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

European Food Safety Authority (EFSA), Maria Anastassiadou, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnar Pedersen, Hermine Reich, Alejandro Rojas, 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 amisulbrom. To assess the occurrence of amisulbrom residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011, 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. All information required by the regulatory framework was present and a risk to consumers was not identified.

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

Amisulbrom was included in Annex I to Directive 91/414/EEC on 1 July 2014 by Commission Implementing Regulation (EU) No 193/2014, 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 14 January 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 14 February 2019 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, Greece, 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 30 May 2019. 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, together with Pesticide Residues Intake Model (PRIMO) calculations and an updated GAP overview file were provided by the RMS to EFSA on 6 September 2019. 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 (EU) No 188/2011, EFSA prepared in March 2020 a draft reasoned opinion, which was circulated to Member States and EURL for consultation via a written procedure. Comments received by 11 May 2020 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of amisulbrom in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as amisulbrom. Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water and high acid content commodities at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses. For processed commodities, the proposed residue definition for risk assessment as sum of amisulbrom and metabolites IT-4 and I-1, expressed as amisulbrom on is tentative since toxicological information is missing for metabolites IT-4 and I-1. Processing factors could be derived for processed grape commodities.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation.

Amisulbrom is authorised for use on potatoes that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

The exposure values calculated using revision 3.1 of the EFSA PRIMO were compared with the toxicological reference values for amisulbrom derived by EFSA (2013). The highest chronic exposure was calculated for Spanish adults, representing 0.7% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for lettuces representing 27% of the acute reference dose (ARfD). For processed commodities, the highest acute exposure was calculated for tomatoes (juice) for children representing 0.8% of the ARfD and for tomatoes (sauce/puree) for adults representing 0.3% of the ARfD. These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health.
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Background

Regulation (EC) No 396/2005¹ (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/EEC² a reasoned opinion on the review of the existing MRLs for that active substance.

Amisulbrom was included in Annex I to Council Directive 91/414/EEC on 1 July 2014 by means of Commission Implementing Regulation (EU) No 193/2014³ which has been deemed to be approved under Regulation (EC) No 1107/2009⁴, in accordance with Commission Implementing Regulation (EU) No 540/2011⁵, as amended by Commission Implementing Regulation (EU) No 541/2011⁶. Therefore, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EU) No 188/2011⁷, Amisulbrom was evaluated by United Kingdom, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2014a). Furthermore, according to the provisions of the approval regulation, confirmatory information was requested, among others, as regards confirmatory data relevant for residues section, to be submitted by 30 June 2016 (EFSA, 2017).

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 14 January 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 14 February 2019 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 18 Member States provided feedback on their national authorisations of amisulbrom. Based on the GAP data submitted, the designated RMS

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¹ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending and extending 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 Implementing Regulation (EU) No 193/2014 of 27 February 2014 approving the active substance amisulbrom, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 59, 28.2.2014, p. 25–29.
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 (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51–55.
Greece 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 30 May 2019.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked Greece to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and updated GAP overview file, were submitted to EFSA on 6 September 2019. 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 2020 a draft reasoned opinion, which was circulated to Member States and EURL for commenting via a written procedure. All comments received by 20 April 2020 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Greece, 2019), taking into account also the information provided by Member States during the collection of data, and the EURL report on analytical methods (EURL, 2019) is 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, 2020a) and the Member States consultation report (EFSA, 2020b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile as well as the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

**Terms of Reference**

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

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

**The active substance and its use pattern**

Amisulbrom is the ISO common name for 3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-N,N-dimethyl-1H-1,2,4-triazole-1- (IUPAC).

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

The EU MRLs for amisulbrom are established in Annexes IIIA of Regulation (EC) No 396/2005. 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 750/2010 | Grapes (EFSA, 2009)      |
| MRL application  | Regulation (EC) No 897/2012 | Tomatoes, aubergines and lettuce (EFSA, 2012) |
| Peer review      | Regulation (EC) No 2015/846 | Grapes (EFSA, 2014b)     |

(a): Commission Regulation (EU) No 750/2010 of 7 July 2010 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products. OJ L 220, 21.8.2010, p. 1–56.

(b): Commission Regulation (EU) No 897/2012 of 1 October 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, amisulbrom, cyazofamid, diflufenican, dimoxystrobin, methoxyfenozide and nicotine in or on certain products. OJ L 266, 2.10.2012, p. 1–31.
For the purpose of this MRL review, all the uses of amisulbrom 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 PROFile and considered in the assessment. The details of the authorised critical GAP for amisulbrom are given in Appendix A.

**Assessment**

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Greece, 2019);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2012, 2013);
- the conclusion on the peer review and confirmatory data of the pesticide risk assessment of the active substance amisulbrom (EFSA, 2014b, 2017);
- the previous reasoned opinions on amisulbrom (EFSA, 2009, 2012).

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 amisulbrom was investigated following foliar treatment in fruits (grapes), roots (potatoes) (United Kingdom, 2012), leafy vegetables (lettuce) and fruiting vegetables (tomatoes) (Spain, 2012). The studies on grapes and potatoes were also assessed in the framework of the peer review (EFSA, 2014b), while the studies on lettuce and tomatoes were assessed in the framework of an MRL application (EFSA, 2012). All studies were conducted with application rates (0.8–1N) that cover the uses reported in this review. Amisulbrom was detected as the main component of the radioactive residues in primary crops and the remaining radioactivity was composed of multiple individual fractions all detected at low levels. The metabolism was similar in fruits, roots and leafy vegetables and the studies cover all GAPs reported in this review.

1.1.2. **Nature of residues in rotational crops**

Amisulbrom is authorised on crops that may be grown in rotation. The field DT₉₀ reported in the soil degradation studies evaluated in the framework of the peer review is 41.7 days (EFSA, 2014b). However, metabolite IT-4 is more persistent (field DT₉₀ not available, but DT₅₀ of 112.9 days – longest value from three lab studies) (EFSA, 2014b).

One confined rotational crop study where amisulbrom was applied at 600 g a.s./ha onto bare soil and carrot, lettuce and wheat were planted at nominal plant back intervals (PBI) of 30, 120 and 365 days after treatment (DAT) is available (United Kingdom, 2012) and was assessed in the framework of the peer review (EFSA, 2014b). Residue uptake was very limited in lettuce as total radioactive residues (TRR) were below 0.01 mg/kg. In wheat and carrots, several factions were present at 5% TRR with the exception of triazole derivative metabolites (TDMs), that were present in straw, grain and carrot leaves at 12% (0.02 mg eq./kg), 14% (0.002 mg eq./kg) and 18% TRR (0.005 mg eq./kg), respectively. Parent and main soil metabolite IT-4 was not detected in rotated plants.

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8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
The metabolism and distribution of amisulbrom in rotational crops are similar to the metabolic pathway observed in primary crops (EFSA, 2014b). It is noted that in rotational crops, following bare soil application, TDMs are formed at low levels.

### 1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed (United Kingdom, 2012; EFSA, 2014b). Amisulbrom was significantly degraded under standard hydrolysis conditions to the metabolite IT-4, up to 10%, 45% and 62% of the applied radioactivity (AR) under pasteurisation, boiling and sterilisation, respectively. In addition, metabolites I-1 and T-1 resulting from the cleavage of the molecule were detected at 35% (indole label) and 18% AR (triazole label) under sterilisation conditions, the parent amisulbrom accounting finally for less than 14% AR (EFSA, 2014b). Metabolites observed in the standard hydrolysis study were also present in the plant metabolism studies (EFSA, 2014b).

### 1.1.4. Methods of analysis in plants

In the framework of the peer review, it was concluded that amisulbrom can be monitored by high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) with an LOQ of 0.01 mg/kg in high water (potatoes) and high acid (grapes) content commodities. However, data to demonstrate that metabolite IT-4 does not co-elude with amisulbrom was requested as confirmatory data (EFSA, 2014b). In the assessment of the confirmatory data, it was concluded that the metabolite IT-4 does not co-elude with amisulbrom under the chromatographic conditions employed in the validated HPLC-MS/MS methods for plants (EFSA, 2017).

According to the EURLs, amisulbrom can be monitored in high water content, high acid content and dry commodities with at least an LOQ of 0.01 mg/kg (EURL, 2019). In high fat commodities, validation at 0.01 mg/kg was not successful as the RSD marginally exceeded the threshold (due to poor sensitivity). However, the EURLs assumed that an LOQ of 0.02 mg/kg could be achieved for high fat commodities (EURL, 2019).

Therefore, it can be concluded that fully validated analytical methods with an LOQ of 0.01 mg/kg are available for all commodities reported in this review (high water and high acid content matrices).

### 1.1.5. Stability of residues in plants

Amisulbrom is stable up to 12 months in high acid content matrices and in high water content matrices and 6 months in processed grape fractions (dry pomace, wine juice and red wine) when stored frozen at −18°C (EFSA, 2014b).

### 1.1.6. Proposed residue definitions

The metabolism of amisulbrom was similar in all crops assessed (fruits, leafy vegetables and roots) and the metabolism in rotational crops is similar to the metabolism observed in primary crops. The residue definition for risk assessment is proposed as amisulbrom for primary and rotational crops. Although, following bare soil application, TDMs are formed at low levels in rotational crops, significant residues are not expected, and therefore, a specific residue definition including the TDMs is not deemed necessary. This residue definition may need to be revisited considering further authorisations.

In the framework of the peer review, there was not enough information to address the toxicity of the metabolites formed under hydrolysis conditions, and the residue definition for risk assessment for processed commodities was provisionally set as amisulbrom and metabolites IT-4 and I-1 (EFSA, 2014b). Since new toxicological information was not received in the current Art 12 review, the residue definition derived in the peer review is still applicable and is proposed as sum of amisulbrom and metabolites IT-4 and I-1, expressed as amisulbrom on a tentative basis.

As the parent compound was found to be a sufficient marker in fruits, leafy vegetables and roots, the residue definition for enforcement is proposed as amisulbrom only.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in high water and high acid content matrices is available (EURL, 2019). According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses in high water, high acid and dry content matrices, and assumed that an LOQ of 0.02 mg/kg could be achieved for high oil content matrices (EURL, 2019). It is noted that the analytical standard for amisulbrom is commercially available (EURL, 2019).
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of amisulbrom residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Greece, 2019) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2014b) or in the framework of a previous MRL application (EFSA, 2012). 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).

For all crops, available residue trials are sufficient to derive MRL and risk assessment values.

1.2.2. Magnitude of residues in rotational crops

Field rotational crop studies were not available for this review. The available confined rotational crop study (see Section 1.1.2) was performed at 1N of the most critical GAP reported in this review (GAP on potatoes). Therefore, residues (including TDMs) are expected to be below 0.01 mg/kg if amisulbrom is applied according to the uses reported in this review.

1.2.3. Magnitude of residues in processed commodities

Processing studies on grape were submitted and assessed in the framework of the peer review, but samples were analysed for amisulbrom only and no toxicological information was provided on metabolites IT-4 and I-1; a data gap was set to provide such data (EFSA, 2014b). A new processing study on grapes with samples analysed for parent and metabolites IT-4 and I-1 was submitted on the framework of the current review (Greece, 2019). The results indicated that after application of amisulbrom at three times the maximum application rate there was a concentration of amisulbrom in raisins, dry and wet pomace, while there were no residues of I-1 above the LOQ of 0.01 mg/kg in any sample. Residues of IT-4 were detected in raisins, wet pomace and dry pomace and could not be detected in juice, young or aged wine (Greece, 2019).

An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for grape raisins, juice and wine and while limited processing factors (not fully supported by data) were derived for grape dry and wet pomace.

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 MRL proposals as well as risk assessment values for all commodities under evaluation.

2. Residues in livestock

Amisulbrom is authorised for use on potatoes that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Although not necessary for this current review, the metabolism of amisulbrom was investigated in lactating goats under the framework of the peer review (EFSA, 2014b) and in laying hens under the assessment of confirmatory data evaluated in the context of supporting information for the ecotoxicology assessment (EFSA, 2017). The residue definition for ruminant products was provisionally proposed as IT-4 and IT-4-N-glucuronide for monitoring and as IT-4, IT-4-N-glucuronide and IT-5 for risk assessment (EFSA, 2014b), pending the conclusion on the toxicity of metabolite IT-4. Regarding the poultry metabolism study, storage stability of amisulbrom and its metabolites was not sufficiently
addressed; therefore, a conclusion on the actual metabolic profile in poultry matrices, particularly in liver, could not be made be derived (EFSA, 2017).

Since the trigger value is not exceeded for any group of livestock, deriving a residue definition is not necessary for this current review.

Analytical methods, storage stability studies and feeding studies are not available and are not required since MRLs for livestock products are not needed.

3. **Consumer risk assessment**

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where an MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values for amisulbrom derived by EFSA (2014a). The highest chronic exposure was calculated for Spanish adults, representing 0.7% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for lettuces representing 27% of the ARfD. For processed commodities, the highest acute exposure was calculated for tomatoes (juice) for children representing 0.8% of the ARfD and for tomatoes (sauce/puree) for adults representing 0.3% of the ARfD. These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health.

**Conclusions**

The metabolism of amisulbrom in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as amisulbrom. Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water and high acid content commodities at the LOQ of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses. For processed commodities, the proposed residue definition for risk assessment as sum of amisulbrom and metabolites IT-4 and I-1, expressed as amisulbrom on is tentative since toxicological information is missing for metabolites IT-4 and I-1. Processing factors could be derived for processed grape commodities.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation.

Amisulbrom is authorised for use on potatoes that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

The exposure values calculated using revision 3.1 of the EFSA PRIMo were compared with the toxicological reference values for amisulbrom derived by EFSA (2014a). The highest chronic exposure was calculated for Spanish adults, representing 0.7% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for lettuces representing 27% of the ARfD. For processed commodities, the highest acute exposure was calculated for tomatoes (juice) for children representing 0.8% of the ARfD and for tomatoes (sauce/puree) for adults representing 0.3% of the ARfD. These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health.

**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.

It is highlighted that toxicological information on metabolites IT-4 and I-1, formed under hydrolysis conditions, is not available. The exposure to amisulbrom in the current review is very low and these
two metabolites were detected also at very low levels. Therefore, the data gap identified is not expected to impact on the validity of the MRLs derived in the current review but might have an impact if further authorisations would lead to a significant exposure to metabolites IT-4 and I-1. In such cases, the following data would be required:

Information on the toxicology of metabolites IT-4 and I-1.

According to the information provided by the EURLs, the analytical standard for amisulbrom is commercially available (EURL, 2019).

Table 2: Summary table

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|-------------------------|----------------------|-----------------------|---------|
| 151010      | Table grapes | 0.5 | – | 0.4 | Recommended\(^{(a)}\) |
| 151020      | Wine grapes  | 0.5 | – | 0.4 | Recommended\(^{(a)}\) |
| 211000      | Potatoes   | 0.01* | – | 0.01* | Recommended\(^{(a)}\) |
| 231010      | Tomatoes   | 0.4 | – | 0.4 | Recommended\(^{(a)}\) |
| 231030      | Aubergines (egg plants) | 0.4 | – | 0.4 | Recommended\(^{(a)}\) |
| 251020      | Lettuce    | 4 | – | 4 | Recommended\(^{(a)}\) |
| –           | Other commodities of plant and/or animal origin | See Reg. 2015/846 | – | – | Further consideration needed\(^{(b)}\) |

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

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

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

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

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Abbreviations

a.i. active ingredient
a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARFD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CAS Chemical Abstract Service
CF conversion factor for enforcement residue definition to risk assessment residue definition
CIRCA (EU) Communication & Information Resource Centre Administrator
CS capsule suspension
CV coefficient of variation (relative standard deviation)
CXL codex maximum residue limit
DALA days after last application
DAR draft assessment report
DAT days after treatment
| Abbreviation | Definition |
|--------------|------------|
| DB           | dietary burden |
| DM           | dry matter |
| DP           | dustable powder |
| DS           | powder for dry seed treatment |
| DT<sub>90</sub> | period required for 90% dissipation (define method of estimation) |
| EC           | emulsifiable concentrate |
| EDI          | estimated daily intake |
| EMS          | evaluating Member State |
| eq           | residue expressed as a.s. equivalent |
| EURs         | European Union Reference Laboratories for Pesticide Residues (former CRLs) |
| FAO          | Food and Agriculture Organization of the United Nations |
| FID          | flame ionisation detector |
| GAP          | Good Agricultural Practice |
| GS           | growth stage |
| HPLC         | high-performance liquid chromatography |
| HPLC-MS      | high-performance liquid chromatography with mass spectrometry |
| HPLC-MS/MS   | high-performance liquid chromatography with tandem mass spectrometry |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| IESTI        | international estimated short-term intake |
| ILV          | independent laboratory validation |
| ISO          | International Organisation for Standardization |
| IUPAC        | International Union of Pure and Applied Chemistry |
| LC           | liquid chromatography |
| LC-MS/MS     | liquid chromatography with tandem mass spectrometry |
| LOD          | limit of detection |
| LOQ          | limit of quantification |
| Mo           | monitoring |
| MRL          | maximum residue level |
| MS           | Member States |
| MS/M/MS      | tandem mass spectrometry detector |
| MW           | molecular weight |
| NEU          | northern European Union |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant back interval |
| PF           | processing factor |
| PHI          | preharvest interval |
| P<sub>ow</sub> | partition coefficient between <i>n</i>-octanol and water |
| ppm          | parts per million (10<sup>-6</sup>) |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| PROFile      | (EFSA) Pesticide Residues Overview File |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| R<sub>ber</sub> | statistical calculation of the MRL by using a non-parametric method |
| R<sub>max</sub> | statistical calculation of the MRL by using a parametric method |
| RA           | risk assessment |
| RD           | residue definition |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| RSD          | relative standard deviation |
| SANCO        | Directorate-General for Health and Consumers |
| SC           | suspension concentrate |
| SEU          | southern European Union |
| SMILES       | simplified molecular-input line-entry system |
| SL           | soluble concentrate |
| SP           | water soluble powder |
| Acronym | Description                        |
|---------|-----------------------------------|
| STMR    | supervised trials median residue  |
| TAR     | total applied radioactivity        |
| TMDI    | theoretical maximum daily intake   |
| TRR     | total radioactive residue          |
| UV      | ultraviolet (detector)            |
| WHO     | World Health Organization          |
| WP      | wettable powder                    |
## 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 G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-------------|-------------------------------|----------------|---------|
|                       |               | FG or I     |                                   | Type(b)     | Conc. a.s.  | Method kind                   | a.s./hL min–max | Water L/ha min–max | Rate and unit |               |
| Table grapes          | FR            | F           | Downy mildew (Plasmopara viticola) | SC          | 200 g/L    | Foliar treatment – broadcast spraying | 12–83          | 3–10               | –              | 75 g a.i./ha | 28          | –           |
| Wine grapes           | AT/DE/FR      | F           | Downy mildew (PLASVI, Plasmopara viticola) | WG          | 50 g/kg    | Foliar treatment – broadcast spraying | 14–83          | 4–10               | –              | 75 g a.i./ha | 28          | –           |
| Potatoes              | AT/DE/FR/NL/CZ/FI/BE/UK/EE/LT/SE/PL | F           | Phytophthora infestans             | SC          | 200 g/L    | Foliar treatment – broadcast spraying | 21–97          | 6–7                | –              | 100 g a.i./ha | 7           | –           |

MS: Member State.
(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 pre-harvest interval.
### A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|------------|--------------------------------|--------------|---------|
| **Table grapes**      | EL/FR/ES/IT/ BG/HR/PT | F           | Downy mildew (Plasmopara viticola) | SC          | 200 g/L    | Foliar treatment – broadcast spraying | 12–83        | 3       | 10     | –      | 75 g a.i./ha | 28      |         |
| **Wine grapes**       | ES/IT/EL/HR/ PT | F           | Plasmopara viticola Botrytis cinerea Phomopsis viticola | WG 50 g/kg | Foliar treatment – broadcast spraying | 21–83        | 1–3    | 10     | –      | 75 g a.i./ha | 28      |         |
| **Potatoes**          | HR/FR/PT/ BG/EL/IT/ES | F           | Phytophthora infestans | SC 200 g/L  | Foliar treatment – broadcast spraying | 91           | 6      | 7      | –      | 100 g a.i./ha | 7       |         |
| **Tomatoes**          | EL/ES/IT      | F           | Phytophthora infestans | SC 200 g/L  | Foliar treatment – broadcast spraying | 63–88        | 3–3    | 7      | –      | 120 g a.i./ha | 3       |         |
| **Aubergines**        | EL/ES/IT      | F           | Phytophthora infestans | SC 200 g/L  | Foliar treatment – broadcast spraying | 63–88        | 3–3    | 7      | –      | 120 g a.i./ha | 3       |         |
| **Lettuces**          | EL/ES/IT      | F           | Plasmopara viticola | SC 200 g/L  | Foliar treatment – broadcast spraying | 21–91        | 3      | 7      | –      | 120 g a.i./ha | 3       |         |

**MS:** Member State.
(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 plantst

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DALA) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Grapes      | Foliar, 4 × 75 g a.s./ha, 10 days interval | 0, 28          | Radiolabelled active substance: $^{14}$C-indole and $^{14}$C-triazole amisulbrom Samples: grapes, foliage (United Kingdom, 2012; EFSA, 2014b) |
|                                   |             | Foliar, 4 × 91 g a.s./ha (indole label) | 14             | Radiolabelled active substance: $^{14}$C-indole and $^{14}$C-triazole amisulbrom Bunches were sampled to assess translocation (United Kingdom, 2012; EFSA, 2014b) |
|                                   |             | Tomatoes Foliar, 3 × 120 g a.s./ha, 7 days interval | 0, 3, 7        | Radiolabelled active substance: $^{14}$C-indole and $^{14}$C-triazole amisulbrom Samples: tomatoes, foliage at 7 DALA only (EFSA 2012; Spain, 2012) |
| Root crops                        | Potatoes    | Foliar, 5 × 100 g a.s./ha, 7 days interval | 0, 7, 14       | Radiolabelled active substance: $^{14}$C-indole and $^{14}$C-triazole amisulbrom Samples: tuber, foliage (United Kingdom, 2012; EFSA, 2014b) |
| Leafy crops                       | Lettuce     | Foliar, 3 × 120 g a.s./ha, 7 days interval | 3              | Radiolabelled active substance: $^{14}$C-indole and $^{14}$C-triazole amisulbrom (EFSA, 2012; Spain, 2012) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/ tuber crops                  | Carrot      | 1 × 600 g a.s./ha, onto bare soil | 30, 120, 365 | Radiolabelled active substance $^{14}$C-[indole] + $^{14}$C-[triazole], mixture 1:1 (United Kingdom, 2012; EFSA, 2014b) Samples at 365 DAT not assessed |
| Leafy crops                        | Lettuce     | 1 × 600 g a.s./ha, onto bare soil | 30, 120, 365 | Radiolabelled active substance $^{14}$C-[indole] + $^{14}$C-[triazole], mixture 1:1 (United Kingdom, 2012; EFSA, 2014b) |
| Cereal (small grain)               | Wheat       | 1 × 600 g a.s./ha, onto bare soil | 30, 120, 365 | Radiolabelled active substance $^{14}$C-[indole] + $^{14}$C-[triazole], mixture 1:1 (United Kingdom, 2012; EFSA, 2014b) |
Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source
--- | --- | --- | ---
| Pasteurisation (20 min, 90°C, pH 4) | No | Degraded to metabolite IT-4 (10% AR) (EFSA, 2014b) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | No | Degraded to metabolite IT-4 (45% AR) (EFSA, 2014b) |
| Sterilisation (20 min, 120°C, pH 6) | No | Degraded to metabolite IT-4 (54 and 62% AR, indole and triazole labels, respectively) and to metabolite I-1 (35% AR, indole label only) and T-1 (18% AR, triazole label only) (United Kingdom, 2012; EFSA, 2014b) |

Other processing conditions – –

Can a general residue definition be proposed for primary crops?

- Yes
- Rotational crop and primary crop metabolism similar?
  - Yes
  - It is noted that TDMs are also formed at low levels in rotational crops
- Residue pattern in processed commodities similar to residue pattern in raw commodities?
  - No
  - Under hydrolytic conditions relevant residue levels of metabolites IT-4 and I-1 are detected
- Plant residue definition for monitoring (RD-Mo)
  - Amisulbrom
  - For primary and rotational crops: amisulbrom
  - For processed commodities: sum of amisulbrom and metabolites IT-4 and I-1, expressed as amisulbrom (tentative; pending toxicological information on metabolite IT-4 and I-1).
- Plant residue definition for risk assessment (RD-RA)
- Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)
  - Matrices with high water content and high acid content: HPLC–MS/MS, LOQ 0.01 mg/kg
  - Confirmatory method available
  - ILV available (EFSA, 2014)
  - According to the EURLs the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses in high water, high acid and dry content matrices, and assumed that an LOQ of 0.02 mg/kg could be achieved for high oil content matrices (EURL, 2019)

as: active substance; DAT: days after treatment; DALA: days after last application; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
## B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|-----------------|-------------------|---------------|
|                                    | High water content | Potato, Tomato | –18 | 12 Months | Amisulbrom | United Kingdom (2012), EFSA (2014b) |
|                                    | High acid content | Grapes | –18 | 12 Months | Amisulbrom | United Kingdom (2012), EFSA (2014b) |
|                                    | Processed products | Grapes, dry pomace, red juice and red wine | –18 | 6 Months | Amisulbrom | United Kingdom (2012), EFSA (2014b) |

## B.1.2. Magnitude of residues in plants

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

| Commodity | Region/indoor(6) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|-----------|------------------|---------------------------------------------------------------|----------------|------------------------|---------------|----------------|
| Amisulbrom |                  | Trials on wine grapes compliant with GAP (Greece, 2019). Extrapolation to table grapes is applicable | 0.4 | 0.28 | 0.11 |
| Table grapes | NEU | 2 × 0.03; 0.05; 3 × 0.06; 2 × 0.10; 2 × 0.11; 2 × 0.12; 0.13; 0.15; 0.16; 0.18; 0.21; 0.23; 0.28 | Trials on wine grapes compliant with GAP (EFSA, 2014b). Extrapolation to table grapes is applicable MRLOECD = 0.39 | 0.3 | 0.23 | 0.09 |
| Wine grapes | SEU | 0.05; 0.07; 3 × 0.08; 2 × 0.09; 0.10; 0.11; 0.12; 0.23 | Trials on wine grapes compliant with GAP (EFSA, 2014b). Extrapolation to table grapes is applicable MRLOECD = 0.3 | 0.3 | 0.23 | 0.09 |
| Potatoes | NEU | 8 × < 0.01 | Trials compliant with GAP (EFSA, 2014b) MRLOECD = 0.01 | 0.01* | 0.01 | 0.01 |
|           | SEU | 8 × < 0.01 | Trials compliant with GAP (EFSA, 2014b) MRLOECD = 0.01 | 0.01* | 0.01 | 0.01 |
| Tomatoes | SEU | 2 × 0.05; 2 × 0.06; 0.10; 0.11; 2 × 0.13; 0.17; 0.19; 0.21; 0.22 | Trials on tomatoes compliant with GAP (EFSA, 2012). Extrapolation to aubergines/eggplants is applicable MRLOECD = 0.37 | 0.4 | 0.22 | 0.12 |
| Aubergines/eggplants | | | | | |
| Lettuces | SEU | 0.69; 0.76; 0.96; 0.96; 1.19; 1.59; 1.91; 2.12 | Trials on lettuce compliant with GAP (EFSA, 2012) MRLOECD = 3.82 | 4 | 2.12 | 1.08 |

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

*: Indicates that the MRL is proposed at the limit of quantification.
B.1.2.2. Residues in rotational crops

**a) Overall summary**

| Question | Answer |
|----------|--------|
| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | - |

The confined rotational crop study was performed at 1N of the most critical GAP reported in this review (GAP on potatoes). Based on this study, residues are expected to be below 0.01 mg/kg if amisulbrom is applied according to the uses reported in this review.

GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies (a) | Processing Factor (PF) | CFp (b) | Comment/Source |
|---------------------|-----------------------------|------------------------|---------|----------------|
| Grapes, raisin      | 5                           | 1.0; 1.2; 1.2; 1.7; 2.3 | 1.2     | 1.2 Greece (2019) |
| Grapes, wine        | 5                           | 0.02; 0.03; 0.04; 0.07 | 0.04    | 1 Greece (2019) |
| Grapes, juice       | 5                           | 0.03; 0.04; 0.07; 0.15 | 0.07    | 1 Greece (2019) |
| Grapes, dry pomace  | 2                           | 7.2; 22.2              | 14.7    | 1.6 Greece (2019) |
| Grapes, wet pomace  | 2                           | 3.5; 3.7               | 3.6     | 1.1 Greece (2019) |

**Notes:**

- PF: Processing factor (Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo);
- CFp: Conversion factor for risk assessment in processed commodity (Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo).
- (a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
- (b): Median of the individual conversion factors for each processing residues trial.
- (c): A tentative PF is derived based on a limited data set (less than three independent studies).

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup (a) | Most critical commodity (b) | Trigger exceeded (Y/N) | Comments |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|------------------------|----------|
|                            | mg/kg bw per day | mg/kg DM | Median | Maximum | Median | Maximum | Potato, process waste | No | - |
| Cattle (all)                | 0.0015 | 0.0015 | 0.05 | 0.05 | Cattle (dairy) | Potato, process waste | No | - |
| Cattle (dairy only)         | 0.0015 | 0.0015 | 0.04 | 0.04 | Cattle (dairy) | Potato, process waste | No | - |
| Sheep (all)                 | 0.0016 | 0.0016 | 0.05 | 0.05 | Sheep (ram/ewe) | Potato, process waste | No | - |
| Sheep (ewe only)            | 0.0016 | 0.0016 | 0.05 | 0.05 | Sheep (ram/ewe) | Potato, process waste | No | - |
B.3. Consumer risk assessment

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | Comments |
|-----------------------------|--------------------------------------------|---------------------------|---------------------------|------------------------|----------|
|                             | Median | Maximum | Median | Maximum |                        |                        |          |
| Swine (all)                 | 0.0010 | 0.0010  | 0.04  | 0.04    | Swine (breeding)       | Potato, process waste  | No       | –        |
| Poultry (all)               | 0.0007 | 0.0007  | 0.01  | 0.01    | Poultry (turkey)       | Potato, culls         | No       | –        |
| Poultry (layer only)        | 0.0005 | 0.0005  | 0.01  | 0.01    | Poultry (layer)        | Potato, culls         | No       | –        |
| Fish                        | –      | –       | –     | –       | –                       | –                      | –        | –        |

(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’.

ARfD

Highest IESTI, according to EFSA PRIMo (rev.3.1)

| Unprocessed commodities: Lettuces: 27% of ARfD |
| Processed commodities: Tomatoes (juice): 0.8% of ARfD children; Tomatoes (sauce/puree): 0.3% of ARfD adults |

NESTI (% ARfD)

Not assessed in this review.

Assumptions made for the calculations

The calculation is based on the highest residue levels expected in raw agricultural commodities, except for wine/table grapes were the derived processing factor were applied. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

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

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; GAP: Good Agricultural Practice; MRL: maximum residue level.

| Calculation                  | Value                                             |
|------------------------------|---------------------------------------------------|
| TMDI according to EFSA PRIMo | 0.1 mg/kg bw per day (EFSA, 2014a)               |
| NTMDI, according to (to be specified) | Not assessed in this review |
| Highest IEDI, according to EFSA PRIMo (rev.3.1) | 0.7% ADI (ES adult) |
| NEDI (% ADI)                 | Not assessed in this review                       |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation |

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

| Metabolite(s) | ADI (mg/kg bw per day) | Intake of groundwater metabolites (% ADI) |
|---------------|------------------------|------------------------------------------|
|               |                        |                                          |
|               |                        |                                          |
|               |                        |                                          |

**B.4. Proposed MRLs**

| Code number | Commodity          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review          | Comment |
|-------------|--------------------|-------------------------|----------------------|--------------------------------|---------|
|             |                    |                         |                      | MRL (mg/kg)                     |         |
|             |                    |                         |                      |                                |         |
|             |                    |                         |                      |                                |         |
|             |                    |                         |                      |                                |         |
|             |                    |                         |                      |                                |         |
|             |                    |                         |                      |                                |         |
|             |                    |                         |                      |                                |         |
|             |                    |                         |                      |                                |         |

**Enforcement residue definition (existing):** amisulbrom

**Enforcement residue definition (proposed):** amisulbrom

| Code number | Commodity          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|--------------------|-------------------------|----------------------|-----------------------|---------|
|             |                    |                         |                      | MRL (mg/kg)           |         |
|             |                    |                         |                      |                       |         |
|             |                    |                         |                      |                       |         |
|             |                    |                         |                      |                       |         |
|             |                    |                         |                      |                       |         |
|             |                    |                         |                      |                       |         |
|             |                    |                         |                      |                       |         |
|             |                    |                         |                      |                       |         |
|             |                    |                         |                      |                       |         |

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

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

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

(b): 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)

### amisulbrom

| Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults |
|---------------|----------------------------------|-----------------------------------------------|------------------------------------------|---------------------------------------|

#### Review of the existing MRLs for amisulbrom

**PRImo(EU)**

| Source of MRL: | EFSA | Year of evaluation: | EFSA | Year of evaluation: |
|----------------|------|---------------------|------|---------------------|
| LOD (ng/g, d.w.): | 6.7 | LOD (mg/kg, d.w.): | 0.3 | LOD (mg/kg, d.w.): |
| Source of ADI: | EFSA | Source of LOD: | EFSA | Source of LOD: |
| Year of revision: | 2019 | Year of evaluation: | 2019 | Year of evaluation: |

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#### Normal mode

**Chronic risk assessment: JMPR methodology (IEEDU/MDII)**

| No of diet exceeding the ADI: | --- |
|------------------------------|-----|

#### Exposure resulting from the L.C.D. (0-10 % of ADI)

| Component / group of commodities | 2nd contributor to MS diet (0-10 % of ADI) | 2nd contributor to MS diet (0-10 % of ADI) | 2nd contributor to MS diet (0-10 % of ADI) |
|----------------------------------|------------------------------------------|------------------------------------------|------------------------------------------|
| CALCUTR/MEDIR) calculation (base on average food consumption) | Tobacco | Tobacco | Tobacco |
| DL (mg/kg, d.w.): | 0.1% | 0.1% | 0.1% |
| MS Diet: | 0.1% | 0.1% | 0.1% |
| Exposure (ng/kg, d.w. per day) | Tobacco | Tobacco | Tobacco |
| Highest contributor to MS diet (in % of ADI) | Tobacco | Tobacco | Tobacco |
| Community / group of commodities | Tobacco | Tobacco | Tobacco |
| 2nd contributor to MS diet (in % of ADI) | Tobacco | Tobacco | Tobacco |
| Community / group of commodities | Tobacco | Tobacco | Tobacco |
| 3rd contributor to MS diet (in % of ADI) | Tobacco | Tobacco | Tobacco |
| Community / group of commodities | Tobacco | Tobacco | Tobacco |

#### Comment:

The estimated long-term dietary intake (TMDI/NDI/MDI) was below the ADI. The long-term intake of residues of amisulbrom is unlikely to present a public health concern.

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The acute risk assessment is based on the ARID.
The calculation is based on the large portion of the most critical consumer group.

### Show results for all crops

| Unprocessed commodities | Results for children | Results for adults |
|-------------------------|----------------------|--------------------|
|                         | No of commodities for which ARIDADI is exceeded (ESTI) | No of commodities for which ARIDADI is exceeded (ESTI) |
| **ESTI**                |                      |                    |
| Highest % of ARIDADI    | Commodity            | MRL / input for RA (mg/kg) | Exposure (μg/kg bw) |
|                         |                      |                      |                      |
| 27%                     | Lettuce              | 4.2 / 2.12          | 81                   |
| 7%                      | Table grapes         | 0.4 / 0.28          | 20                   |
| 4%                      | Tomatoes             | 0.4 / 0.22          | 13                   |
| 2%                      | Aubergines/egg plants| 0.4 / 0.22          | 5.5                  |
| 0.9%                    | Wine grapes          | 0.4 / 0.28          | 2.6                  |
| 0.5%                    | Potatoes             | 0.01 / 0.01         | 1.5                  |
|                         |                      |                      |                      |
| **ESTI**                |                      |                    |
| Highest % of ARIDADI    | Commodity            | MRL / input for RA (mg/kg) | Exposure (μg/kg bw) |
|                         |                      |                      |                      |
| 9%                      | Lettuce              | 4.2 / 2.12          | 26                   |
| 3%                      | Table grapes         | 0.4 / 0.28          | 9.4                  |
| 2%                      | Wine grapes          | 0.4 / 0.28          | 6.6                  |
| 2%                      | Aubergines/egg plants| 0.4 / 0.22          | 6.0                  |
| 1%                      | Tomatoes             | 0.4 / 0.22          | 3.5                  |
| 0.1%                    | Potatoes             | 0.01 / 0.01         | 0.30                 |

Total number of commodities exceeding the ARIDADI in children and adult diets (ESTI calculation)

### Show results for all crops

| Processed commodities | Results for children | Results for adults |
|-----------------------|----------------------|--------------------|
|                       | No of processed commodities for which ARIDADI is exceeded (ESTI) | No of processed commodities for which ARIDADI is exceeded (ESTI) |
| **ESTI**              |                      |                    |
| Highest % of ARIDADI  | Processed commodities | MRL / input for RA (mg/kg) | Exposure (μg/kg bw) |
|                       |                      |                      |                      |
| 0.8%                  | Tomatoes / juice     | 0.4 / 0.12          | 2.3                  |
| 0.4%                  | Tomatoes / sauce/puree| 0.4 / 0.12          | 1.1                  |
| 0.3%                  | Potatoes / fried     | 0.01 / 0.01         | 0.93                 |
| 0.2%                  | Potatoes / dried (flakes) | 0.01 / 0.05         | 0.59                 |
| 0.2%                  | Wine grapes / juice  | 0.4 / 0.01          | 0.45                 |
|                       |                      |                      |                      |
| **ESTI**              |                      |                    |
| Highest % of ARIDADI  | Processed commodities | MRL / input for RA (mg/kg) | Exposure (μg/kg bw) |
|                       |                      |                      |                      |
| 0.3%                  | Tomatoes / sauce/puree| 0.4 / 0.12          | 0.99                 |
| 0.2%                  | Table grapes / raisins| 0.4 / 0.4           | 0.49                 |
| 0.0%                  | Wine grapes / juice  | 0.4 / 0.01          | 0.23                 |
| 0.03%                 | Wine grapes / wine   | 0.4 / 0.01          | 0.10                 |
| 0.03%                 | Potatoes / chips     | 0.01 / 0.01         | 0.06                 |
| 0.02%                 | Potatoes / dried (flakes) | 0.01 / 0.05         | 0.06                 |
|                       |                      |                      |                      |
| **ESTI**              |                      |                    |

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of amisulbrom is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARIDADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity          | Median dietary burden | Maximum dietary burden |
|-------------------------|-----------------------|------------------------|
|                         | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Risk assessment residue |                       |                        |                       |                        |
| Potato, culls           | 0.01* STMR            |                         | 0.01* HR              |
| Potato, process waste   | 0.01* STMR (default PF not applied) (a) | 0.01* STMR (default PF not applied) (a) |
| Potato, dried pulp      | 0.01* STMR (default PF not applied) (a) | 0.01* STMR (default PF not applied) (a) |

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

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

(a): For potatoes, no default processing factor was applied because residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

D.2. Consumer risk assessment

| Commodity            | Chronic risk assessment | Acute risk assessment |
|----------------------|-------------------------|-----------------------|
|                      | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Risk assessment residue definition: amisulbrom |
| Table grapes         | 0.11 STMR               |                         | 0.28 HR             |
| Wine grapes          | 0.11 STMR               |                         | 0.28 HR             |
| Potatoes             | 0.01* STMR              |                         | 0.01* HR            |
| Tomatoes             | 0.12 STMR               |                         | 0.22 HR             |
| Aubergines/eggplants | 0.12 STMR               |                         | 0.22 HR             |
| Lettuces             | 1.08 STMR               |                         | 2.12 HR             |

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

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|------------------------------------------------|----------------------------------|
| **Amisulbrom**                | 3-[(3-bromo-6-fluoro-2-methyl-1H-indol-1-yl)sulfonyl]-N,N-dimethyl-1H-1,2,4-triazole-1-sulfonamide | ![Structural formula](image1) |
|                               | O=S(-O)(c1ncn(n1)S(=O)(=O)N(C)C)n1c2cc(F)ccc2c(Br)c1C | BREATYVWRHIPIY-UHFFFAOYSA-N    |
| **IT-5**                      | [3-bromo-6-fluoro-1-(1H-1,2,4-triazole-3-sulfonyl)-1H-indol-2-yl]methanol | ![Structural formula](image2) |
|                               | O=S(-O)(n1c2cc(F)ccc2c(Br)c1CO)c1nc[NH]n1 | LJCWSMXSHGRQGY-UHFFFAOYSA-N    |
| **IT-4**                      | 3-bromo-6-fluoro-2-methyl-1-(1H-1,2,4-triazole-3-sulfonyl)-1H-indole | ![Structural formula](image3) |
|                               | O=S(-O)(n1c2cc(F)ccc2c(Br)c1C)c1nc[NH]n1 | YLSKZSBQKHXTFP-UHFFFAOYSA-N    |
| **I-1**                       | 3-bromo-6-fluoro-2-methyl-1H-indole | ![Structural formula](image4) |
|                               | Fc1ccc2c(c1)[NH]c(C)c2Br | PYDNRAMVWHCIQS-UHFFFAOYSA-N    |
| **T-1**                       | 1-(dimethylsulfamoyl)-1H-1,2,4-triazole-3-sulfonic acid | ![Structural formula](image5) |
|                               | OS(=O)(=O)c1ncn(n1)S(=O)(=O)N(C)C | JHCZUICWWIZATE-UHFFFAOYSA-N    |
| **1,2,4-triazole**            | 1H-1,2,4-triazole | ![Structural formula](image6) |
|                               | c1ncn[NH]1 | NSPMIIYGKQRPBQR-UHFFFAOYSA-N    |

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

<sup>(b)</sup>: ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).

<sup>(c)</sup>: ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).