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

European Food Safety Authority (EFSA)

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 penoxsulam. To assess the occurrence of penoxsulam residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC 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.

Keywords: penoxsulam, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, sulfonamide herbicides, triazolopyrimidine herbicides

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Summary

Penoxsulam was included in Annex I to Directive 91/414/EEC on 1 August 2010 by Commission Directive 2010/25/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 penoxsulam was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Italy, the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 8 August 2016 and finalised on 7 October 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 17 November 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS Italy, Portugal, France and the European Union Reference Laboratories (EURL) for Pesticide Residues, EFSA prepared in January 2017 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 6 February 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The primary crop metabolism of penoxsulam was investigated in three different crop categories. Penoxsulam was the only significant residue that was observed in the metabolism studies performed in fruit crops following a soil application, and in cereals and root vegetables following a foliar application. The residue definition for enforcement and risk assessment can be set as penoxsulam only and is limited to the authorised uses under review. An analytical method for enforcement of the proposed residue definition is fully validated for all plant matrices.

The available residue trials were sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation.

According to the confined rotational crop studies in mature crops, penoxsulam was observed at very low levels. It can therefore be concluded that significant residues are not expected in the succeeding crops and rotational crop field trials were not required.

Studies investigating the nature of residues in processed commodities were not required. The studies investigating the magnitude of residues in processed commodities showed no residues of penoxsulam.

The metabolism of penoxsulam was investigated in goats and laying hens and penoxsulam was the only significant residue. In livestock, there was no exceedance of the trigger value of 0.1 mg/kg dry matter (DM). Therefore, it was not necessary to derive a residue definition for monitoring and risk assessment in commodities of animal origin.

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for penoxsulam.

The exposure values calculated were compared with the toxicological reference value for penoxsulam, derived by EFSA (EFSA Journal 2009;7(9):343r) under Directive 91/414/EEC. The highest chronic exposure was calculated for WHO Cluster Diet B, representing 0.3% of the acceptable daily intake (ADI). Based on these calculations, EFSA concludes that all uses of penoxsulam are acceptable with regard to consumer exposure.
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Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC\(^2\) a reasoned opinion on the review of the existing MRLs for that active substance. As penoxsulam was included in Annex I to Council Directive 91/414/EEC on 1 August 2010 by means of Commission Directive 2010/25/EU\(^3\), and has been deemed to be approved under Regulation (EC) No 1107/2009\(^4\), in accordance with Commission Implementing Regulation (EU) No 540/2011\(^5\), as amended by Commission Implementing Regulation (EU) No 541/2011\(^6\), EFSA initiated the review of all existing MRLs for that active substance.

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

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

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

Italy, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for penoxsulam and to prepare a supporting evaluation report (Italy, 2012). The PROFile and the supporting evaluation report were submitted to EFSA on 17 May 2012 and made available to Member States. A request for additional information was addressed to Member States in the framework of a completeness check period which was initiated by EFSA on 8 August 2016 and finalised on 7 October 2016. Additional evaluation reports were submitted by Italy, Portugal, France and the European Union Reference Laboratories (EURL) for Pesticide Residues (EURL, 2016; France, 2016; Italy, 2016; Portugal, 2016) and, after having considered all the information provided by the RMS, Member States and the EURL for Pesticide Residues, EFSA prepared a completeness check report which was made available to all Member States on 17 November 2016. Further clarifications were sought from Member States via a written procedure in December 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by Member States, EFSA prepared in January 2017 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 6 February 2017 were considered by EFSA during the finalisation of the reasoned opinion.

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\(^1\) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

\(^2\) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

\(^3\) Commission Directive 2010/25/EU of 18 March 2010 amending Council Directive 91/414/EEC to include penoxsulam, proquinazid and spiromesifen as active substances. OJ L 69, 19.3.2010, p. 11–15.

\(^4\) 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.
The evaluation report submitted by the RMS (Italy, 2012) and the evaluation reports submitted by the Member States Italy, Portugal, France and the EURL for Pesticide Residues (EURL, 2016; France, 2016; Italy, 2016; Portugal, 2016) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2017a) and the Member States consultation report (EFSA, 2017b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, 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

Penoxsulam is the ISO common name for 3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide (IUPAC).

Penoxsulam belongs to the group of sulfonamide herbicides and triazolopyrimidine herbicides. Penoxsulam acts through inhibition of the enzyme acetolactate synthase (ALS) involved in the synthesis of branched-chain amino acids, leading to the cessation of cell division and subsequent growth processes in plants. Penoxsulam is absorbed via leaves, shoots and roots and is translocated in plants to meristematic tissues. Penoxsulam is a herbicide for controlling a wide range of weeds in rice crops.

The chemical structure of penoxsulam and its main metabolites are reported in Appendix F.

Penoxsulam was evaluated in the framework of Directive 91/414/EEC with Italy designated as RMS. The representative uses supported for the peer review process were post-emergence applications with conventional tractor-mounted spraying devices or self-propelled hydraulic sprayers to control *Echinochloa crus-galli*, sedges and broadleaf weeds in rice, from growth stage of BBCH 11 up to growth stage of BBCH 31, in southern Europe, at a single application at a maximum application rate of 40 g a.s./ha. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2010/25/EU, which entered into force on 1 August 2010. According to Regulation (EU) No 540/2011, penoxsulam is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as a herbicide only.

The EU MRLs for penoxsulam are established in Annexes IIIA of Regulation (EC) No 396/2005 as amended by Commission Regulation (EC) No 839/2008. Codex maximum residue limits (CXL(s)) for penoxsulam are not available.

For the purpose of this MRL review, the critical uses of penoxsulam currently authorised within the EU have been collected by the RMS and reported in the PROFile. The additional Good Agricultural Practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAP(s) for penoxsulam are given in Appendix A.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Italy, 2012), the draft assessment report (DAR) and its addenda prepared

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7 Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products. OJ L 234, 30.8.2008, p. 1-216.
under Council Directive 91/414/EEC (Italy, 2005, 2009), the conclusion on the peer review of the pesticide risk assessment of the active substance penoxsulam (EFSA, 2009), as well as the evaluation reports submitted during the completeness check (EURO, 2016; France, 2016; Italy, 2016; Portugal, 2016). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2016; 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 penoxsulam was investigated in representatives of three different crop categories: fruits/fruiting vegetables (Italy, 2012; France, 2016), cereals (EFSA, 2009; Italy, 2012) and root vegetables (Italy, 2016).

After foliar application on rice and on rice paddy water, it was concluded that the total residues (sum of penoxsulam and metabolites) would be expected to occur at levels below 0.01 mg eq/kg in rice grain, while in rice straw no single compound would be expected to exceed 0.01 mg eq/kg. After foliar application on wheat at the onset of tillering (BBCH 21), residues were below 0.01 mg eq/kg in all plant matrices.

After a foliar application on chicory, the total residues in leaves and roots collected in the field and after forcing were below 0.002 mg eq/kg.

The study on grapes was conducted with a soil application of 20 g a.s./ha at growth stage BBCH 55, and thus done at an earlier stage than the one reported in the critical GAP (cGAP) for grapes (BBCH 75). The residues were below 0.01 mg eq/kg in the fruit. To complement this issue, a non-radiolabelled study was performed on grapes with a soil application performed according to the cGAP. No residues of penoxsulam or metabolites 5-OH, BSTCA or BST were detected in any of the samples collected, since all values were reported as not detected (below 0.01 mg/kg). The information provided by this non-radiolabelled study confirmed that no residues are expected on grapes.

1.1.2. Nature of residues in rotational crops

A confined rotational crop study evaluated in the peer review of penoxsulam showed that after a plant back interval (PBI) of 90 days low residues could still be found in wheat straw and hay, kale and potato foliage (EFSA, 2009). A final conclusion on the relevance of residues in rotated crops was not reached in the peer review and a data requirement for further rotational crop data was then established (EFSA, 2009).

To address this issue, a second rotational crop study was conducted at an application rate of 40 g a.s./ha and after PBIs of 30, 154 and 365 days after treatment (DAT) (France, 2016). The total radioactive residues (TRR) were below 0.01 mg/kg in all sampling intervals with the exception of immature lettuce (0.34 mg/kg), wheat hay (0.03 mg/kg) and wheat straw (0.04 mg/kg) 30 DAT. In mature wheat straw 30 DAT, the metabolite BSTCA was the main contributor (0.011 mg eq/kg). In immature lettuce samples 30 DAT, penoxsulam and metabolites BSTCA and 5,8-OH were observed at 0.060, 0.068 and 0.014 mg eq/kg, respectively. The rotational crop study was conducted at 40 g a.s./ha and rice is the only crop where this application rate is authorised. In the worst-case scenario where rice is rotated with other cereals, no residue uptake is expected to occur. Furthermore, it is very unlikely that other crops such as immature leafy vegetables (e.g. baby lettuce) will be rotated with rice. Therefore, significant residues are not expected in rotational crops. A specific residue definition for rotational crops is unnecessary.
1.1.3. Nature of residues in processed commodities

Studies investigating the effect of processing on the nature of residues of penoxsulam were not necessary since there were no residues in the raw commodities and the chronic exposure is below 10% of the acceptable daily intake (ADI).

1.1.4. Methods of analysis in plants

During the peer review, a multiresidue analytical method using liquid chromatography with tandem mass spectrometry (LC–MS/MS) and its independent laboratory validation (ILV) was validated for the determination of penoxsulam in dry commodities, with a limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2009). Furthermore, France reported a fully validated method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) for the determination of penoxsulam in dry commodities, high water commodities, high oil and acidic commodities with a LOQ of 0.01 mg/kg (France, 2016). In addition, the EURLs also reported data for QuEChERS methods also using LC–MS/MS. These methods are fully validated for the determination of penoxsulam in the four main plant matrices, with a LOQ of 0.01 mg/kg (EURL, 2016; France, 2016). Hence, it is concluded that penoxsulam can be enforced with a LOQ of 0.01 mg/kg in high water content, high acid content, high oil content and dry commodities.

1.1.5. Stability of residues in plants

The storage stability of penoxsulam was demonstrated for a period of 7 months at –20°C in dry commodities (EFSA, 2009), for 12 months at –20°C in high water content commodities, for 10 months at –18°C in oily content commodities (Italy, 2016) and for 14 months at –20°C in high acid content commodities (France, 2016).

1.1.6. Proposed residue definitions

Penoxsulam was the only significant residue that was observed in the metabolism studies performed in fruit crops following a soil application, and in cereals and root vegetables following a foliar application. All the GAPs assessed in this review are supported by the available metabolism studies and the residue definition for enforcement and risk assessment can be set as penoxsulam only.

Since no residues were observed in fruit crops after soil treatment, it is not possible to conclude on a general metabolic pathway in fruit crops. Therefore, EFSA is not proposing a general residue definition.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of penoxsulam residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Italy, 2012), including residue trials evaluated in the framework of the peer review (EFSA, 2009) and additional data submitted during the completeness check (France, 2016; Italy, 2016; Portugal, 2016).

All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2016).

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

- Citrus fruits, Table grapes/Wine grapes, Sorghum grain: The number of residue trials supporting these GAPs is not compliant with the data requirements for these crops. However, the reduced number of residue trials is considered acceptable in these cases because all results were below the LOQ and a no-residue situation is expected. Further residue trials are therefore not required.
1.2.2. Magnitude of residues in rotational crops

In the confined rotational crop studies evaluated (see also Section 1.1.2), the total radioactivity was generally below 0.01 mg eq/kg, with the exception of immature lettuce (30 DAT) and immature wheat straw (30 DAT). In mature crops, penoxsulam was below the LOQ.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was not required since significant residues of penoxsulam are not expected in raw commodities. However, the RMS reported the results of two processing studies conducted on olives and endives (Italy, 2016) and France reported a processing study on grapes (France, 2016). As no residues of penoxsulam were observed in any fraction of raw and processed olives, endives and grapes, no processing factor can be derived from these studies.

1.2.4. Proposed MRLs

Consequently, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. Tentative MRLs were also derived for cereals straw in view of the future need to set MRLs in feed items.

2. Residues in livestock

Penoxsulam is authorised for use on citrus fruits and cereals that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013) that 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. Therefore, it was not necessary to derive a residue definition for monitoring and risk assessment in commodities of animal origin.

Although not necessary, livestock metabolism studies were conducted in lactating goats and laying hens at a repeated dosing of an exaggerated rate (Italy, 2005). In the framework of the peer review, no residue definition for monitoring and risk assessment in commodities of animal origin was proposed (EFSA, 2009).

In the framework of the peer review, no analytical methods were reported for the determination of residues in meat, milk or eggs since no residues of penoxsulam were observed in crops that are components of animal feed (EFSA, 2009). Currently, there is no validation data for commodities of animal origin (EURL, 2016).

3. Consumer risk assessment

3.1. Consumer risk assessment without consideration of the existing CXLs

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. 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 penoxsulam.

The exposure values calculated were compared with the toxicological reference value for penoxsulam, derived by EFSA (2009) under Directive 91/414/EEC. The highest chronic exposure was calculated for WHO Cluster Diet B, representing 0.3% of the ADI. Based on these calculations, EFSA concludes that all uses of penoxsulam are acceptable with regard to consumer exposure.

Conclusions

The primary crop metabolism of penoxsulam was investigated in three different crop categories. Penoxsulam was the only significant residue that was observed in the metabolism studies performed in fruit crops following a soil application, and in cereals and root vegetables following a foliar application.
The residue definition for enforcement and risk assessment can be set as penoxsulam only and is limited to the authorised uses under review. An analytical method for enforcement of the proposed residue definition is fully validated for all plant matrices.

The available residue trials were sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. According to the confined rotational crop studies in mature crops, penoxsulam was observed at very low levels. It can therefore be concluded that significant residues are not expected in the succeeding crops and rotational crop field trials were not required. Studies investigating the nature of residues in processed commodities were not required. The studies investigating the magnitude of residues in processed commodities showed no residues of penoxsulam.

The metabolism of penoxsulam was investigated in goats and laying hens and penoxsulam was the only significant residue. In livestock there was no exceedance of the trigger value of 0.1 mg/kg DM. Therefore, it was not necessary to derive a residue definition for monitoring and risk assessment in commodities of animal origin.

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for penoxsulam.

The exposure values calculated were compared with the toxicological reference value for penoxsulam, derived by EFSA (2009) under Directive 91/414/EEC. The highest chronic exposure was calculated for WHO Cluster Diet B, representing 0.3% of the ADI. Based on these calculations, EFSA concludes that all uses of penoxsulam are acceptable with regard to consumer exposure.

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 1 below). 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.

**Table 1: Summary table**

| Code number(a) | Commodity                  | Existing EU MRL (mg/kg) | Outcome of the review | Comment       |
|----------------|----------------------------|-------------------------|-----------------------|---------------|
| 110010         | Grapefruits                | 0.01*                   | 0.01*                 | Recommended(b) |
| 110020         | Oranges                    | 0.01*                   | 0.01*                 | Recommended(b) |
| 110030         | Lemons                     | 0.01*                   | 0.01*                 | Recommended(b) |
| 110040         | Limes                      | 0.01*                   | 0.01*                 | Recommended(b) |
| 110050         | Mandarinis                 | 0.01*                   | 0.01*                 | Recommended(b) |
| 151010         | Table grapes               | 0.01*                   | 0.01*                 | Recommended(b) |
| 151020         | Wine grapes                | 0.01*                   | 0.01*                 | Recommended(b) |
| 161030         | Table olives               | 0.01*                   | 0.01*                 | Recommended(b) |
| 401030         | Poppy seeds                | 0.01*                   | 0.01*                 | Recommended(b) |
| 402010         | Olives for oil production  | 0.01*                   | 0.01*                 | Recommended(b) |
| 500010         | Barley grains              | 0.01*                   | 0.01*                 | Recommended(b) |
| 500060         | Rice grains                | 0.01*                   | 0.01*                 | Recommended(b) |
| 500070         | Rye grains                 | 0.01*                   | 0.01*                 | Recommended(b) |
| 500080         | Sorghum grains             | 0.01*                   | 0.01*                 | Recommended(b) |
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### Table: Review of the existing MRLs for penoxsulam

| Code number(a) | Commodity | Existing EU MRL (mg/kg) | Outcome of the review |
|---------------|-----------|-------------------------|----------------------|
| 500090        | Wheat grains | 0.01* | 0.01* Recommended(b) |
| –             | Other commodities of plant and animal origin | See Regulation (EC) No 839/2008 | – | Further consideration needed(c) |

**MRL:** maximum residue level.

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

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.

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

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

a.i. active ingredient
a.s. active substance
ADI acceptable daily intake
ALS acetolactate synthase
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
cGAP critical GAP
CXL codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DB dietary burden
DM dry matter
eq residue expressed as a.s. equivalent
EURLs EU Reference Laboratories (former CRLs)
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HPLC–MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardization
IUPAC International Union of Pure and Applied Chemistry
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS/MS tandem mass spectrometry detector
NEU northern European Union
OD oil dispersion
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PHI pre-harvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
PROFile (EFSA) Pesticide Residues Overview File
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC  suspension concentrate
SEU  southern European Union
STMR supervised trials median residue
TMDI theoretical maximum daily intake
TRR  total radioactive residue
WHO  World Health Organization
Appendix A – Summary of authorised uses considered for the review of MRLs

| Crop | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application |
|------|----------------|--------|----------------|-------------------------|----------------|-------------|-------------|
|      |                |        |                |                         |                | Type        | Content      | Method                  | Growth stage | Number | Interval (days) | Rate | PHI or waiting period (days) |
|      |                |        |                |                         |                | Conc. Unit  |              |                         | From BBCH   | Until BBCH | Min. | Max. | Min. | Max. | Unit |
| Wine grapes | Vitis vinifera | NEU | Outdoor | FR | Annual broadleaf weeds | OD | 20.0 g/L | Soil treatment – general (see also comment field) | 13 | 75 | 1 | | 15.00 | g a.i./ha | 56 | Tractor mounted spray. Product to be applied under vine row as a banded application, i.e. on 1/2 of the total area. Do not apply in the presence of grape shoots or 'root suckers' |
| Barley | Hordeum vulgare | NEU | Outdoor | DE, UK, CZ, HU | Annual grass and broadleaf weeds | SC | 15.0 g/L | Foliar treatment – general (see also comment field) | 11 | 29 | 1 | | 7.50 | 15.00 | g a.i./ha | n.a. | DE – autumn uses only. UK – an application window up to Christmas if 'leaching' model allows it. Max pre-emergence rate of 0.5–0.6 L/ha is for crop safety reasons |
| Rye | Secale cereale | NEU | Outdoor | DE, UK, CZ | Annual grass and broadleaf weeds | SC | 15.0 g/L | Foliar treatment – general (see also comment field) | 11 | 29 | 1 | | 7.50 | 15.00 | g a.i./ha | n.a. | See barley, NEU Outdoor |
| Crop       | Scientific name | Region | Outdoor/ indoor | Member state or country | Pest controlled                  | Formulation Type | Content Conc. | Method | Growth stage From BBCH | Growth stage Until BBCH | Application Number | Interval (days) | Rate | PHI or waiting period (days) | Comments (max. 250 characters) |
|------------|----------------|--------|----------------|-------------------------|----------------------------------|------------------|---------------|--------|-------------------------|----------------------|--------------------|----------------|------|-------------------------------|--------------------------|
| Wheat      | *Triticum aestivum* | NEU    | Outdoor        | DE, UK, CZ, HU          | Annual grass and broadleaf weeds | SC 15.0 g/L      | Foliar treatment – general (see also comment field) | 11     | 29                       | 1                    | 7.50               | 15.00          | g a.i./ha | n.a.                          | See barley, NEU Outdoor |

### Critical outdoor GAPs for Southern Europe

| Crop      | Scientific name | Region | Outdoor/ indoor | Member state or country | Pest controlled                  | Formulation Type | Content Conc. | Method | Growth stage From BBCH | Growth stage Until BBCH | Application Number | Interval (days) | Rate | PHI or waiting period (days) | Comments (max. 250 characters) |
|-----------|----------------|--------|----------------|-------------------------|----------------------------------|------------------|---------------|--------|-------------------------|----------------------|--------------------|----------------|------|-------------------------------|--------------------------|
| Grapefruits | *Citrus paradisi* | SEU    | Outdoor        | IT, PT, ES              | Annual broadleaf weeds           | OD 20.0 g/L      | Soil treatment – general (see also comment field) | 0                  | 81                       | 1                    | 15.00              | g a.i./ha | 30                            | Pre-emergence of weeds. PHI: 30 days for spring application on late varieties. PHI: 120 days for normal situation (harvest in November–January) |
| Oranges   | *Citrus sinensis* | SEU    | Outdoor        | IT, PT, ES              | Annual broadleaf weeds           | OD 20.0 g/L      | Soil treatment – general (see also comment field) | 0                  | 81                       | 1                    | 15.00              | g a.i./ha | 30                            | Pre-emergence of weeds. PHI: 30 days for spring application on late varieties. PHI: 120 days for normal situation (harvest in November–January) |
| Lemons    | *Citrus limon*   | SEU    | Outdoor        | IT, PT, ES              | Annual broadleaf weeds           | OD 20.0 g/L      | Soil treatment – general (see also comment field) | 0                  | 81                       | 1                    | 15.00              | g a.i./ha | Pre-emergence of weeds        |                                                                           |
| Crop            | Scientific name | Region | Outdoor/indoor | Pest controlled | Formulation Type | Content Conc. | Method          | Growth stage From BBCH | Until BBCH | Number | Interval (days) | Rate Conc. Unit | PHI or waiting period (days) | Comments (max. 250 characters) |
|-----------------|-----------------|--------|----------------|-----------------|------------------|---------------|----------------|------------------------|------------|---------|----------------|----------------|--------------------------|-------------------------------|
| Limes           | *Citrus* aurantifolia | SEU    | Outdoor        | IT, PT, ES      | Annual broadleaf weeds | OD 20.0 g/L   | Soil treatment – general (see also comment field) | 0 | 81 | 1 | 15.00 g a.i./ha | 56 | Tractor mounted spray. Product to be applied under vine row as a banded application, i.e. on 1/2 of the total area. Do not apply in the presence of grape shoots or 'root suckers' |
| Mandarins       | *Citrus* reticulata, syn: *Citrus* deliciosa | SEU    | Outdoor        | IT, PT, ES      | Annual broadleaf weeds | OD 20.0 g/L   | Soil treatment – general (see also comment field) | 0 | 81 | 1 | 15.00 g a.i./ha | 56 | Pre-emergence of weeds |
| Table grapes    | *Vitis* vinifera | SEU    | Outdoor        | FR              | Annual broadleaf weeds | OD 20.0 g/L   | Soil treatment – general (see also comment field) | 13 | 75 | 1 | 15.00 g a.i./ha | 56 | See Table grapes, SEU Outdoor |
| Wine grapes     | *Vitis* vinifera | SEU    | Outdoor        | FR              | Annual broadleaf weeds | OD 20.0 g/L   | Soil treatment – general (see also comment field) | 13 | 75 | 1 | 15.00 g a.i./ha | 56 | |
| Common name | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation Type | Content Conc. | Unit | Method | Growth stage | Number | Interval (days) | Rate | PHI or waiting period (days) | Comments (max. 250 characters) |
|-------------|-----------------|--------|---------------|--------------------------|-----------------|------------------|----------------|------|---------|--------------|--------|----------------|------|-----------------------------|---------------------------------|
| Table olives | *Olea europaea* | SEU    | Outdoor       | IT, PT, ES               | Annual broadleaf weeds | OD 20.0 g/L     | Soil treatment – general (see also comment field) | 81   | 89   | 1 | 10.00 | 15.00 g a.i./ha | 15 | Pre-emergence of weeds. Do not apply with olives already fallen in the soil |
| Poppy seeds  | *Papaver somniferum* subsp. *somniferum* | SEU    | Outdoor       | PT                       | Annual broadleaf weeds | OD 20.0 g/L     | Soil treatment – general (see also comment field) | 14   | 35   | 1 | 10.00 | 15.00 g a.i./ha | 60 | Common application timing between 4 and 8 leaves of poppies. Seeds used in bakery (bread/cakes) |
| Olives for oil production | *Olea europaea* var. *europaea* | SEU    | Outdoor       | IT, PT, ES               | Annual broadleaf weeds | OD 20.0 g/L     | Soil treatment – general (see also comment field) | 81   | 89   | 1 | 10.00 | 15.00 g a.i./ha | 15 | Pre-emergence of weeds. Do not apply with olives already fallen in the soil |
| Rice         | *Oryza sativa*  | SEU    | Outdoor       | IT, ES, PT, EL, FR       | *Echinochloa crus-galli*, sedges and broadleaf weeds | OD 20.0 g/L     | Foliar treatment – general (see also comment field) | 11   | 31   | 1 | 30.00 | 40.00 g a.i./ha | n.a. | Broadcast spray; aerial; product to be used in environmentally protected area |
| Common name | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|-------------|-----------------|--------|----------------|-------------------------|-----------------|--------------|-------------|-----------------------------|-------------------------------|
| Sorghum     | Sorghum bicolor | SEU    | Outdoor        | FR                      | Echinochloa crus-galli, sedges and broadleaf weeds | OD 20.0 g/L | Foliar treatment – general (see also comment field) | 13 | 15 | 1 | 16.00 g a.i./ha | 60–90 | Broadcast spray, boom application foliar. PHI: 60 days is for sorghum to be used for silage only. PHI: 90 days is for sorghum harvest for grain in September–October |

n.a.: not applicable; GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; NEU: northern European Union; SEU: southern European Union; OD: oil dispersion; SC: suspension concentrate; a.i.: active ingredient.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups        | Crop(s)       | Application(s) | Sampling (DAT) |
|----------------------------------|--------------------|---------------|----------------|----------------|
| Fruit crops<sup>(a)</sup>        | Grapes             | Bare soil, 1 × 20 g a.s./ha | 56, 63         |
| Roots and tuber                  | Chicory            | Foliar, 2–3 × 7.5 g a.s./ha  | 21<sup>(b)</sup>, 120<sup>(c)</sup>, 148<sup>(d)</sup> |
| Cereals/grass crops              | Rice               | Rice: foliar and paddy water, 1 × 20 g a.s./ha; | Rice: 0, 3, 7, 14, and 30 (immature); 134 (mature) |
|                                  |                    | Wheat         | Wheat: Foliar, 1 × 28 g a.s./ha. | Wheat: 0, 14, 34, 63 |

Source(s): EFSA (2009), Italy (2012, 2016), France (2016).

<sup>(a)</sup>: Study where non-radiolabelled samples from trials on grapes were analysed for potential residues of penoxsulam and metabolites 5-OH, BSTCA and BST (France, 2016).

<sup>(b)</sup>: Field sampling of immature foliage and root.

<sup>(c)</sup>: Field sampling of mature foliage and root.

<sup>(d)</sup>: Chicon (witloof) and roots sampling after forcing phase.

| Rotational crops (available studies) | Crop groups        | Crop(s)       | Application(s) | PBI (DAT) |
|-------------------------------------|--------------------|---------------|----------------|-----------|
| Root/tuber crops                    | Radish             | Bare soil, 40 g a.s./ha | 30, 154, 365   |
| Leafy crops                         | Lettuce            | Bare soil, 40 g a.s./ha | 30, 154, 365   |
| Cereal (small grain)                | Wheat              | Bare soil, 40 g a.s./ha | 30, 154, 365   |

Source: France (2016).

| Processed commodities (hydrolysis study) | Conditions                                      | Investigated? |
|-----------------------------------------|-------------------------------------------------|---------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4)              | No            |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5)| No            |
|                                        | Sterilisation (20 min, 120°C, pH 6)              | No            |
|                                        | Not available and not required                   |               |

Can a general residue definition be proposed for primary crops? No

Rotational crop and primary crop metabolism similar? Yes

Residue pattern in processed commodities similar to residue pattern in raw commodities? Not required

Plant residue definition for monitoring (RD-Mo) penoxsulam

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

Conversion factor (monitoring to risk assessment) Not relevant

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

HPLC-MS/MS (EURL, 2016; France, 2016):

- Method EN 15662:2008 validated in high water and high acid content commodities
- QuEChERS method (EN 15662:2008) validated in dry commodities
- QuOil method (BVL L 13.04-5:2013-08) validated in high oil content commodities
- LOQ: 0.01 mg/kg
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity | $T$ (°C) | Stability (months) |
|-----------------------------------|-------------------|-----------|----------|-------------------|
| High water content                | Chicory           | $-20$     | 12       |
| High oil content                  | Olive             | $-18$     | 10       |
| Dry                               | Rice              | $-20$     | 7        |
| High acid content                 | Grapes            | $-20$     | 14       |

Sources: EFSA (2009), France (2016), Italy (2016).
## B.1.2. Magnitude of residues in plants

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

| Crop                              | Region/ indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR (mg/kg)<sup>(b)</sup> | STMR (mg/kg)<sup>(c)</sup> |
|-----------------------------------|------------------------------|----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------|--------------------------|--------------------------|
| Citrus fruits                     | SEU                          | 4 × < 0.01                                                                                                       | Trials compliant with GAP (Italy, 2016). All results were below the LOQ and a no-residue situation is expected MRL<sub>OECD</sub> = 0.01 | 0.01*                 | 0.01                     | 0.01                     |
| Table grapes/wine grapes          | SEU                          | 3 × < 0.01                                                                                                       | Trials performed on wine grapes at 1.33 N rate (France, 2016). All results were below the LOQ and a no-residue situation is expected MRL<sub>OECD</sub> = 0.01 | 0.01*                 | 0.01                     | 0.01                     |
| Wine grapes                       | NEU                          | 3 × < 0.01                                                                                                       | Trials performed on wine grapes at 1.33 N rate (France, 2016). All results were below the LOQ and a no-residue situation is expected MRL<sub>OECD</sub> = 0.01 | 0.01*                 | 0.01                     | 0.01                     |
| Table olives/olives for oil production | SEU                           | 8 × < 0.01                                                                                                       | Trials compliant with GAP (Italy, 2016). All results were below the LOQ and a no-residue situation is expected MRL<sub>OECD</sub> = 0.01 | 0.01*                 | 0.01                     | 0.01                     |
| Poppy seeds                       | SEU                          | 4 × < 0.01                                                                                                       | Trials compliant with GAP (Portugal, 2016). All results were below the LOQ and a no-residue situation is expected MRL<sub>OECD</sub> = 0.01 | 0.01*                 | 0.01                     | 0.01                     |
| Barley grains/rye grains/wheat grains | NEU                          | 8 × < 0.01                                                                                                       | Combined data set of trials on wheat (4) and barley (4) compliant with GAP (Italy, 2012). All results were below the LOQ and a no-residue situation is expected MRL<sub>OECD</sub> = 0.01 | 0.01*                 | 0.01                     | 0.01                     |
| Rice grains                       | SEU                          | 15 × < 0.01                                                                                                      | Trials compliant with GAP (Italy, 2005; France, 2016). All results were below the LOQ and a no-residue situation is expected MRL<sub>OECD</sub> = 0.01 | 0.01*                 | 0.01                     | 0.01                     |
| Sorghum grains                    | SEU                          | 4 × < 0.01                                                                                                       | Trials compliant with GAP (Italy, 2012). All results were below the LOQ and a no-residue situation is expected MRL<sub>OECD</sub> = 0.01 | 0.01*                 | 0.01                     | 0.01                     |
| Crop                                      | Region/ indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR (mg/kg) | STMR (mg/kg) |
|-------------------------------------------|----------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-----------------------|------------|-------------|
| Rice straw                                | SEU            | $13 \times < 0.01; 0.03; 0.08$                                                                  | Trials compliant with GAP (Italy, 2005; France 2016) MRL$_{OECD} = 0.09$                                        | 0.09                  | 0.08       | 0.01        |
| Barley straw/rye straw/Wheat straw        | NEU            | $4 \times < 0.01$                                                                               | Trials performed on wheat straw compliant with GAP (Italy, 2012). All results were below the LOQ and a no-residue situation is expected MRL$_{OECD} = 0.01$ | 0.01*                 | 0.01       | 0.01        |

GAP: Good Agricultural Practice; MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; 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.
(c): Supervised trials median residue.
B.1.2.2. Residues in succeeding crops

| Confined rotational crop study (quantitative aspect) | The TRR was generally below 0.01 mg eq/kg, with the exception of mature wheat straw (30 DAT) and immature lettuce (30 DAT). No residues are expected in rotational crops |
| Field rotational crop study | Not available and not required |

B.2. Residues in livestock

| Relevant groups | Dietary burden expressed in mg/kg bw per day | Most critical diet(a) | Most critical commodity(a) | Trigger exceeded (Y/N) |
|-----------------|----------------------------------------------|-----------------------|---------------------------|------------------------|
|                 | Med. | Max. | Med. | Max. | Cattle (dairy) | Rice, straw | N |
| Cattle (all diets) | 0.0005 | 0.0005 | 0.01(b) | 0.02(b) | Cattle (dairy) | Rice, straw | N |
| Cattle (dairy only) | 0.0005 | 0.0005 | 0.01 | 0.01 | Cattle (dairy) | Rice, straw | N |
| Sheep (all diets) | 0.0007 | 0.0010 | 0.02 | 0.02 | Sheep (lamb) | Rice, straw | N |
| Sheep (ewe only) | 0.0005 | 0.0007 | 0.02 | 0.02 | Sheep (ram/ewe) | Rice, straw | N |
| Swine (all diets) | 0.0003 | 0.0003 | 0.01 | 0.01 | Swine (finishing) | Barley, grain | N |
| Poultry (all diets) | 0.0009 | 0.0009 | 0.01 | 0.01 | Poultry (layer) | Wheat gluten, meal | N |
| Poultry (layer only) | 0.0009 | 0.0009 | 0.01 | 0.01 | Poultry (layer) | Wheat gluten, meal | N |

bw: body weight; DM: dry matter.
(a): Calculated for the maximum dietary burden.
(b): The highest dietary burdens expressed in mg/kg DM result from beef cattle.

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

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

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | N rate/comment |
|-------------------------------|--------|------------------------|----------------|---------------|
| Laying hen                    | 11     | 7                      | > 10,000 N rate |
| Lactating goat                | 11     | 5                      | > 10,000 N rate |

Source: Italy (2005).

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

| Metabolism in rat and ruminant similar (Yes/No) | Yes |
| Animal residue definition for monitoring (RD-Mo) | Not relevant |
| Animal residue definition for risk assessment (RD-RA) | Not relevant |
| Conversion factor (monitoring to risk assessment) | Not relevant |
| Fat soluble residues (Yes/No) | Not relevant |
| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | EURL (2016): No method available |
B.3. Consumer risk assessment

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

| ADI | 0.05 mg/kg bw per day (EFSA, 2009) |
| Highest IEDI, according to EFSA PRIMo | 0.3% ADI (WHO Cluster Diet B) |

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

| ARfD | Not deemed necessary (EFSA, 2009) |
| Highest IESTI, according to EFSA PRIMo | Not relevant |

Assumptions made for the calculations: Not relevant.

B.4. Proposed MRLs

| Code number(a) | Commodity | Existing EU MRL (mg/kg) | Outcome of the review |
|----------------|-----------|-------------------------|----------------------|
|                |           | MRL (mg/kg)             | Comment              |
| 110010         | Grapefruits | 0.01*                   | Recommended(b)       |
| 110020         | Oranges    | 0.01*                   | Recommended(b)       |
| 110030         | Lemons     | 0.01*                   | Recommended(b)       |
| 110040         | Limes      | 0.01*                   | Recommended(b)       |
| 110050         | Mandarins  | 0.01*                   | Recommended(b)       |
| 151010         | Table grapes | 0.01*                 | Recommended(b)       |
| 151020         | Wine grapes | 0.01*                  | Recommended(b)       |
| 161030         | Table olives | 0.01*                  | Recommended(b)       |
| 401030         | Poppy seeds | 0.01*                  | Recommended(b)       |
| 402010         | Olives for oil production | 0.01*              | Recommended(b)       |
| 500010         | Barley grains | 0.01*                 | Recommended(b)       |
| 500060         | Rice grains | 0.01*                  | Recommended(b)       |
| 500070         | Rye grains | 0.01*                   | Recommended(b)       |
| 500080         | Sorghum grains | 0.01*              | Recommended(b)       |
| 500090         | Wheat grains | 0.01*                 | Recommended(b)       |
| –              | Other commodities of plant and animal origin | See Regulation (EC) No 839/2008 | Further consideration needed(c) |

MRL: maximum residue level.
*: Indicates that the MRL is set/proposed at the limit of quantification.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G–I in Appendix E).
(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A–I in Appendix E).
### Appendix C – Pesticide Residue Intake Model (PRiMo)

#### Penoxsulam

| Status of the active substance | Approved |
|--------------------------------|----------|
| LOQ (mg/kg bw)                | 0.05     |

| Toxicological end points |
|--------------------------|
| ADI (mg/kg bw/day)       | n.n.     |
| Source of ADI:           | EFSA     |
| Year of evaluation       | 2009     |

| ARfD (mg/kg bw)          | n.n.     |
| Source of ARfD:          | EFSA     |
| Year of evaluation       | 2009     |

| No of diets exceeding ADI | --- |

#### Chronic risk assessment – refined calculations

| Highest calculated TMDI values in % of ADI | MS Diet | Highest contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | pTMRLs at LOQ (in % of ADI) |
|-------------------------------------------|---------|---------------------------------------------|---------------------------------|----------------------------------------|---------------------------------|----------------------------------------|---------------------------------|-----------------------------|
|                                           |         |                                             |                                 |                                        |                                 |                                        |                                 |                             |
| 0.3 WHO Cluster diet B                   | 0.2     | Wheat                                       | 0.0                             | Oranges for oil production            | 0.0                             | Wine grapes                            | 0.0                             |                             |
| 0.2 DE child                              | 0.1     | Wheat                                       | 0.1                             | Oranges                               | 0.0                             | Table grapes                           | 0.0                             |                             |
| 0.2 DK child                              | 0.1     | Wheat                                       | 0.1                             | Rye                                    | 0.0                             | Table grapes                           | 0.0                             |                             |
| 0.2 NL child                              | 0.1     | Wheat                                       | 0.1                             | Oranges                               | 0.0                             | Table grapes                           | 0.0                             |                             |
| 0.2 WHO cluster diet D                   | 0.1     | Wheat                                       | 0.0                             | Rice                                   | 0.0                             | Rice                                   | 0.0                             |                             |
| 0.2 PT General population                 | 0.1     | Wheat                                       | 0.1                             | Wine grapes                            | 0.0                             | Oranges                                | 0.0                             |                             |
| 0.2 FR all population                    | 0.1     | Wine grapes                                 | 0.0                             | Barley                                 | 0.0                             | Barley                                 | 0.0                             |                             |
| 0.2 WHO cluster diet E                   | 0.1     | Wheat                                       | 0.0                             | Wine grapes                            | 0.0                             | Barley                                 | 0.0                             |                             |
| 0.2 IE adult                              | 0.0     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Oranges for oil production            | 0.0                             |                             |
| 0.2 ES child                              | 0.1     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Rye                                    | 0.0                             |                             |
| 0.2 IT kids/toddler                      | 0.1     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Rye                                    | 0.0                             |                             |
| 0.1 UK Toddler                           | 0.1     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Rye                                    | 0.0                             |                             |
| 0.1 WHO Cluster diet F                   | 0.1     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Rye                                    | 0.0                             |                             |
| 0.1 FR toddler                           | 0.1     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Rye                                    | 0.0                             |                             |
| 0.1 ES adult                             | 0.0     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Barley                                 | 0.0                             |                             |
| 0.1 NL general                           | 0.0     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Wine grapes                            | 0.0                             |                             |
| 0.1 SE general population 90th percentile| 0.1     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Mandarins                              | 0.0                             |                             |
| 0.1 IT adult                             | 0.1     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Rice                                   | 0.0                             |                             |
| 0.1 WHO regional European diet           | 0.1     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Rice                                   | 0.0                             |                             |
| 0.1 UK infant                            | 0.1     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Rice                                   | 0.0                             |                             |
| 0.1 DK adult                             | 0.0     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Rye                                    | 0.0                             |                             |
| 0.1 UK vegetarian                       | 0.0     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Wine grapes                            | 0.0                             |                             |
| 0.1 UK Adult                             | 0.0     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Oranges                                | 0.0                             |                             |
| 0.1 FI adult                             | 0.0     | Wheat                                       | 0.0                             | Oranges                                | 0.0                             | Rye                                    | 0.0                             |                             |
| 0.1 LT adult                             | 0.0     | Wheaat                                      | 0.0                             | Oranges                                | 0.0                             | Rice                                   | 0.0                             |                             |
| 0.0 FR infant                            | 0.0     | Oranges                                     | 0.0                             | Wheat                                  | 0.0                             | Mandarins                              | 0.0                             |                             |
| 0.0 PL general population                | 0.0     | Table grapes                                 | 0.0                             | Lemons                                 | 0.0                             | Mandarins                              | 0.0                             |                             |

**Conclusion:**
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below ADI. A long-term intake of residues of penoxsulam is unlikely to present a public health concern.
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 calculation, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

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

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

**pTMRL**: provisional temporary MRL.

**pTMRL** for unprocessed commodity.

**Conclusion:**

As no ARfD was considered necessary, it is concluded that the short-term intake of penoxsulam 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                | Input value (mg/kg) | Comment                |
| **Risk assessment residue definition – penoxsulam**                   |                       |                        |                       |
| Citrus, dried pulp          | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) |
| Barley, grain               | 0.01*                 | STMR                   | 0.01*                 | STMR                   |
| Brewer's grain, dried       | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) |
| Rice, bran/ pollard         | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) |
| Rye, grain                  | 0.01*                 | STMR                   | 0.01*                 | STMR                   |
| Sorghum, grain              | 0.01*                 | STMR                   | 0.01*                 | STMR                   |
| Triticale, grain            | 0.01*                 | STMR                   | 0.01*                 | STMR                   |
| Wheat, grain                | 0.01*                 | STMR                   | 0.01*                 | STMR                   |
| Wheat, distiller's grain    | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) |
| Wheat gluten, meal          | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) |
| Wheat, milled by-pds        | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) | 0.01*                 | STMR (default PF not applied)\(^{(a)}\) |
| Barley, straw               | 0.01*                 | STMR                   | 0.01*                 | HR                     |
| Rice, straw                 | 0.01*                 | STMR                   | 0.08                  | HR                     |
| Rye, straw                  | 0.01*                 | STMR                   | 0.01*                 | HR                     |
| Triticale, straw            | 0.01*                 | STMR                   | 0.01*                 | HR                     |
| Wheat, straw                | 0.01*                 | STMR                   | 0.01*                 | HR                     |

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 fruit pomace, forage hay, cereal bran, no default processing factor was applied because penoxsulam is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

### D.2. Consumer risk assessment

| Commodity                  | Chronic risk assessment |
|----------------------------|-------------------------|
|                            | Input value (mg/kg)     | Comment |
| **Risk assessment residue definition - penoxsulam** |                       |         |
| Grapefruits                | 0.01*                  | STMR    |
| Oranges                    | 0.01*                  | STMR    |
| Lemons                     | 0.01*                  | STMR    |
| Limes                      | 0.01*                  | STMR    |
| Mandarins                  | 0.01*                  | STMR    |
| Table grapes               | 0.01*                  | STMR    |
| Wine grapes                | 0.01*                  | STMR    |
| Table olives               | 0.01*                  | STMR    |
| Poppy seeds                | 0.01*                  | STMR    |
| Olives for oil production  | 0.01*                  | STMR    |
| Barley grains              | 0.01*                  | STMR    |
### Commodity

| Commodity       | Chronic risk assessment |
|-----------------|------------------------|
|                 | Input value (mg/kg)    | Comment |
| Rice grains     | 0.01*                  | STMR    |
| Rye grains      | 0.01*                  | STMR    |
| Sorghum grains  | 0.01*                  | STMR    |
| Wheat grains    | 0.01*                  | STMR    |

STMR: supervised trials median residue.

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

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg QM in EU
  - Yes
  - No
  - MRL fully supported by data?
    - Yes
    - No

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

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

Recommendations resulting from EU authorisations and import tolerances

(A) Specific LOQ or default MRL?
(B) Specific LOQ or default MRL?
(C) Maintain current EU MRL?
(D) Specific LOQ or default MRL?
(E) Establish tentative EU MRL?
(F) Specific LOQ or default MRL?
(G) MRL is recommended
Comparison of the EU recommendation with the existing CXL

- **CXL available?**
  - Yes
  - No

- **RD comparable?**
  - Yes
  - No

- **CXL higher?**
  - Yes
  - No

Consumer risk assessment with consideration of the existing CXL

- **Input values for the RA remain unchanged?**
  - Yes
  - No

- **CXL is included in the RA?**
  - Yes
  - No

- **Codex median/ highest residues are included in the RA?**
  - Yes
  - No

Recommendations with consideration of the existing CXL

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

| Code/trivial name | Chemical name/SMILES notation                                                                                                                                                                                                 | Structural formula |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Penoxsulam        | 3-(2,2-Difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide FC(F)(F)c1cccc(OCC(F)F)c1S(=O)(=O)Nc2nc3c(cnc(OC)n3n2)OC | ![Penoxsulam Structural Formula](image) |
| BSTCA             | 3-([(2-(2,2-Difluoroethoxy)-6-(trifluoromethyl)phenyl)sulfonyl]amino)-1H-1,2,4-triazole-5-carboxylic acid O=S(=O)(Nc1nc(nn1)C(=O)O)c2c(cccc2OCC(F)F)c(F)(F)F | ![BSTCA Structural Formula](image) |
| BST               | 2-(2,2-Difluoroethoxy)-N-(1H-1,2,4-triazol-3-yl)-6-(trifluoromethyl)benzenesulfonamide O=S(=O)(Nc1ncnn1)c2c(cccc2OCC(F)F)c(F)(F)F | ![BST Structural Formula](image) |
| 5-OH              | 2-(2,2-Difluoroethoxy)-N-(5-hydroxy-8-methoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide FC(F)(F)c1cccc(OCC(F)F)c1S(=O)(=O)Nc2nc3c(cnc(OC)n3n2)OC | ![5-OH Structural Formula](image) |
| 5,8-OH            | 2-(2,2-Difluoroethoxy)-N-(5,8-dihydroxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide FC(F)(F)c1cccc(OCC(F)F)c1S(=O)(=O)Nc2nc3c(O)cnc(O)n3n2 | ![5,8-OH Structural Formula](image) |

SMILES: simplified molecular-input line-entry system.