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

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance pyroxsulam. To assess the occurrence of pyroxsulam 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. 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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Keywords: pyroxsulam pyroxsulam, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, herbicide

Requestor: European Commission

Question number: EFSA-Q-2013-00910

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Acknowledgement: EFSA wishes to thank Laszlo Bura, Viktoria Krivova, Silvia Ruocco and Viktor Toth for the support provided, and the rapporteur Member State, Denmark, for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Theobald A, Vagenende B and Verani A, 2020. Reasoned Opinion on the review of the existing residue levels for pyroxsulam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(10):6260, 26 pp. https://doi.org/10.2903/j.efsa.2020.6260

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Pyroxsulam was approved on 1 May 2014 by means of Commission Implementing Regulation (EU) No 1176/2013 in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

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

As the basis for the MRL review, on 16 September 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 14 October 2019 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, Denmark, 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 5 February 2020. 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 were provided by the RMS to EFSA on 16 March 2020. 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 June 2020 a draft reasoned opinion, which was circulated to Member States and EURL for consultation via a written procedure. Comments received by 30 July 2020 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of pyroxsulam in plant 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 pyroxsulam, limited to cereals’ crop group only. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all major matrices at the LOQ of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable in routine analyses.

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

Pyroxsulam is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. 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. Nevertheless, metabolism studies performed in lactating goats and laying hens are available. Based on these studies, pyroxsulam is considered a sufficient marker in case a residue definition for livestock will need to be established in the future. Pending the additional uses, the need to include conjugates of pyroxsulam to the residue definition for risk assessment may also need to be considered.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure represented 0.01% of the ADI (Danish child). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.
Table of contents

Abstract ................................................................................................................................................... 1
Summary ................................................................................................................................................. 3
Background ............................................................................................................................................. 5
Terms of Reference .................................................................................................................................. 6
The active substance and its use pattern ................................................................................................... 6
Assessment .............................................................................................................................................. 6
1. Residues in plants .................................................................................................................................. 7
   1.1. Nature of residues and methods of analysis in plants ........................................................................ 7
       1.1.1. Nature of residues in primary crops ................................................................................................. 7
       1.1.2. Nature of residues in rotational crops .............................................................................................. 7
       1.1.3. Nature of residues in processed commodities ................................................................................... 7
       1.1.4. Methods of analysis in plants ........................................................................................................... 7
       1.1.5. Stability of residues in plants ........................................................................................................... 8
       1.1.6. Proposed residue definitions............................................................................................................ 8
       1.2. Magnitude of residues in plants ....................................................................................................... 8
           1.2.1. Proposed MRLs ............................................................................................................................. 8
2. Residues in livestock ........................................................................................................................... 8
3. Consumer risk assessment .................................................................................................................... 9
Conclusions .............................................................................................................................................. 9
Recommendations .................................................................................................................................... 10
References ............................................................................................................................................... 10
Abbreviations ........................................................................................................................................... 11
Appendix A – Summary of authorised uses considered for the review of MRLs ........................................ 13
Appendix B – List of end points ................................................................................................................. 15
Appendix C – Pesticide Residue Intake Model (PRIMo) ........................................................................ 21
Appendix D – Input values for the exposure calculations ........................................................................ 23
Appendix E – Decision tree for deriving MRL recommendations ................................................................ 24
Appendix F – Used compound codes ......................................................................................................... 26
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 pyroxsulam was approved on 1 May 2014 by means of Commission Implementing Regulation (EU) No 1176/2013\(^3\) in the framework of Regulation (EC) No 1107/2009\(^4\) as amended by Commission Implementing Regulations (EU) No 540/2011\(^5\) and 541/2011\(^6\), 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 188/2011, pyroxsulam was evaluated by Denmark, 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, 2013). According to the provisions of the approval regulation, the approval of pyroxsulam was pending the submission of confirmatory information, that was assessed by EFSA in 2017, addressing all outstanding matters (European Commission, 2018).

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 16 September 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 14 October 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, 21 Member States provided feedback on their national authorisations of pyroxsulam. Based on the GAP data submitted, the designated RMS, Denmark, 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 5 February 2020.

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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 Implementing Regulation (EU) No 1176/2013 of 20 November 2013 approving the active substance pyroxsulam, 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 312, 21.11.2013, p. 23–27.
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.
On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked Denmark 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, were submitted to EFSA on 16 March 2020. 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 June 2020 a draft reasoned opinion, which was circulated to Member States and EURL for commenting via a written procedure. All comments received by 30 July 2020 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Denmark, 2020), taking into account also the information provided by Member States during the collection of data, and the EURL report on analytical methods (EURL, 2020) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 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

Pyroxsulam is the ISO common name for N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide (IUPAC).

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

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

For the purpose of this MRL review, all the uses of pyroxsulam 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. No GAPs were reported in third countries. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for pyroxsulam 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 (Denmark, 2020);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2013);
- the conclusion on the peer review of the pesticide risk assessment of the active substance pyroxsulam (EFSA, 2013);
- the review report on pyroxsulam (European Commission, 2018).
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,b,c,d,e,f,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 pyroxsulam was investigated in cereals after foliar treatment and assessed in the framework of the peer review (EFSA, 2013). In the study, pyroxsulam was radiolabelled either on the pyridine or triazolopyrimidine ring of the molecule. After a single application at a rate of 37.5 g a.s./ha (2N rate) on wheat, pyroxsulam was rapidly metabolised. Pyroxsulam accounted for 6% and up to 2% of the total radioactive residue (TRR) after 7 and 51 days after treatment (DAT) in forage and hay samples, respectively. Metabolite 5-OH-XDE-742 free and conjugated accounted for up to 70% TRR (up to 0.48 mg eq./kg) in forage and ca. 50% TRR (ca. 0.05 mg eq./kg) in hay. In mature plants, 92 DAT, TRRs were only 0.03 mg eq./kg in straw and less than 0.002 mg eq./kg in grain. Due to the low level of TRRs found in both straw and grain, characterisation of the residues was not attempted and is not considered necessary. The study adequately covers the metabolism of the crops under assessment.

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

Pyroxsulam is authorised on cereals that may be grown in rotation. The DT50 reported under laboratory conditions evaluated in the framework of the peer review was up to 16 days (EFSA, 2013). Considering the low persistence of pyroxsulam in soil, significant residues are not expected in rotational crops. This is also confirmed by a confined rotational crop study assessed in the framework of the peer review (EFSA, 2013). Pyroxsulam radiolabelled either on the pyridine or triazolopyrimidine ring of the molecule was applied to bare soil at a rate of 18.75 g a.s./ha (1N). Potato, lettuce and wheat were planted with a plant back interval of 30 days following treatment. Irrespective of the radiolabelled ring, at harvest TRRs were below 0.01 mg eq./kg in all edible crops and below 0.05 mg eq./kg in all feed items. The tentative characterisation of the residues indicates that the metabolism in rotational crops is similar to that in primary crops.

1.1.3. **Nature of residues in processed commodities**

There were no studies investigating the nature of residues of pyroxsulam in processed commodities available for this review. As in all food commodities residues were below the LOQ of 0.01 mg/kg and the highest international estimated daily intake is low (0.01% of the ADI), the investigation of the nature of residues in processed commodities is not required.

1.1.4. **Methods of analysis in plants**

During the peer review, a DFG S19 multi-residue method based on high-performance liquid chromatography (HPLC) coupled to tandem mass spectroscopy (MS/MS) detection was fully validated in high water (tomato), high acid (orange), high oil (oilseed rape) and dry (wheat grain) matrices, with a limit of quantification (LOQ) of 0.01 mg/kg for pyroxsulam. The method is considered suitable for enforcing pyroxsulam in high water, high acid, high oil and dry matrices with an LOQ of 0.01 mg/kg (EFSA, 2013).

During the completeness check, the EURLs concluded that pyroxsulam can be routinely monitored with an LOQ of 0.01 mg/kg using HPLC-MS/MS in all major matrices. The analytical method was
successfully validated in all commodity groups even at 0.005 mg/kg (EURL, 2020). The analytical standard for pyroxsulam is commercially available (EURL, 2020).

1.1.5. Stability of residues in plants

The storage stability of pyroxsulam was investigated in the framework of the peer review (EFSA, 2013). In high water content (spinach, tomato, wheat forage), high oil content (soybean) matrices, dry/high starch content (wheat grain, potato tuber) commodities and in wheat straw, the available studies demonstrated that pyroxsulam is stable for a period of at least 6 months when stored at –20°C.

1.1.6. Proposed residue definitions

The metabolism of pyroxsulam was investigated in cereals only. Residues are not expected in rotational crops in view of the low persistence of pyroxsulam and supported by a confined rotational crops study. In the peer review, it was concluded that no individual component is expected to be present at significant levels in plants at maturity and the residue definition for monitoring and risk assessment was proposed by default as pyroxsulam, limited to the cereals’ crop group only. These residue definitions are considered still applicable. As in forage and hay metabolite 5-OH-XDE-742 (free and conjugated) represent a major part of the residues, if further uses are envisaged on crops (e.g. pastures) where its contribution to the livestock dietary burden may be potentially significant, inclusion of this metabolite in the residue definition for risk assessment may need to be reconsidered.

An analytical method for the enforcement of pyroxsulam at the LOQ of 0.01 mg/kg in all matrices is available (EFSA, 2013). According to the EURLs, the LOQ of 0.01 mg/kg is achievable in routine analyses (EURL, 2020).

1.2. Magnitude of residues in plants

To assess the magnitude of pyroxsulam residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Denmark, 2020) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2013). 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 was 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.

There were no studies investigating the magnitude of residues in rotational crops available for this review. Nevertheless, based on the confined rotational crop study and considering the low persistence of pyroxsulam in soil, residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that pyroxsulam is applied in compliance with the GAPs reported in Appendix A.

No processing studies are available or required considering that the residues in cereal grain are below the LOQ of 0.01 mg/kg.

1.2.1. Proposed MRLs

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 cereal straw, in view of the future need to set MRLs in feed items.

2. Residues in livestock

Pyroxsulam is authorised for use on 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), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D.1. 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.

Similarly, the calculated dietary burden did not exceed the trigger value during the peer review. Nonetheless, studies in lactating goats and laying hens investigating the metabolism of pyroxsulam
residues were assessed in the framework of the peer review (United Kingdom, 2012; EFSA, 2013). These studies are reported here only for completeness. In all studies, pyroxsulam was radiolabelled either on the pyridine or triazolopyrimidine ring of the molecule.

\(^{14}\)C-pyroxsulam was administered to lactating goats for 7 days at a dose rate of 0.4 mg/kg body weight/day. The majority of the dose was excreted via urine and faeces, the transfer of residues to milk and tissues was very limited. TRR levels greater than 0.01 mg eq./kg were only found in liver and kidney, and even in these matrices, they remained below 0.025 mg eq./kg. Pyroxsulam accounted for over 94% of the TRR in milk, whereas in kidney and liver, it was mostly found in the form of its conjugates (40–60% TRR). Residues in other tissues were not characterised and it is not needed given the low level of TRR.

The study performed on laying hens dosed with 10 mg \(^{14}\)C-pyroxsulam/kg body weight (bw) per day for 7 days showed almost exclusive excretion of the administered dose. TRR levels only exceeded 0.01 mg/kg in liver (0.019 mg/kg; < 0.01% of dose).

Based on these studies, it can be concluded that pyroxsulam, and its conjugates is the most relevant component of the residues in livestock commodities. Considering the low animal burden, there is no need to propose residue definitions. Nonetheless, pyroxsulam is considered a sufficient marker in case a residue definition for livestock will need to be established in the future. Pending the additional uses, the need to include conjugates of pyroxsulam to the residue definition for risk assessment may also need to be considered.

Based on the partition coefficient (log Pow < 3), pyroxsulam is not considered fat soluble.

A DFG S19 multi-residue method using HPLC/MS-MS detection was fully validated for the determination of pyroxsulam in all animal tissues, milk and eggs, with an LOQ of 0.01 mg/kg (EFSA, 2013).

MRLs for animal products are not required because livestock are not expected to be exposed to significant levels of pyroxsulam residues.

3. **Consumer risk assessment**

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where 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.2. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

The exposure values calculated were compared with the toxicological reference value for pyroxsulam derived by EFSA (2013). The highest chronic exposure was calculated for Danish child, representing 0.01% of the acceptable daily intake (ADI). Therefore, these uses are unlikely to pose a risk to consumer's health.

**Conclusions**

The metabolism of pyroxsulam in plant 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 pyroxsulam, limited to the cereals’ crop group only. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all major matrices at the LOQ of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable in routine analyses.

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

Pyroxsulam is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. 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. Nevertheless, metabolism studies performed in lactating goats and laying hens are available. Based on these studies, pyroxsulam is considered a sufficient marker in case a residue definition for livestock will need to be established in the future. Pending the
additional uses, the need to include conjugates of pyroxsulam to the residue definition for risk assessment may also need to be considered.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure represented 0.01% of the ADI (Danish child). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 1). 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 | Commodity     | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment                        |
|-------------|---------------|-------------------------|----------------------|-----------------------|--------------------------------|
|             |               |                         |                      |                       |                                 |
| 500070      | Rye grain     | 0.01*                   | –                    | 0.01*                 | Recommended                     |
| 500090      | Wheat grain   | 0.01*                   | –                    | 0.01*                 | Recommended                     |
| –           | Other commodities of plant and/or animal origin | See Reg. 839/2008 | –                    | –                     | Further consideration needed    |

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
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
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
DB dietary burden
DM dry matter
DT$_{90}$ period required for 90% dissipation (define method of estimation)
EC emulsifiable concentrate
EMS evaluating Member State
EURLs European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
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

www.efsa.europa.eu/efsajournal 11 EFSA Journal 2020;18(10):6260
| Abbreviation | Full Form |
|--------------|-----------|
| IESTI        | International estimated short-term intake |
| ILV          | Independent laboratory validation |
| ISO          | International Organisation for Standardization |
| IUPAC        | International Union of Pure and Applied Chemistry |
| JMPR         | Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| LC           | Liquid chromatography |
| LC-MS/MS     | Liquid chromatography with tandem mass spectrometry |
| LOQ          | Limit of quantification |
| Mo           | Monitoring |
| MRL          | Maximum residue level |
| MS           | Member States |
| MS           | Mass spectrometry detector |
| MS/MS        | Tandem mass spectrometry detector |
| MW           | Molecular weight |
| 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 n-octanol and water |
| ppm          | Parts per million (10<sup>-6</sup>) |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| PROFFile     | (EFSA) Pesticide Residues Overview File |
| RA           | Risk assessment |
| RD           | Residue definition |
| RAC          | Raw agricultural commodity |
| RD           | Residue definition |
| RMS          | Rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SEU          | Southern European Union |
| SMILES       | Simplified molecular-input line-entry system |
| STMR         | Supervised trials median residue |
| TMDI         | Theoretical maximum daily intake |
| TRR          | Total radioactive residue |
| WG           | Water dispersible granule |
| WHO          | World Health Organization |
### Appendix A – Summary of authorised uses considered for the review of MRLs

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

| Crop and/or situation | MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-----------|-------------------------------|---------------|
|                       |               | F G or I    |                                   | Type(b)     | Conc. a.s. | Method kind                   | a.s./hL min-max | Water L/ha min-max | Rate and unit |               |
| Rye                   | CZ, DE, EE, FI, FR, IE, LT, NL, PL, UK | F           | Grasses and broadleaf weeds        | WG          | 75 g/kg   | Foliar treatment – spraying   | –             | –                | 18.75 g a.i./ha | n.a.         |
| Wheat                 | CZ, DE, EE, FI, FR, IE, LT, NL, PL, UK | F           | Grasses and broadleaf weeds        | WG          | 75 g/kg   | Foliar treatment – spraying   | –             | –                | 18.75 g a.i./ha | n.a.         |

MS: Member State.

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

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017.

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

(d): PHI – minimum preharvest interval.

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

| Crop and/or situation | MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-----------|-------------------------------|---------------|
|                       |               | F G or I    |                                   | Type(b)     | Conc. a.s. | Method kind                   | a.s./hL min-max | Water L/ha min-max | Rate and unit |               |
| Rye                   | BG, EL, ES, HR, IT, PT | F           | Grasses and broadleaf weeds        | WG          | 75 g/kg   | Foliar treatment – spraying   | –             | –                | 18.75 g a.i./ha | n.a.         |
| Wheat                 | BG, EL, ES, FR, HR, IT, PT | F           | Grasses and broadleaf weeds        | WG          | 75 g/kg   | Foliar treatment – spraying   | –             | –                | 18.75 g a.i./ha | n.a.         |

MS: Member State.

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

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI – minimum preharvest interval.
### Appendix B – List of end points

#### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Cereals/grass                     | Wheat       | 37.5 g a.s./ha | 7, 51, 92      | EFSA (2013), radiolabel on pyridine or triazolopyrimidine ring |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     | Potato      | Bare soil, 18.75 g a.s./ha | 30 | EFSA (2013), radiolabel on pyridine or triazolopyrimidine ring |
| Leafy crops                          | Lettuce     | Bare soil, 18.75 g a.s./ha | 30 |             |
| Cereal (small grain)                 | Wheat       | Bare soil, 18.75 g a.s./ha | 30 |             |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|--------|----------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | Not triggered | Residues in cereal grain < 0.01 mg/kg |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered | |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Not triggered | |
Can a general residue definition be proposed for primary crops?

| | No | Only cereals covered |
|---|---|---|
| Rotational crop and primary crop metabolism similar? | Yes | - |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | not applicable | Hydrolysis study not available and not required. |

Plant residue definition for monitoring (RD-Mo)

- Cereals' crop group: Pyroxsulam

Plant residue definition for risk assessment (RD-RA)

- Cereals' crop group: Pyroxsulam

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

- Matrices with high water content (tomato), high oil content (oilseed rape), high acid content (orange) and dry matrices (wheat grain): DFG S19(HPLC–MS/MS), LOQ 0.01 mg/kg
- Confirmatory method available.
- ILV available.
  (EFSA, 2013)
- Matrices with high water content, high oil content, high acid content and dry matrices can be routinely monitored with an LOQ of 0.01 mg/kg (EURL, 2020)

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period Value Unit | Compounds covered | Comment/ Source |
|---|---|---|---|---|---|---|
| High water content | Spinach, tomato, wheat forage | –20 | 6 Months | Pyroxsulam | EFSA (2013) |
| High oil content | Soybean | –20 | 6 Months | Pyroxsulam | EFSA (2013) |
| Dry/High starch content | Wheat grain, potato tuber | –20 | 6 Months | Pyroxsulam | EFSA (2013) |
| Others | Wheat straw | –20 | 6 Months | Pyroxsulam | EFSA (2013) |

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
### B.1.2. Magnitude of residues in plants

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

| Commodity       | Region/ indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|-----------------|-------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|--------------|
| Wheat grains    | NEU               | $8 \times < 0.01$                                                | Residue trials on wheat compliant with GAP (EFSA, 2013). Extrapolation to rye is applicable | 0.01*                  | 0.01         | 0.01         |
| Rye grains      | NEU               | $8 \times < 0.01$                                                | Residue trials on wheat compliant with GAP (EFSA, 2013). Extrapolation to rye is applicable | 0.01*                  | 0.01         | 0.01         |
| Wheat straw     | NEU               | $8 \times < 0.01$                                                | Residue trials on wheat compliant with GAP (EFSA, 2013). Extrapolation to rye is applicable | 0.01* (d) (tentative)  | 0.01         | 0.01         |
| Rye straw       | SEU               | $5 \times 0.01; 2 \times 0.01; 0.02$                              | Residue trials on wheat compliant with GAP (EFSA, 2013). Extrapolation to rye is applicable | 0.03 (d) (tentative)   | 0.02         | 0.01         |

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

*: 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.
(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(d): Tentative MRLs are derived for feed commodities in view of the future need to set MRLs in these commodities.
B.1.2.2. Residues in rotational crops

**Overall summary**

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No | Based on the low persistence and the confined rotational crop study residues are not expected in succeeding crops. |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered | No study available and not required |

B.1.2.3. Processing factors

Not available and not required as residues are below 0.01 mg/kg in the raw agricultural commodities.

B.2. Residues in livestock

**Dietary burden expressed in**

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup\(a\) | Most critical commodity\(b\) | Trigger exceeded (Y/N) |
|----------------------------|---------------------------------------------|-----------------------------|-----------------------------|-----------------------|
| Cattle (all)               | 0.001 0.001                                | Dairy cattle                | Wheat, milled by-products   | No                    |
| Cattle (dairy only)        | 0.001 0.001                                | Dairy cattle                | Wheat, milled by-products   | No                    |
| Sheep (all)                | 0.002 0.002                                | Lamb                        | Wheat, milled by-products   | No                    |
| Sheep (ewe only)           | 0.001 0.001                                | Ram/Ewe                     | Wheat, milled by-products   | No                    |
| Swine (all)                | 0.001 0.001                                | Swine (finishing)           | Wheat, milled by-products   | No                    |
| Poultry (all)              | 0.002 0.002                                | Poultry layer               | Wheat, milled by-products   | No                    |
| Poultry (layer only)       | 0.002 0.002                                | Poultry layer               | Wheat, milled by-products   | 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’.

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/d) | Duration (days) | Comment/Source |
|-------------------------------|--------|-------------------|----------------|---------------|
| Laying hen                    | 10     | 7                 | Radiolabel on pyridine or triazolopyrimidine ring (United Kingdom, 2012). (5,000N) |
| Lactating ruminants           | 0.4    | 7                 | Lactating goat: radiolabel on pyridine or triazolopyrimidine ring (United Kingdom, 2012). (200N) |
B.2.1.2. Stability of residues in livestock

Not available and not required.

B.3. Consumer risk assessment

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

Chronic risk assessment:

| Parameter                                      | Calculation                                                                 |
|-----------------------------------------------|-----------------------------------------------------------------------------|
| ADI                                           | 0.9 mg/kg bw per day (EFSA, 2013)                                           |
| TMDI according to EFSA PRIMo                  | Not assessed in this review                                                 |
| NTMDI, according to (to be specified)          | Not assessed in this review                                                 |
| Highest IEDI, according to EFSA PRIMo (rev.3.1)| 0.01% ADI (DK child)                                                       |
| 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 |

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.
Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/2/2003)

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

B.4. Proposed MRLs

| Code number | Commodity     | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|---------------|-------------------------|----------------------|-----------------------|---------|
| 500070      | Rye grain     | 0.01*                   | –                    | 0.01*                 | Recommended (a) |
| 500090      | Wheat grain   | 0.01*                   | –                    | 0.01*                 | Recommended (a) |
| –           | Other commodities of plant and/or animal origin | See Reg. 839/2008 | – | – | Further consideration needed (b) |

Enforcement residue definition: pyroxsulam

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).
### Pesticide Residue Intake Model (PRIMo)

#### PRIMO EU

**LOQs (mg/kg)** range from: 0.01 to: 0.01

**ADI (mg/kg bw per day):** 0.9

**ARfD (mg/kg bw):** not necessary

**Source of ADI:** EFSA

**Source of ARfD:** EFSA PRIMo revision 3.1; 2019/03/19

**Year of evaluation:** 2013

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### Calculated exposure (% of ADI)

| Commodity/group of commodities | Exposure resulting from | % of diets exceeding the ADI |
|--------------------------------|-------------------------|-----------------------------|
|                                |                         |                             |

### Exposure resulting from

- **Grapefruits**
- **Wheat**
- **Rye**
- **Grapes**
- **IT toddler**
- **PT**
- **EFSA**
- **DE child**
- **ES child**
- **NL toddler**
- **FI 3 yr**
- **FR child 3-15 yr**
- **FI adult**
- **DE women 14-50 yr**
- **UK infant**
- **FR adult**
- **DE general**
- **IE adult**
- **FR toddler 2-3 yr**
- **UK general**
- **IE child**
- **DE child**
- **FR general**
- **IE child**
- **BU child**
- **FI 6 yr**
- **DE adult**
- **IE adult**
- **FR infant**
- **FR adult**

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### Conclusion:

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

**Details – chronic risk assessment:**

- **UK adult**
- **DK adult**
- **IE child**
- **Grapefruits**
- **Wheat**
- **Rye**
- **Grapes**
- **IT toddler**
- **PT**
- **EFSA**
- **DE child**
- **ES child**
- **NL toddler**
- **FI 3 yr**
- **FR child 3-15 yr**
- **FI adult**
- **DE women 14-50 yr**
- **UK infant**
- **FR adult**
- **DE general**
- **IE adult**
- **FR toddler 2-3 yr**
- **UK general**
- **IE child**
- **DE child**
- **FR general**
- **IE child**
- **BU child**
- **FI 6 yr**
- **DE adult**
- **IE adult**
- **FR infant**
- **FR adult**

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### Normal mode

#### Chronic risk assessment: JMPR methodology (IEDI/TMDI)

| Commodity/group of commodities | Exposure resulting from | % of diets exceeding the ADI |
|--------------------------------|-------------------------|-----------------------------|
|                                |                         |                             |

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**Input values**

- **Details – chronic risk assessment**
- **Supplementary results – chronic risk assessment**
- **Details – acute risk assessment/children**
- **Details – acute risk assessment/adults**

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**www.efsa.europa.eu/efsajournal 21 EFSA Journal 2020;18(10):6260**

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**Appendix C – Pesticide Residue Intake Model (PRIMo)**

**European Food Safety Authority**

**EFSA PRIMo revision 3.1; 2019/03/19**
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

|                | Acute risk assessment/children | Acute risk assessment/adults/general population |
|----------------|-------------------------------|-----------------------------------------------|
|                | Details – acute risk assessment/children | Details – acute risk assessment/adults |

### Table: Results for children and adults

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

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

**Show results for all crops**

|                  | Results for children | Results for adults |
|------------------|----------------------|--------------------|
| **IESTI**        | No. of commodities for which ARfD/ADI is exceeded (IESTI): | No. of commodities for which ARfD/ADI is exceeded (IESTI): |
| **Processed commodities** | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|                  | Commodities         |                          |                   |

**Conclusion:**

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

**Results for children**

No of processed commodities for which ARfD/ADI is exceeded (IESTI):

**Results for adults**

No of processed commodities for which ARfD/ADI is exceeded (IESTI):

**Processed commodities**

Show results for all crops
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: pyroxsulam |
| Rye, 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 (dry)              | 0.03 STMR × default PF (3.3) | 0.03 STMR × default PF (3.3) |
| Wheat gluten, meal                          | 0.02 STMR × default PF (1.8) | 0.02 STMR × default PF (1.8) |
| Wheat, milled by-products                   | 0.07 STMR × default PF (7) | 0.07 STMR × default PF (7) |
| Rye, straw                                  | 0.01* STMR            | 0.02 HR                |
| Triticale, straw                            | 0.01* STMR            | 0.02 HR                |
| Wheat, straw                                | 0.01* STMR            | 0.02 HR                |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
*: Indicates that the input value is proposed at the limit of quantification.
In the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in the relevant commodities.

D.2. Consumer risk assessment

| Commodity                  | Chronic risk assessment |
|----------------------------|-------------------------|
|                            | Input value (mg/kg)     | Comment |
| Risk assessment residue definition: pyroxsulam |
| Rye and wheat grain        | 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
## Appendix F – Used compound codes

| Code/Trivial name<sup>(a)</sup> | Chemical name<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-----------------------------|----------------------------------|
| pyroxsulam                     | \(N-(5,7\text{-dimethoxy}[1,2,4]\text{-triazolo}[1,5-\text{a}]\text{pyrimidin-2-yl})-2\text{-methoxy-4-(trifluoromethyl)}\text{pyridine-3-sulfonamide}\) |
|                                | \(\text{FC}(\text{F})(\text{F})\text{c1ccnc(OC)c1S(-O)(=O)Nc1nc2nc(cc(OC)n2n1)OC}\) |
|                                | \(\text{GLBLPMUBLHYFCW-UHFFFAOYSA-N}\) |
| 5-OH-pyroxsulam                | \(N-(5\text{-hydroxy-7-methoxy}[1,2,4]\text{-triazolo}[1,5-\text{a}]\text{pyrimidin-2-yl})-2\text{-methoxy-4-(trifluoromethyl)}\text{3-pyridinesulfonamide}\) |
| 5-OH-XDE-742                   | \(\text{FC}(\text{F})(\text{F})\text{c1ccnc(OC)c1S(-O)(=O)Nc1nc2nc(O)cc(OC)n2n1}\) |
|                                | \(\text{LKRLPTYSSSFIQB-UHFFFAOYSA-N}\) |

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).