate, ethirimol, de-ethyl ethirimol  | Netherlands (2018)          |
|                                   | High acid content       | Strawberry   | −18    | 12 Months        | Bupirimate, ethirimol, de-ethyl ethirimol  | Netherlands (2018)          |
|                                   | Processed products      | Strawberry jam| −18    | 12 Months        | Bupirimate, ethirimol, de-ethyl ethirimol  | Netherlands (2018)          |
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR_Mo(b) (mg/kg) | STMR_Mo(c) (mg/kg) | CF(d) |
|-----------|------------------|---------------------------------------------------------------|-----------------|------------------------|------------------|------------------|-------|
| **Apples** | NEU | Mo: 0.05; 0.05; 0.04; 0.02; 0.05; 0.18; 0.13; 0.15; 0.04; 0.057; 0.069; 0.026; 0.1; 0.07; 0.07; 0.11; 0.03 | Trials compliant with GAP (Netherlands, 2018). Extrapolation to apples is applicable MRL_OECD = 0.26 | 0.3 | 0.18 | 0.06 | 1.70 |
| | SEU | Mo: < 0.01; 0.01; 0.02; 0.029; 0.03; 0.03; 0.04; 0.044; 0.05; 0.07; 0.071; 0.13 | Trials compliant with GAP (Netherlands, 2018) MRL_OECD = 0.18 | 0.2 | 0.13 | 0.04 | 1.75 |
| **Pears** | NEU | Direct extrapolation from apples NEU. | | 0.3 | 0.18 | 0.06 | 1.70 |
| | SEU | Mo (scaled): < 0.01; 0.01; 0.01; 0.02; 0.02; 0.02; 0.03; 0.03; 0.03; 0.04; 0.05; 0.09 | Data from residue trials on apples scaled using the proportionality approach (Netherlands, 2018) MRL_OECD = 0.12 | 0.15 | 0.09 | 0.03 | 1.67 |
| **Apricots** | SEU | Mo: 0.04; 0.08; 0.16; 0.11; 0.045; 0.072; 0.076; 0.088 | Combined data set of four trials on peaches and four trials on apricots compliant with GAP (Netherlands, 2018). Extrapolation to apricots is applicable MRL_OECD = 0.25 | 0.3 | 0.16 | 0.08 | 1.59 |
| **Peaches** | SEU | RA: | | | | | |

Residue definition for enforcement – **bupirimate**
Residue definition for risk assessment – **sum of bupirimate, ethirimol and de-ethyl ethirimol, expressed as bupirimate**
| Commodity          | Region/ Indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR \(_{Mo}^{(b)}\) (mg/kg) | STMR \(_{Mo}^{(c)}\) (mg/kg) | CF\(_{d}^{(d)}\) |
|--------------------|----------------|---------------------------------------------------------------|--------------------------------------------------------------------------------|-------------------------|----------------------------|-------------------------------|--------------|
| Table grapes       | SEU            | **Mo**: 0.03; 0.04; 0.16; 0.21; 0.24; 0.30; 0.36; 0.38; 0.56; 0.86 | Trials on wine grapes compliant with GAP (Netherlands, 2018). Extrapolation to table grapes is applicable  \(\text{MRL}_{OECD} = 1.31\) | 1.5                     | 0.86                       | 0.27                          | 3.62\(_{e}^{(e)}\) |
| Wine grapes        |                | **RA**: –                                                      |                                                                                 |                         |                            |                               |              |
| Strawberries       | NEU            | **Mo**: 0.04; 0.04; 0.05; 0.05; 0.10; 0.11; 0.14; 0.24; 0.26; 0.42; 0.49 | Trials compliant with GAP (Netherlands, 2018)  \(\text{MRL}_{OECD} = 0.81\) | 0.8                     | 0.49                       | 0.11                          | 1.14         |
|                    | SEU            | **Mo**: 0.06; 0.065; 0.15; 0.15; 0.16; 0.16; 0.17; 0.17; 0.19; 0.41; 0.50 | Trials compliant with GAP (Netherlands, 2018)  \(\text{MRL}_{OECD} = 0.74\) | 0.8                     | 0.50                       | 0.16                          | 1.20         |
|                    | EU             | **Mo**: 0.053; 0.058; 0.09; 0.12; 0.13; 0.20; 0.21; 0.22; 0.28; 0.51; 0.61; 1.1 | Trials compliant with GAP (Netherlands, 2018)  \(\text{MRL}_{OECD} = 1.54\) | 1.5                     | 1.10                       | 0.21                          | 1.56         |
| Raspberries        | NEU            | **Mo**: 0.053; 0.082; 0.082; 0.13; 0.13; 0.16 | Trials compliant with GAP (Netherlands, 2018)  \(\text{MRL}_{OECD} = 0.32\) | 0.4                     | 0.16                       | 0.11                          | 1.63         |
| (red and yellow)   |                | **RA**: 0.11; 0.14; 0.17; 0.17; 0.18; 0.25 |                                                                                 |                         |                            |                               |              |
|                    | SEU            | **Mo**: 0.027; 0.033; 0.06; 0.07; 0.076; 0.085 | Trials compliant with GAP (Netherlands, 2018)  \(\text{MRL}_{OECD} = 0.18\) | 0.2                     | 0.09                       | 0.07                          | 2.18         |
|                    | EU             | **Mo**: 0.061; 0.15; 0.20; 0.22; 0.47; 0.56 | Trials compliant with GAP (Netherlands, 2018)  \(\text{MRL}_{OECD} = 1.06\) | 1.5                     | 0.56                       | 0.21                          | 1.41         |
| Blackberries       | NEU            | **Mo** (scaled): 0.035; 0.055; 0.055; 0.087; 0.087; 0.11 | Trials on raspberries scaled using the proportionality approach (Netherlands, 2018) | 0.3                     | 0.11                       | 0.07                          | 1.62         |
| Dewberries         |                | **Mo** (unscaled): 0.053; 0.082; 0.082; 0.13; 0.13; 0.16 |                                                                                 |                         |                            |                               |              |
|                    |                | **RA**: 0.073; 0.093; 0.11; 0.11; 0.12; 0.17 |                                                                                 |                         |                            |                               |              |
| Commodity                  | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|---------------------------|------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|----------------------|-------------------------|-----------------|
|                           | EU               | **Mo** (*scaled*): 0.041; 0.10; 0.13; 0.15; 0.31; 0.37          | Trials on raspberries scaled using the proportionality approach (Netherlands, 2018) | 0.7                    | 0.37                 | 0.14                    | 1.39            |
|                           |                  | **Mo** (*unscaled*): 0.061; 0.15; 0.20; 0.22; 0.47; 0.56       |                                                                                  |                        |                      |                         |                 |
|                           |                  | **RA**: 0.065; 0.17; 0.21; 0.18; 0.36; 0.39                    |                                                                                  |                        |                      |                         |                 |
| Blueberries               | NEU              | **Mo**: 0.11; 0.20; 0.34; 0.38; 0.44; 0.51                      | Trials on currants compliant with GAP (Netherlands, 2018). GAP authorised for currants and gooseberries only. Extrapolation to gooseberries is applicable MRL\(_{OECD}\) = 0.99 | 1                      | 0.51                 | 0.36                    | 1.60            |
| Cranberries               |                  | **RA**: 0.29; 0.23; 0.60; 0.61; 0.70; 0.61                    |                                                                                  |                        |                      |                         |                 |
| Currants (black, red and white) |               | **Mo**: 0.036; 0.12; 0.16; 0.43; 0.45; 0.58                   | Combined data set of trials on currants (5) and gooseberries (1) compliant with GAP (Netherlands, 2018). Extrapolation to blueberries, cranberries, gooseberries, rose hips, mulberries, azaroles and elderberries is applicable MRL\(_{OECD}\) = 1.17 | 1.5                    | 0.58                 | 0.30                    | 3.62            |
| (green, red and yellow)     |                  | **RA**: 0.18; 0.23; 0.55; 0.57; 1.9; 2.2                     |                                                                                  |                        |                      |                         |                 |
| Gooseberries              | SEU              | **Mo**: 0.12; 0.16; 0.20; 0.40; 0.45; 0.55                    | Combined data set of trials on currants (5) and gooseberries (1) compliant with GAP (Netherlands, 2018). Extrapolation to blueberries, cranberries, gooseberries, rose hips, mulberries, azaroles and elderberries is applicable MRL\(_{OECD}\) = 1.02 | 1                      | 0.55                 | 0.30                    | 2.51            |
| (green, red and yellow)     |                  | **RA**: 0.38; 0.44; 0.46; 0.94; 1.2; 0.85                   |                                                                                  |                        |                      |                         |                 |
| Rose hips                 |                  | **Mo**: 0.01; 0.02; 0.03; 0.07; 0.08; 0.09; 0.12; 0.14       | Trials compliant with GAP (Netherlands, 2018) MRL\(_{OECD}\) = 0.26              | 0.3                    | 0.14                 | 0.08                    | 1.44            |
| Mulberries                |                  | **RA**: 0.04; 0.5; 0.06; 0.10; 0.11; 0.13; 0.15; 0.17       |                                                                                  |                        |                      |                         |                 |
| (black and white)         |                  |                                                             |                                                                                  |                        |                      |                         |                 |
| Azaroles/ Mediterranean medlars |            | **Mo**: 0.01; 0.02; 0.03; 0.07; 0.08; 0.09; 0.12; 0.14       | Tests not available                                                              |                        |                      |                         |                 |
| (black and white)         |                  | **RA**: 0.04; 0.5; 0.06; 0.10; 0.11; 0.13; 0.15; 0.17       |                                                                                  |                        |                      |                         |                 |
| Elderberries              | SEU              | –                                                               | No residue trials available                                                      |                        |                      |                         |                 |
| Radishes                  |                  | **Mo**: 0.01; 0.02; 0.03; 0.07; 0.08; 0.09; 0.12; 0.14       |                                                                                  |                        |                      |                         |                 |
| Tomatoes                  | SEU              | **RA**: 0.04; 0.5; 0.06; 0.10; 0.11; 0.13; 0.15; 0.17       |                                                                                  |                        |                      |                         |                 |
| Commodity                  | Region/Indoors(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR Mo(b) (mg/kg) | STMR Mo(c) (mg/kg) | CF(d) |
|---------------------------|-------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|------------------|------------------|-------|
| EU                        |                   |                                                               |                                                                                 |                        |                  |                  |       |
| Sweet peppers/bell peppers| SEU               | Mo: 0.02; 0.03; 0.14; 0.22; 0.29; 0.44; 0.64; 0.74             | Trials compliant with GAP (Netherlands, 2018) MRL = 1.09                          | 1.5                    | 0.64             | 0.14             | 1.30  |
| EU                        |                   | Mo: < 0.01; 0.08; 0.11; 0.22; 0.29; 0.53; 0.89               | Trials compliant with GAP (Netherlands, 2018) MRL = 1.45                          | 1.5                    | 0.89             | 0.25             | 1.11  |
| Aubergines/eggplants      | SEU               | Mo (scaled): 0.02; 0.03; 0.04; 0.11; 0.12; 0.13; 0.19; 0.21  | Residue trials on tomatoes scaled using the proportionality approach (Netherlands, 2018). Extrapolation to aubergines is applicable MRL = 0.039 | 0.4                    | 0.21             | 0.12             | 3.62  |
| EU                        |                   | Mo (scaled): 0.21; 0.23; 0.28; 0.34; 0.42; 0.49; 0.60; 0.64 | Residue trials on tomatoes scaled using the proportionality approach (Netherlands, 2018). Extrapolation to aubergines is applicable MRL = 1.2 | 1.5                    | 0.64             | 0.38             | 3.62  |
| Cucumbers Gherkins Courgettes| SEU          | Mo: 0.02; 0.022; 0.068; 0.08; 0.11; 0.17; 0.36; 0.65; 0.73; 0.74; 1.34 | Trials on courgettes compliant with GAP (Netherlands, 2018). Extrapolation to gherkins and cucumbers is applicable MRL = 2.09 | 2                      | 1.34             | 0.17             | 1.32  |
| EU                        |                   | Mo: 0.07; 0.07; 0.07; 0.09; 0.10; 0.12; 0.13; 0.32; 0.38; 0.56 | Combined data set of trials on cucumbers (9) and courgette (last 3) compliant with GAP (Netherlands, 2018). Extrapolation to gherkins and cucumbers applicable MRL = 0.84 | 0.9                    | 0.56             | 0.11             | 1.08  |
| Commodity      | Region/ Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sub>Mo</sub><sup>(b)</sup> (mg/kg) | STMR<sub>Mo</sub><sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|----------------|-----------------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------|------------------------|----------------------------------------|----------------------------------------|------------|
| Melons         | SEU                         | **Mo (scaled):**<sup>(e)</sup> < 0.01; < 0.01; < 0.01; 0.01; 0.02; 0.02; 0.02; 0.02; 0.02; 0.02; 0.03; 0.03; 0.03; 0.05; 0.11 | Trials on melons scaled using the proportionality approach (Netherlands, 2010; 2018) MRL<sub>OECD</sub> = 0.12 | 0.15                  | 0.11                                   | 0.02                                   | 2.60       |
| Melons         | SEU                         | **Mo (unscaled):**<sup>(e)</sup> 0.02; < 0.01; 0.02; < 0.01; 0.01; 0.01; 0.01; 0.07; 0.016; 0.01; 0.014; 0.030; 0.050; 0.020; 0.025; 0.026 | RA: < 0.04; < 0.04; 0.04; < 0.052; 0.060; 0.05; 0.05; 0.067; 0.04; 0.057; < 0.057; < 0.093 | 0.09                  | 0.06                                   | 0.03                                   | 1.95       |
| Melons         | EU                          | **Mo:**<sup>(e)</sup> < 0.05; < 0.05; 0.06; 0.06; 0.08; 0.08; 0.09; 0.10; 0.11; 0.13; 0.13; 0.17 | Trials on melons compliant with GAP (Netherlands, 2018). Extrapolation to pumpkins and watermelons is applicable MRL<sub>OECD</sub> = 0.08 | 0.3                   | 0.17                                   | 0.09                                   | 1.37       |
| Peas (without pods) | SEU                           | –                                                             | No residue trials available                                                   | –                      | –                                      | –                                      | –          |
| Globe artichokes | SEU                         | **Mo:**<sup>(e)</sup> < 0.02; < 0.02; 0.05; 0.08 | Trials compliant with GAP (Netherlands, 2018). Since metabolism studies on leafy vegetables are not available no MRL is proposed | –                      | –                                      | –                                      | –          |
| Hops           | SEU                         | –                                                             | No residue trials available                                                   | –                      | –                                      | –                                      | –          |
| Sugar beet roots | SEU                         | –                                                             | No residue trials available                                                   | –                      | –                                      | –                                      | –          |
| Commodity       | Region/Indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR \(M_o\)\(^{(b)}\) (mg/kg) | STMR \(M_o\)\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|-----------------|--------------------------|---------------------------------------------------------------|----------------|------------------------|----------------------------|--------------------------------|----------|
| Sugar beet tops | SEU                      | –                                                             | No residue trials available | –                      | –                          | –                              | –        |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; LOQ: limit of quantification; 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, Indoor: indoor EU trials or Country code: if non-EU trials.

\(^{(b)}\): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

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

\(^{(d)}\): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

\(^{(e)}\): Highest conversion factor derived from currants (CF = 3.62) was applied to table/wine grapes and aubergines.

\(^{(f)}\): MRL is tentative because residue trials analysed according to the residue definition for risk assessment are needed.
### B.1.2.2. Summary of residues data from the supervised residue trials – Primary crops (ethirimol)

| Commodity          | Region/Indoor | 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) |
|--------------------|---------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------------------|-----------------------------|
| Apples             | NEU           | Mo: 0.01; 0.03; 0.01; 0.02; 0.05; 0.03; 0.02; < 0.01; 0.015; 0.01; 0.02; 0.01; 0.01; < 0.01 | Trials compliant with GAP (Netherlands, 2018) MRL<sub>OECD</sub> = 0.06             | 0.06                   | 0.05                      | 0.01                        |
|                    | SEU           | Mo: < 0.01; 0.01; 0.02; 0.029; 0.03; 0.03; 0.04; 0.044; 0.05; 0.07; 0.071; 0.13 | Trials compliant with GAP (Netherlands, 2018) MRL<sub>OECD</sub> = 0.03             | 0.04                   | 0.02                      | 0.01                        |
| Pears              | NEU           | Direct extrapolation from apples. | Direct extrapolation from apples MRL<sub>OECD</sub> = 0.06 | 0.06                   | 0.05                      | 0.01                        |
|                    | SEU           | Mo<sup>(scaled)</sup>: < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01 | Data from residue trials on apples scaled using the proportionality approach (Netherlands, 2018) MRL<sub>OECD</sub> = 0.02 | 0.02                   | 0.01                      | 0.01                        |
|                    |               | Mo<sup>(unscaled)</sup>: < 0.01; 0.01; 0.02; 0.029; 0.03; 0.03; 0.04; 0.044; 0.05; 0.07; 0.071; 0.13 |                                                              |                        |                          |                              |
| Apricots           | SEU           | Mo: < 0.01; < 0.01; 0.018; < 0.01; < 0.01; < 0.01; < 0.01; 0.026; 0.020 | Combined data set of four trials on peach and four trials on apricots compliant with GAP (Netherlands, 2018). Extrapolation to apricots is applicable MRL<sub>OECD</sub> = 0.04 | 0.04                   | 0.03                      | 0.01                        |
| Peaches            |               |                                                                                  |                                                                                |                        |                          |                              |
| Table grapes       | SEU           | Mo: < 0.01; 0.01; 0.04; 0.04; 0.09; 0.11; 0.11; 0.14; 0.16; 0.20 | Trials on wine grapes compliant with GAP (Netherlands, 2018) MRL<sub>OECD</sub> = 0.35 | 0.4                    | 0.20                      | 0.10                        |
| Wine grapes        |               |                                                                                  |                                                                                |                        |                          |                              |
| Strawberries       | NEU           | Mo: < 0.01; < 0.01; < 0.01; < 0.01; 0.01; 0.042; 0.01; 0.03; 0.06; 0.03; 0.03 | Trials compliant with GAP (Netherlands, 2018) MRL<sub>OECD</sub> = 0.09             | 0.09                   | 0.06                      | 0.01                        |
|                    | SEU           | Mo: 0.01; < 0.01; 0.03; < 0.01; < 0.01; 0.02; 0.07; 0.07; 0.04; 0.18; 0.05 | Trials compliant with GAP (Netherlands, 2018) MRL<sub>OECD</sub> = 0.25 | 0.3                    | 0.18                      | 0.03                        |
|                    | EU            | Mo: < 0.01; < 0.01; 0.02; < 0.01; < 0.01; 0.01; < 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01; 0.01 | Trials compliant with GAP (Netherlands, 2018) MRL<sub>OECD</sub> = 0.1 | 0.1                    | 0.07                      | 0.01                        |

<sup>(a)</sup> Indoor

<sup>(b)</sup> HR = 

<sup>(c)</sup> STMR

<sup>(d)</sup> Tentative
| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|------------------------|------------------------|------------------------|
| Blackberries | NEU | Mo: 0.019; 0.017; 0.021; 0.009; 0.013; 0.034 | Trials on raspberries scaled using the proportionality approach (Netherlands, 2018) | 0.06 | 0.034 | 0.018 |
| | EU | Mo: 0.009; 0.019; 0.041; 0.013; 0.018; < 0.01 Mo (unscaled): 0.013; 0.029; 0.062; 0.019; 0.027; < 0.01 | Trials on raspberries scaled using the proportionality approach (Netherlands, 2018) | 0.07 | 0.041 | 0.015 |
| Dewberries | NEU | Mo: 0.029; 0.025; 0.031; 0.014; 0.020; 0.051 | Trials compliant with GAP (Netherlands, 2018) MRL<sub>OECD</sub> = 0.08 | 0.09 | 0.05 | 0.03 |
| Raspberries (red and yellow) | NEU | Mo: 0.029; 0.025; 0.031; 0.014; 0.020; 0.051 | Trials compliant with GAP (Netherlands, 2018) MRL<sub>OECD</sub> = 0.13 | 0.15 | 0.06 | 0.03 |
| | SEU | Mo: 0.011; < 0.01; 0.06; 0.063; 0.039; 0.024 | Trials compliant with GAP (Netherlands, 2018) MRL<sub>OECD</sub> = 0.1 | 0.1 | 0.06 | 0.02 |
| | EU | Mo: 0.013; 0.029; 0.062; 0.019; 0.027; < 0.01 | Trials compliant with GAP (Netherlands, 2018) MRL<sub>OECD</sub> = 0.1 | 0.3 | 0.14 | 0.05 |
| Blueberries | NEU | Mo: 0.058; < 0.01; 0.064; 0.045; 0.14; 0.045 | Trials on currants compliant with GAP (Netherlands, 2018). GAP authorised for currants and gooseberries only. Extrapolation to gooseberries is applicable MRL<sub>OECD</sub> = 0.23 | 0.3 | 0.14 | 0.05 |
| Cranberries | SEU | Mo: 0.064; 0.021; 0.16; 0.052; 0.67; 0.74 | Combined data set of trials on currants (5) and gooseberries (1) compliant with GAP (Netherlands, 2018). Extrapolation to blueberries, cranberries, gooseberries, rose hips, mulberries, azaroles and elderberries is applicable MRL<sub>OECD</sub> = 1.6 | 2 | 0.74 | 0.11 |
| Currants (black, red and white) | EU | Mo: 0.14; 0.14; 0.26; 0.40; 0.13 | Combined data set of trials on currants (5) and gooseberries (1) compliant with GAP (Netherlands, 2018). Extrapolation to blueberries, cranberries, gooseberries, rose hips, mulberries, azaroles and elderberries is applicable MRL<sub>OECD</sub> = 0.64 | 0.7 | 0.40 | 0.14 |
| Gooseberries (green, red and yellow) | | | | | | |
| Rose hips | | | | | | |
| Mulberries (black and white) | | | | | | |
| Azaroles/ Mediterranean medlars | | | | | | |
| Elderberries | | | | | | |
| Commodity                        | Region/ Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|---------------------------------|-------------------------------|------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|---------------------------|---------------------------|
| Radishes                        | SEU                           | –                                                               | No residue trials available                                                     | 0.01*                  | 0.01                      | 0.01                      |
| Tomatoes                        | SEU                           | Mo: 8 x < 0.01                                                  | Trials compliant with GAP (Netherlands, 2018)                                   | 0.01*                  | 0.01                      | 0.01                      |
|                                | EU                            | Mo: 8 x < 0.01                                                  | Trials compliant with GAP (Netherlands, 2018)                                   | 0.01*                  | 0.01                      | 0.01                      |
| Sweet peppers/bell peppers      | SEU                           | Mo: 5 x < 0.01; 0.02; 0.05; 0.04                                 | Trials compliant with GAP (Netherlands, 2018)                                   | 0.09                   | 0.05                      | 0.01                      |
|                                | EU                            | Mo: 5 x < 0.01; 3 x < 0.02                                      | Trials compliant with GAP (Netherlands, 2018)                                   | 0.04                   | 0.02                      | 0.01                      |
| Aubergines/ eggplants           | SEU                           | Mo: –                                                           | No residue trials available. Residue trials on tomatoes cannot be used to derive MRL values for aubergines since all ethirimol residues were below the LOQ and therefore cannot be upscaled | –                     | –                         | –                         |
|                                | EU                            | Mo: –                                                           | No residue trials available. Residue trials on tomatoes cannot be used to derive MRL and risk assessment values for aubergines since all ethirimol residues were below the LOQ and therefore cannot be upscaled to derive values for aubergines | –                     | –                         | –                         |
| Cucumbers Gherkins Courgettes   | SEU                           | Mo: 9 x < 0.01; 0.01; 0.02;                                     | Trials on courgettes compliant with GAP (Netherlands, 2018). Extrapolation to gherkins and cucumbers is applicable | 0.03                   | 0.02                      | 0.01                      |
|                                | EU                            | Mo: < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.01; < 0.01; < 0.01 | Combined data set of trials on cucumbers (9) and courgette (last 3) compliant with GAP (Netherlands, 2018). Extrapolation to gherkins and cucumbers is applicable | 0.05                   | 0.05                      | 0.05                      |
| Melons                          | SEU                           | **Mo (scaled):** 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01 | Trials on melons scaled using the proportionality approach (Netherlands, 2010; 2018) | 0.02                   | 0.02                      | 0.01                      |
|                                |                               | **Mo (unscaled):** 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01 |                                                                  |                        |                          |                           |

<sup>(a)</sup> Indoor

<sup>(b)</sup> HR

<sup>(c)</sup> STMR
| Commodity       | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|-----------------|------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------------|-----------------|
| Pumpkins        | SEU              | **Mo**: 0.02; 0.01; 0.02; < 0.01; < 0.01; < 0.01; 0.01; 0.01; 0.01; < 0.01; 0.01 | Trials on melons compliant with GAP (Netherlands, 2010) and scaled using the proportionality approach (Netherlands, 2018). Extrapolation to pumpkins and watermelons is applicable. MRL\textsubscript{OECD} = 0.02 | 0.03                  | 0.02          | 0.01            |
| Watermelons     |                  |                                                               |                                                                                                                                                                                                              |                       |               |                 |
| Melons          | EU               | **Mo**: < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.01; < 0.01 | Trials on melons compliant with GAP (Netherlands, 2018). Extrapolation to pumpkins and watermelons is applicable. MRL\textsubscript{OECD} = 0.11 | 0.15                  | 0.05          | 0.05            |
| Pumpkins        |                  |                                                               |                                                                                                                                                                                                              |                       |               |                 |
| Watermelons     | SEU              | –                                                             |                                                                                                                                                                                                              | –                     | –             | –               |
| Peas (without pods) | SEU         | –                                                             | No residue trials available                                                                                                                                                                                     | –                     | –             | –               |
| Globe artichokes| SEU              | **Mo**: 4 x < 0.02                                             | Trials compliant with GAP (Netherlands, 2018). Since metabolism studies on leafy vegetables are not available no MRL is proposed                                                                                   | –                     | –             | –               |
| Hops            | SEU              | –                                                             | No residue trials available                                                                                                                                                                                     | –                     | –             | –               |
| Sugar beet roots| SEU              | –                                                             | No residue trials available                                                                                                                                                                                     | –                     | –             | –               |
| Sugar beet tops | SEU              | –                                                             | No residue trials available                                                                                                                                                                                     | –                     | –             | –               |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; LOQ: limit of quantification.

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

(a): NEU: Outdoor trials conducted in northern Europe; SEU: Outdoor trials conducted in southern Europe; Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue refers to the whole commodity and not to the edible portion.

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

(d): MRL is tentative because residue trials analysed according to the residue definition for risk assessment are needed.
B.1.2.3. Residues in rotational crops

a) Overall summary

Residues in rotational and succeeding crops expected based on confined rotational crop study?

| Yes | Occurrence of residues in rotated crops cannot be excluded. Moreover, soil concentrations measured in the confined study suggest that the study was under-dosed in comparison with the plateau concentration in soil expected following multiannual application according to the most critical GAP assessed in this review. |
| Inconclusive | Rotational crop field trials not available and required. |

GAP: Good Agricultural Practice.

b) Summary of residues data from the rotational crops residue trials

No data available.
### B.1.2.4. Processing factors

| Processed commodity | Number of valid studies\(^{(a)}\) | Processing Factor (PF)\(\text{bupirimate}\) individual values | Median PF | Processing Factor (PF)\(\text{ethirimol}\) individual values | Median PF | \(\text{CP}_\text{F}^{(b)}\) (bupirimate) | Comment/Source |
|---------------------|-----------------------------------|---------------------------------------------------------------|------------|---------------------------------------------------------------|------------|-----------------------------|-----------------|
| Apple/wet pomace    | 4                                 | 2.2, 3.5, 5.0, 3.31                                          | 3.41       | 0.5, 1.0, 3.0                                                | 1          | –                           | Netherlands (2018) |
| Apple/juice         | 4                                 | 0.07, 0.09, < 0.2, < 0.5                                     | 0.15       | 0.81, < 0.5, < 1.0                                           | 0.81       | –                           |                 |
| Apple/sauce (puree) | 4                                 | 0.07, < 0.07, < 0.07, 0.12                                    | 0.07       | 0.90, < 0.5                                                 | 0.7        | –                           |                 |
| Peach/juice         | 4                                 | 0.14, 0.37, 0.52, 1.37                                       | 0.45       | 1.03, 1.18, 2.39                                            | 1.18       | 2.29                        |                 |
| Peach/puree         | 4                                 | 0.13, 0.24, 0.44, 0.56                                       | 0.34       | 0.71, 1.02, 1.19                                            | 1.02       | 2.39                        |                 |
| Peach/canned        | 4                                 | 0.03, 0.16, 0.20, 0.14                                       | 0.15       | 0.55, 0.10, 0.39                                            | 0.39       | 3.04                        |                 |
| Apricot/jam         | 4                                 | 0.26, 0.44, 0.50, 0.55                                        | 0.47       | 1.53, 2.7                                                   | 2.1        | 3.85                        |                 |
| Apricot/dried       | 4                                 | 2.47, 2.64, 4.12, 6.45                                       | 3.38       | 10.53, 14                                                   | 12.3       | 2.77                        |                 |
| Grapes/must         | 5                                 | 0.38, 0.10, 0.42, 3.10, 0.81                                    | 0.42       | 1.25, 0.18, 3.58, 0.94                                       | 1.1        | –                           |                 |
| Grapes/red wine     | 3                                 | 0.17, 0.07, 0.11                                             | 0.11       | 1.6, 0.09, 1.13                                             | 1.13       | –                           |                 |
| Grapes/juice        | 3                                 | 0.42, 0.36, 0.22                                             | 0.36       | 2.50, 1.94                                                 | 2.22       | 4.67                        |                 |
| Grapes/wet pomace   | 3                                 | 2.25, 0.76, 2.45                                             | 2.25       | 6.25, 2.63                                                 | 4.44       | 1.77                        |                 |
| Grapes/raisin       | 3                                 | 0.92, 0.67, 0.35                                             | 0.67       | 3.50, 3.38                                                 | 3.44       | 4.06                        |                 |
| Strawberries/canned strawberries | 4 | 0.46, 0.8, 0.13, 0.33                                         | 0.4        | 0.57, 1.0                                                  | 0.79       | –                           |                 |
| Strawberries/strawberry jam | 4 | 0.15, 0.25, 0.4, < 0.07                                       | 0.20       | 1.11, < 1.0, 1.0                                           | 1.0        | –                           |                 |
| Melons/melon pulp (peeling factor) | 24 | < 0.05, < 1.0, < 0.5, < 1.0, < 1.0, < 1.0, 0.12, < 0.17, < 1.0, < 0.09, < 0.07, < 0.33, < 0.02, < 0.33, < 0.5, < 0.25, < 0.2, < 0.4, < 0.38, < 0.2 | < 0.38 | < 1.0, < 1.0, < 0.5, < 1.0, < 0.33, < 0.5, < 1.1, 2.0, < 1.0, < 0.83, < 0.8 | < 1.0 | – | |
| Melons/melon peel   | 29                                | 9.0, 6.0, 10.0, 5.0, 5.0, 8.0, 8.0, 8.0, 5.5, 4.5, 2.0, 2.6, 2.43, 2.54, 2.0, 2.83, 2.4, 1.85, 2.7, 2.1, 1.88, 1.92, 1.67, 2.5, 2.0, 2.2, 1.94, 2.15, 2.54 | 2.54 | 7.0, 3.0, 7.0, 10.0, < 1.0, 1.9, 1.7, 1.4, < 1.0, 2.0, 1.67, < 1.0, 1.54 | 1.7 | 1.33 | |
| Currants/juice      | 2                                 | 0.37, 0.42                                                   | 0.40\(^{(c)}\) | 0.57, 1.40                                                  | 0.99\(^{(c)}\) | 4.46 | |
| Currants/jam        | 2                                 | 0.25, 0.21                                                   | 0.23\(^{(c)}\) | 0.97, 0.85                                                  | 0.91\(^{(c)}\) | 6.80 | |
| Currants/canned     | 2                                 | 1.0, 0.70                                                   | 0.85\(^{(c)}\) | 1.04, 0.88                                                  | 0.96\(^{(c)}\) | 2.79 | |
| Processed commodity       | Number of valid studies<sup>(a)</sup> | Processing Factor (PF) bupirimate | Processing Factor (PF) ethirimol | CF<sub>p</sub><sup>(b)</sup> (bupirimate) | Comment/Source |
|--------------------------|---------------------------------------|----------------------------------|----------------------------------|---------------------------------|----------------|
| Tomato/juice             | 2                                     | 0.04, 0.03                       | 0.91, 0.83                       | 0.87<sup>(c)</sup>                        | –              |
| Tomato/puree             | 2                                     | 1.11, 0.36                       | 10.0, 5.0                        | 7.5<sup>(c)</sup>                        | 1.78           |
| Tomato/paste             | 2                                     | 2.07, 0.31                       | 48.18, 11.67                     | 29.9<sup>(c)</sup>                        | 2.92           |
| Tomato/canned            | 2                                     | 0.04, 0.03                       | 0.91, 0.83                       | 0.87<sup>(c)</sup>                        | –              |
| Tomato/dried             | 2                                     | 4.58, 23.04                      | 32.27, 9.17                      | 20.7<sup>(c)</sup>                        | 1.12           |
| Tomato/ketchup           | 2                                     | 0.04, 0.22                       | 0.91, 5.0                        | 2.96<sup>(c)</sup>                        | 3.38           |
| Parsley (herbs)/dried leaves | 2                        | 8.94, 2.68                       | 5.81<sup>(c)</sup>                | –                                 | 1.19           |
| Apple/dry pomace         | 1                                     | 9.23                             | –                                 | 6.67                             | –              |
| Grapes/white wine        | 1                                     | 0.42                             | –                                 | –                                 | –              |
| Grapes/dry pomace        | 1                                     | 7.98                             | –                                 | 20.63                            | –              |

PF: Processing factor (= Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); CF<sub>p</sub>: conversion factor for risk assessment in processed commodity (= Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo)

<sup>(a)</sup>: Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)

<sup>(b)</sup>: Median of the individual conversion factors for each processing residues trial.

<sup>(c)</sup>: A tentative/indicative PF is derived based on a limited data set (less than 3 independent studies available).
### B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup<sup>(a)</sup> | Most critical commodity<sup>(b)</sup> | Trigger exceeded (Y/N) | Comments |
|-----------------------------|-----------------------------|-------------------------------------|-----------------------------------|------------------------|----------|
|                             | mg/kg bw per day | mg/kg DM | Median | Maximum | Median | Maximum |                                            |
| Cattle (all diets)          | 0.0041           | 0.0041   | 0.17   | 0.17    | Cattle (beef) | Apple, pomace, wet | Yes     | –                                  |
| Cattle (dairy only)         | 0.0033           | 0.0033   | 0.09   | 0.09    | Cattle (dairy) | Apple, pomace, wet | No      | –                                  |
| Sheep (all diets)           | 0.0036           | 0.0036   | 0.09   | 0.09    | Sheep (lamb)  | Apple, pomace, wet | No      | –                                  |
| Sheep (ewe only)            | 0.0028           | 0.0028   | 0.09   | 0.09    | Sheep (ram/ewe) | Apple, pomace, wet | No      | –                                  |
| Swine (all diets)           | 0.0000           | 0.0000   | 0.00   | 0.00    | Swine (breeding) | – | No | –                                  |
| Poultry (all diets)         | 0.0000           | 0.0000   | 0.00   | 0.00    | Poultry (broiler) | – | No | –                                  |
| Poultry (layer only)        | 0.0000           | 0.0000   | 0.00   | 0.00    | Poultry (layer) | – | No | –                                  |

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.
B.2.1. Nature of residues and methods of analysis in livestock

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

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | Comment/Source |
|------------------------------|--------|-------------------------|-----------------|----------------|
| Lactating ruminants          | 0.0066 (low dose level) and 0.33 (high-dose level) twice a day | 6               | Study on lactating goat (Netherlands, 2018) |

bw: body weight.

Time needed to reach a plateau concentration in milk and eggs (days)

|                      | Milk: – |                        |
|----------------------|---------|-------------------------|
|                      | Eggs: – |                        |

Metabolism in rat and ruminant similar

Can a general residue definition be proposed for animals?

|                        | –       |
|------------------------|---------|
| No                     | –       |

Animal residue definition for monitoring (RD-Mo)

Animal residue definition for risk assessment (RD-RA)

Fat soluble residues

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

Not available and required

B.2.1.2. Stability of residues in livestock

Not available and not required.

Not available and required.
### B.2.2. Magnitude of residues in livestock

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

Not available. MRL proposed at the LOQ based on the metabolism study.

### B.3. Consumer risk assessment

| ARfD | Not relevant since no ARfD has been considered necessary (EFSA, 2010) |
|------|------------------------------------------------------------------|
| ADI  | Bupirimate: 0.05 mg/kg bw per day (EFSA, 2010)                    |
|      | Ethirimol: 0.035 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 2.0) | 36% ADI (UK toddler) |
| 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, multiplied by the conversion factor for risk assessment. The highest conversion factor (CF = 3.62 from currants) was applied to table/wine grapes and aubergines. The median peeling factor derived from the studies on melon was applied to all cucurbits with inedible peel. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. As a worst case, the risk assessment was performed using the lowest ADI value derived for ethirimol |

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; IEDI: international estimated daily intake; GAP: Good Agricultural Practice; MRL: maximum residue level

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

| Metabolite(s) | Not assessed in this review |
|--------------|----------------------------|
| ADI (mg/kg bw per day) | Not assessed in this review |
| Intake of groundwater metabolites (% ADI) | Not assessed in this review |
### B.4. Proposed MRLs

| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|-------------------------|-----------------------|---------|
|             |           |                         | MRL (mg/kg)           |         |
| **Enforcement residue definition 1: bupirimate** | | | | |
| 130010 | Apples | 0.3 | 0.3 | Recommended<sup>a</sup> |
| 130020 | Pears | 0.2 | 0.3 | Recommended<sup>a</sup> |
| 140010 | Apricots | 0.3 | 0.3 | Recommended<sup>a</sup> |
| 140030 | Peaches | 0.3 | 0.3 | Recommended<sup>a</sup> |
| 151010 | Table grapes | 1.5 | 1.5 | Further consideration needed<sup>b</sup> |
| 151020 | Wine grapes | 1.5 | 1.5 | Further consideration needed<sup>b</sup> |
| 152000 | Strawberries | 2.0 | 1.5 | Recommended<sup>a</sup> |
| 153010 | Blackberries | 1.5 | 0.7 | Recommended<sup>a</sup> |
| 153020 | Dewberries | 1.5 | 0.7 | Recommended<sup>a</sup> |
| 153030 | Raspberries (red and yellow) | 1.5 | 1.5 | Recommended<sup>a</sup> |
| 154010 | Blueberries | 0.05 | 1.5 | Recommended<sup>a</sup> |
| 154020 | Cranberries | 0.05 | 1.5 | Recommended<sup>a</sup> |
| 154030 | Currants (black, red and white) | 5 | 1.5 | Recommended<sup>a</sup> |
| 154040 | Gooseberries (green, red and yellow) | 5 | 1.5 | Recommended<sup>a</sup> |
| 154050 | Rose hips | 0.05 | 1.5 | Recommended<sup>a</sup> |
| 154060 | Mulberries (black and white) | 0.05 | 1.5 | Recommended<sup>a</sup> |
| 154070 | Azaroles/Mediterranean medlars | 0.05 | 1.5 | Recommended<sup>a</sup> |
| 154080 | Elderberries | 0.05 | 1.5 | Recommended<sup>a</sup> |
| 213080 | Radishes | 0.05 | 0.05 | Further consideration needed<sup>c</sup> |
| 231010 | Tomatoes | 2 | 0.8 | Recommended<sup>a</sup> |
| 231020 | Sweet peppers/bell peppers | 2 | 1.5 | Recommended<sup>a</sup> |
| 231030 | Aubergines/eggplants | 2 | 1.5 | Further consideration needed<sup>b</sup> |
| 232010 | Cucumbers | 1 | 2 | Recommended<sup>a</sup> |
| 232020 | Gherkins | 1 | 2 | Recommended<sup>a</sup> |
| 232030 | Courgettes | 3 | 2 | Recommended<sup>a</sup> |
| 233010 | Melons | 0.3 | 0.3 | Recommended<sup>a</sup> |
| 233020 | Pumpkins | 0.3 | 0.3 | Recommended<sup>a</sup> |
| 233030 | Watermelons | 0.3 | 0.3 | Recommended<sup>a</sup> |
| 260040 | Peas (without pods) | 0.5 | 0.5 | Further consideration needed<sup>c</sup> |
| 270050 | Globe artichokes | 0.05 | 0.05 | Further consideration needed<sup>c</sup> |
| 700000 | Hops | 10 | 10 | Further consideration needed<sup>c</sup> |
| 900010 | Sugar beet roots | 0.5 | 0.5 | Further consideration needed<sup>c</sup> |

-- Other commodities of plant origin See Reg. 2015/846 – Further consideration needed<sup>d</sup>

**Enforcement residue definition 2: ethirimol**

| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|-------------------------|-----------------------|---------|
|             |           |                         | MRL (mg/kg)           |         |
| 130010 | Apples | 0.1 | 0.06 | Recommended<sup>a</sup> |
| 130020 | Pears | 0.1 | 0.06 | Recommended<sup>a</sup> |
| 140010 | Apricots | 0.05 | 0.04 | Recommended<sup>a</sup> |
| 140030 | Peaches | 0.05 | 0.04 | Recommended<sup>a</sup> |
| 151010 | Table grapes | 0.5 | 0.4 | Further consideration needed<sup>b</sup> |
| 151020 | Wine grapes | 0.5 | 0.4 | Further consideration needed<sup>b</sup> |
| 152000 | Strawberries | 0.2 | 0.3 | Recommended<sup>a</sup> |
| 153010 | Blackberries | 0.1 | 0.07 | Recommended<sup>a</sup> |
| 153020 | Dewberries | 0.1 | 0.07 | Recommended<sup>a</sup> |
| 153030 | Raspberries (red and yellow) | 0.1 | 0.15 | Recommended<sup>a</sup> |
| Code number | Commodity                          | Existing EU MRL (mg/kg) | Outcome of the review | Comment |
|------------|-----------------------------------|-------------------------|-----------------------|---------|
| 154010     | Blueberries                       | 0.05                    | 2                     | Recommended (a) |
| 154020     | Cranberries                       | 0.05                    | 2                     | Recommended (a) |
| 154030     | Currants (black, red and white)   | 2                       | 2                     | Recommended (a) |
| 154040     | Gooseberries (green, red and yellow) | 2                      | 2                     | Recommended (a) |
| 154050     | Rose hips                         | 0.05                    | 2                     | Recommended (a) |
| 154060     | Mulberries (black and white)      | 0.05                    | 2                     | Recommended (a) |
| 154070     | Azaroles/Mediterranean medlars     | 0.05                    | 2                     | Recommended (a) |
| 154080     | Elderberries                      | 0.05                    | 2                     | Recommended (a) |
| 213080     | Radishes                          | 0.05                    | 0.05                  | Further consideration needed (c) |
| 231010     | Tomatoes                           | 0.1                     | 0.01*                 | Recommended (a) |
| 231020     | Sweet peppers/bell peppers        | 0.1                     | 0.09                  | Recommended (a) |
| 231030     | Aubergines/eggplants               | 0.1                     | 0.1                   | Further consideration needed (c) |
| 232010     | Cucumbers                          | 0.2                     | 0.05                  | Recommended (a) |
| 232020     | Gherkins                           | 0.2                     | 0.05                  | Recommended (a) |
| 232030     | Courgettes                         | 0.2                     | 0.05                  | Recommended (a) |
| 233010     | Melons                             | 0.08                    | 0.15                  | Recommended (a) |
| 233020     | Pumpkins                           | 0.08                    | 0.15                  | Recommended (a) |
| 233030     | Watermelons                        | 0.08                    | 0.15                  | Recommended (a) |
| 260040     | Peas (without pods)               | 0.5                     | 0.5                   | Further consideration needed (c) |
| 270050     | Globe artichokes                   | 0.05                    | 0.05                  | Further consideration needed (c) |
| 700000     | Hops                                | 10                      | 10                    | Further consideration needed (c) |
| 900010     | Sugar beet roots                   | 0.05                    | 0.05                  | Further consideration needed (c) |
| –          | Other commodities of plant origin  |                         |                       | Further consideration needed (c) |

**Enforcement residue definition 3: de-ethyl ethirimol**

| Code number | Commodity      | Existing EU MRL (mg/kg) | Outcome of the review | Comment |
|------------|----------------|-------------------------|-----------------------|---------|
| 1012010    | Bovine muscle  | 0.05                    | 0.01*                 | Further consideration needed (b) |
| 1012020    | Bovine fat tissue | 0.05                  | 0.01*                 | Further consideration needed (b) |
| 1012030    | Bovine liver   | 0.05                    | 0.01*                 | Further consideration needed (b) |
| 1012040    | Bovine kidney  | 0.05                    | 0.01*                 | Further consideration needed (b) |
| 1015010    | Equine muscle  | 0.05                    | 0.01*                 | Further consideration needed (b) |
| 1015020    | Equine fat tissue | 0.05             | 0.01*                 | Further consideration needed (b) |
| 1015030    | Equine liver   | 0.05                    | 0.01*                 | Further consideration needed (b) |
| 1015040    | Equine kidney  | 0.05                    | 0.01*                 | Further consideration needed (b) |
| –          | Other commodities of animal origin |               |                       | Further consideration needed (c) |

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

*: 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): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).

(d): 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)**

#### Bupirimate

| Status of the active substance: | Code no. | LOQ (mg/kg) | Proposed LOQ | Toxicological end points |
|--------------------------------|----------|-------------|--------------|-------------------------|
| Code no. | LOQ (mg/kg) | Proposed LOQ | ADI (mg/kg bw per day): | Source of ADI: | ARfD (mg/kg bw): | Source of ARfD: | Year of evaluation: | Year of evaluation: |
|----------|-------------|--------------|----------------|----------------|----------------|----------------|----------------|----------------|
| Code no. | LOQ (mg/kg) | Proposed LOQ | ADI (mg/kg bw per day): | Source of ADI: | ARfD (mg/kg bw): | Source of ARfD: | Year of evaluation: | Year of evaluation: |
| Code no. | LOQ (mg/kg) | Proposed LOQ | ADI (mg/kg bw per day): | Source of ADI: | ARfD (mg/kg bw): | Source of ARfD: | Year of evaluation: | Year of evaluation: |
| Code no. | LOQ (mg/kg) | Proposed LOQ | ADI (mg/kg bw per day): | Source of ADI: | ARfD (mg/kg bw): | Source of ARfD: | Year of evaluation: | Year of evaluation: |
| Code no. | LOQ (mg/kg) | Proposed LOQ | ADI (mg/kg bw per day): | Source of ADI: | ARfD (mg/kg bw): | Source of ARfD: | Year of evaluation: | Year of evaluation: |
| Code no. | LOQ (mg/kg) | Proposed LOQ | ADI (mg/kg bw per day): | Source of ADI: | ARfD (mg/kg bw): | Source of ARfD: | Year of evaluation: | Year of evaluation: |

**Source of ADI:** EFSA  
**Source of ARfD:** EFSA  
**Year of evaluation:** 2010

#### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI |
|--------------------------------|-------------------------|
| Commodity/group of commodities | Minimum | Maximum |
| Sugar beet (root) | 0.7 | Table grapes |
| Sugar beet (root) | 0.6 | Peas (without pods) |
| Sugar beet (root) | 0.8 | Tomatoes |
| Sugar beet (root) | 0.3 | Tomatoes |
| Sugar beet (root) | 0.5 | Tomatoes |
| Sugar beet (root) | 0.4 | Tomatoes |
| Sugar beet (root) | 0.3 | Tomatoes |
| Sugar beet (root) | 0.2 | Tomatoes |
| Sugar beet (root) | 0.1 | Tomatoes |
| Sugar beet (root) | 0.0 | Tomatoes |
| Sugar beet (root) | 0.9 | Tomatoes |
| Sugar beet (root) | 0.8 | Tomatoes |
| Sugar beet (root) | 0.7 | Tomatoes |
| Sugar beet (root) | 0.6 | Tomatoes |
| Sugar beet (root) | 0.5 | Tomatoes |
| Sugar beet (root) | 0.4 | Tomatoes |
| Sugar beet (root) | 0.3 | Tomatoes |
| Sugar beet (root) | 0.2 | Tomatoes |
| Sugar beet (root) | 0.1 | Tomatoes |
| Sugar beet (root) | 0.0 | Tomatoes |
| Sugar beet (root) | 0.9 | Tomatoes |
| Sugar beet (root) | 0.8 | Tomatoes |
| Sugar beet (root) | 0.7 | Tomatoes |
| Sugar beet (root) | 0.6 | Tomatoes |
| Sugar beet (root) | 0.5 | Tomatoes |
| Sugar beet (root) | 0.4 | Tomatoes |
| Sugar beet (root) | 0.3 | Tomatoes |
| Sugar beet (root) | 0.2 | Tomatoes |
| Sugar beet (root) | 0.1 | Tomatoes |
| Sugar beet (root) | 0.0 | Tomatoes |

**Conclusion:**  
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.  
A long-term intake of residues of bupirimate is unlikely to present a public health concern.
### Acute risk assessment /children – refined calculations

Acute risk assessment is not necessary.

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

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

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

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

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

| Commodity Type | IESTI 1 | IESTI 2 |
|----------------|---------|---------|
| No of commodities for which ARID is exceeded | --- | --- |
| No of commodities for which ARID is exceeded | --- | --- |

| Commodity Type | IESTI 1 | IESTI 2 |
|----------------|---------|---------|
| Highest % of ARID | --- | --- |
| pTMRL/ threshold MRL (mg/kg) | --- | --- |

| Commodity Type | IESTI 1 | IESTI 2 |
|----------------|---------|---------|
| No of commodities for which ARID is exceeded | --- | --- |
| No of commodities for which ARID is exceeded | --- | --- |

| Commodity Type | IESTI 1 | IESTI 2 |
|----------------|---------|---------|
| Highest % of ARID | --- | --- |
| pTMRL/ threshold MRL (mg/kg) | --- | --- |

---

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

**pTMRL: provisional temporary.

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

---

**Conclusion:**

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

D.1. Livestock dietary burden calculations

| Feed commodity         | Median dietary burden | Maximum dietary burden |
|------------------------|-----------------------|------------------------|
|                        | Input value (mg/kg)   | Comment                |
|                        |                      |                        |

Risk assessment residue definition: sum of bupirimate, ethirimol and de-ethyl ethirimol, expressed as bupirimate

Apple, pomace, wet

|                        | 0.34 | STMR × PF (3.41) × CF (1.75)(a) |
|------------------------|------|---------------------------------|
|                        | 0.34 | STMR × PF (3.41) × CF (1.75)(a) |

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

(a): Conversion factor from RAC (apple) was used, since processing studies on apple wet pomace were not analysed according to the residue definition for risk assessment.

D.2. Consumer risk assessment

| Commodity              | Chronic risk assessment |
|------------------------|-------------------------|
|                        | Input value (mg/kg)     | Comment                |
|                        |                        |                       |

Risk assessment residue definition 1: sum of bupirimate, ethirimol and de-ethyl ethirimol, expressed as bupirimate

Apples

|                        | 0.10 | STMRMo × CF (1.75) |

Pears

|                        | 0.097 | STMRMo × CF (1.70) |

Apricots

|                        | 0.12  | STMRMo × CF (1.59) |

Peaches

|                        | 0.12  | STMRMo × CF (1.59) |

Table grapes

|                        | 0.98  | STMRMo × CF (3.62) |

Strawberries

|                        | 0.33  | STMRMo × CF (1.56) |

Blackberries

|                        | 0.23  | STMRMo × CF (1.62) |

Dewberries

|                        | 0.23  | STMRMo × CF (1.62) |

Raspberries (red and yellow)

|                        | 0.46  | STMRMo × CF (2.18) |

Blueberries

|                        | 1.08  | STMRMo × CF (3.62) |

Cranberries

|                        | 1.08  | STMRMo × CF (3.62) |

Currants (black, red and white)

|                        | 1.30  | STMRMo × CF (3.62) |

Gooseberries (green, red and yellow)

|                        | 1.30  | STMRMo × CF (3.62) |

Rose hips

|                        | 1.08  | STMRMo × CF (3.62) |

Mulberries (black and white)

|                        | 1.08  | STMRMo × CF (3.62) |

Azaroles/Mediterranean medlars

|                        | 1.08  | STMRMo × CF (3.62) |

Elderberries

|                        | 1.08  | STMRMo × CF (3.62) |

Radishes

|                        | 0.05  | EU MRL (tentative) |

Tomatoes

|                        | 0.37  | STMRMo × CF (1.44) |

Sweet peppers/bell peppers

|                        | 0.33  | STMRMo × CF (1.30) |

Aubergines/eggplants

|                        | 1.37  | STMRMo × CF (3.62) |

Cucumbers

|                        | 0.23  | STMRMo × CF (1.32) |

Gherkins

|                        | 0.23  | STMRMo × CF (1.32) |

Courgettes

|                        | 0.23  | STMRMo × CF (1.32) |

Melons

|                        | 0.084 | STMRMo × CF (2.60) × PF (0.38) |

Pumpkins

|                        | 0.063 | STMRMo × CF (1.95) × PF (0.38) |

Watermelons

|                        | 0.063 | STMRMo × CF (1.95) × PF (0.38) |

Peas (without pods)

|                        | 0.5   | EU MRL (tentative) |

www.efsa.europa.eu/efsajournal 53 EFSA Journal 2019;17(7):5757
| Commodity               | Input value (mg/kg) | Comment          |
|------------------------|--------------------|------------------|
| Globe artichokes       | 0.05               | EU MRL (tentative) |
| Hops                   | 10                 | EU MRL (tentative) |
| Sugar beet roots       | 0.5                | EU MRL (tentative) |

**Risk assessment residue definition 2:** de-ethyl ethirimol

| Commodity               | Input value (mg/kg) | Comment          |
|------------------------|--------------------|------------------|
| Bovine muscle          | 0.01*              | STMR (tentative) |
| Bovine fat tissue      | 0.01*              | STMR (tentative) |
| Bovine liver           | 0.01*              | STMR (tentative) |
| Bovine kidney          | 0.01*              | STMR (tentative) |
| Equine muscle          | 0.01*              | STMR (tentative) |
| Equine fat tissue      | 0.01*              | STMR (tentative) |
| Equine liver           | 0.01*              | STMR (tentative) |
| Equine kidney          | 0.01*              | STMR (tentative) |

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

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

Evaluation of the GAPs and available residues data at EU level

1. GAP or DB ≤ 0.1 mg/kg DM in EU
   - Yes
   - MRL And RA derived for this commodity?
     - No
     - Is RD-RA derived for this commodity?
       - No
       - MRL fully supported by data?
         - No
         - Consumer risk assessment for GAPs evaluated at EU level – EU scenarios
   - No
   - No

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

- Not considered for the RA
- Not considered for the RA
- Current EU MRL is included in the RA
- Tentative median/highest values are included in the RA

- Risk identified?
  - Yes
  - Risk identified?
    - Yes
    - Risk identified?
      - Yes
      - Risk identified?
        - Yes
        - Risk identified?
          - Yes
          - Risk identified?
            - Yes
            - Risk identified?
              - Yes
              - Risk identified?
                - Yes

Recommendations resulting from EU authorisations and import tolerances

- Comparison with CXLs

(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 bupirimate

Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes
        - No
      - No
    - No
  - No

- CXL supported by data?
  - No
  - Yes

Consumer risk assessment with consideration of the existing CXL

- Input values for the RA remain unchanged.
- CXL is included in the RA.
- Risk identified?
  - Yes
  - No

Recommendations with consideration of the existing CXL

- (I) Maintain EU recommendation indicating that no CXL is available.
- (II) Maintain EU recommendation indicating CXL is not compatible.
- (III) Maintain EU recommendation indicating CXL is covered.
- (IV) Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
- (V) Maintain EU recommendation; higher CXL is not safe for consumer.
- (VI) Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
- (VII) CXL is recommended; EU recommendation is covered as well.
## Appendix F – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| Bupirimate           | 5-butyl-2-ethylamino-6-methylpyrimidin-4-yl dimethylsulfamate  
CCNc1nc (C)c(CCCC)c(OS(=O)(=O)N(C)C)n1  
DSKPMWIHSOYEA-UHFFFAOYSA-N | ![Structural formula of Bupirimate](image) |
| Ethirimol            | 5-butyl-2-ethylamino-6-methyl pyrimidin-4-ol  
CCNc1nc(C)c(CCCC)c(O)n1  
BBXXLROWFHFQY-UHFFFAOYSA-N | ![Structural formula of Ethirimol](image) |
| De-ethyl-ethirimol   | 2-amino-5-butyl-6-methylpyrimidin-4-ol  
Cc1nc(N)nc(O)c1CCCC  
VYCNDBQWMCGZAA-UHFFFAOYSA-N | ![Structural formula of De-ethyl-ethirimol](image) |
| Hydroxyl ethirimol   | 2-(ethylamino)-5-[(3RS)-3-hydroxybutyl]-6-methylpyrimidin-4-ol  
CCNc1nc(C)c(CCC(O)C(O)n1  
UUSXZDACEUWGCS-UHFFFAOYSA-N | ![Structural formula of Hydroxyl ethirimol](image) |
| Ethyl guanidine      | 1-ethylguanidine  
KEWLVUBYGUZFKX-UHFFFAOYSA-N  
N=C(N)NCC | ![Structural formula of Ethyl guanidine](image) |

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

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