Review of the existing maximum residue levels for aminopyralid 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 aminopyralid. To assess the occurrence of aminopyralid residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. All information required by the regulatory framework was present and a risk to consumers was not identified.

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

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Summary

Aminopyralid was approved on 1 January 2015 by means of Commission Implementing Regulation (EU) No 891/2014 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 14 June 2019 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 22 July 2019 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS) Finland 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 23 October 2019. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations were provided by the RMS to EFSA on 31 January 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 EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011 and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in April 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 15 May 2020 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of aminopyralid in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as the sum of aminopyralid and its conjugates, expressed as aminopyralid. This residue definition is also applicable to processed commodities. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all four crop matrices at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURLs the LOQ of 0.05 mg/kg is achievable by using the QuEChERS method (QuOil for high oil content commodities) for the routine analysis of free aminopyralid in all matrices. A modified QuEChERS method including an alkaline hydrolysis step to release the conjugated residues of aminopyralid would be suitable to cover the proposed enforcement residue definition for food of plant origin.

Available residue trials data were sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. To avoid the occurrence of significant residues in succeeding crops, Member States should consider taking adequate risk mitigation measures. Alternatively, setting specific MRLs for rotational crops might be considered; in that case rotational crop residue trials would be required.

Aminopyralid is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were, therefore, performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for cattle, sheep and swine were found to exceed the trigger value of 0.1 mg/kg dry matter. Behaviour of residues was therefore assessed in these groups of livestock.

The metabolism of aminopyralid residues in livestock was investigated in lactating goats and laying hens at dose rates covering or approximating the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement and risk assessment in livestock commodities was proposed as aminopyralid only. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all animal matrices is available. According to the EURLs, aminopyralid can be monitored in milk and liver with an LOQ of 0.05 mg/kg, and the same LOQ of 0.05 mg/kg should be also achievable in eggs, fat, kidney and muscle.

A livestock feeding study on dairy cows was used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of this livestock feeding study were relied upon to derive the MRL and risk assessment values in pigs. Poultry
are not expected to be significantly exposed to aminopyralid residues, thus no MRLs are required for this group.

Chronic and acute 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 0.3% of the acceptable daily intake (ADI) (NL toddler) and the highest acute exposure amounted to 0.5% of the acute reference dose (ARfD) (cattle milk).

Apart from the MRLs evaluated in the framework of this review, internationally recommended Codex residue limits (CXLs) have also been established for aminopyralid. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 0.3% of the ADI (NL toddler) and the highest acute exposure amounted to 1% of the ARfD (bovine kidney).

These calculations indicate that the uses assessed under this review and the CXLs currently established are not expected to be of concern for European consumers.
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Background

Regulation (EC) No 396/2005 (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 a reasoned opinion on the review of the existing MRLs for that active substance.

As aminopyralid was approved on 1 January 2015 by means of Commission Implementing Regulation (EU) No 891/2014 in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011, 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 aminopyralid was evaluated by United Kingdom, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA conclusion (EFSA, 2013b).

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

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

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

As the basis for the MRL review, on 14 June 2019 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 22 July 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, 20 Member States provided feedback on their national authorisations of aminopyralid. Based on the GAP data submitted, the re-assigned RMS Finland 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 23 October 2019.

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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 891/2014 of 14 August 2014 approving the active substance aminopyralid, 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 243, 15.8.2014, p. 47-51.
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. O J L 309, 24.11.2009, p. 1-50.
5 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.
6 Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187-188.
7 Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.
On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked Finland 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 31 January 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, and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limits; CXLs), EFSA prepared in April 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 15 May 2020 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Finland, 2020), taking into account also the information provided by Member States during the collection of data, and the EURLs report on analytical methods (EURLs, 2019) 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 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**

Aminopyralid is the ISO common name for 4-amino-3,6-dichloropyridine-2-carboxylic acid (IUPAC). The chemical structure of the active substance is reported in Appendix F.

The EU MRLs for aminopyralid are established in Annex III of Regulation (EC) No 396/2005. CXLs for aminopyralid were also established by the CAC. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

| Procedure | Legal implementation | Remarks |
|-----------|----------------------|---------|
| MRL application | Commission Regulation (EU) 2019/1015(a) | Certain cereals (barley, millet, oat, rye, sorghum) (EFSA, 2019b) |
| MRL application | Commission Regulation (EU) 2017/171(b) | Maize (EFSA, 2016) |
| MRL application | Commission Regulation (EU) No 36/2014(c) | Animal commodities (EFSA, 2013a) |
| MRL application | Commission Regulation (EU) No 251/2013(d) | Rapeseed (EFSA, 2012) |
| MRL application | Commission Regulation (EU) No 459/2010(e) | Grass and bovine kidney (EFSA, 2009) |
For the purpose of this MRL review, all the uses of aminopyralid currently authorised within the EU as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for aminopyralid are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

**Assessment**

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Finland, 2020);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2006, 2013);
- the conclusion on the peer review of the pesticide risk assessment of the active substance aminopyralid (EFSA, 2013b);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation reports (FAO, 2006, 2007);
- the previous reasoned opinions on aminopyralid (EFSA, 2009, 2012, 2013a, 2016, 2019b).

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 (OECD, 2013, 2008, 2011; European Commission, 1997a-g, 2000, 2010a,b, 2017).

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.

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**Procedure Legal implementation Remarks**

| Procedure | Legal implementation | Remarks |
|-----------|----------------------|---------|
| Implementation of CAC | Commission Regulation (EU) No 36/2014 | Animal products The CXLs for food of animal origin were implemented as an alternative to the modifications of the MRLs requested by the applicant (see EFSA, 2013a) since the CXLs are based on the same scientific considerations. Risk managers agreed to take over the CXLs in the EU legislation although the residue definition derived at Codex level did not fully comply with the EU residue definition for enforcement. |

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

(a): Commission Regulation (EU) 2019/1015 of 20 June 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, captan, cyazofamid, flutianil, kresoxim-methyl, lambda-cyhalothrin, mandipropamid, pyraclostrobin, spiromesifen, spirotetramat, tefubenzuron and tetraconazole in or on certain products. OJ L 165, 21.6.2019, p. 23–64.

(b): Commission Regulation (EU) 2017/171 of 30 January 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, azoxystrobin, cyantraniliprole, cyfluafenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxyfop, isofetamid, metaaxyl, profenoxadione, propaziquafop, pyrimethanil, Trichoderma atroviride strain SC1 and zoxamide in or on certain products. OJ L 30, 3.2.2017, p. 45–111.

(c): Commission Regulation (EU) No 36/2014 of 16 January 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, chlorantraniliprole, cyfluafenamid, mepiquat, metalaxyl-M, propamocarb, pyriproxyfen and quinoxifen in or on certain products. OJ L 17, 21.1.2014, p. 1–41.

(d): Commission Regulation (EU) No 251/2013 of 22 March 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, bifenazate, captan, fluzinam, flupicloxide, folpet, kresoxim-methyl, penthiopyrad, proquinazid, pyridate and tembotrione in or on certain products. OJ L 88, 27.3.2013, p. 1–44.

(e): Commission Regulation (EU) No 459/2010 of 27 May 2010 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products. OJ L 129, 28.5.2010, p. 3–49.

For the purpose of this MRL review, all the uses of aminopyralid currently authorised within the EU as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for aminopyralid are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.
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 aminopyralid was investigated in three varieties of grass and in cereals (United Kingdom, 2006, 2013) and assessed in the framework of the peer review (EFSA, 2013b). In both studies, aminopyralid radiolabelled in the positions 2 and 6 of the pyridine ring of the molecule, was applied as a single foliar treatment.

In the first study, after one foliar application of 360 g a.s./ha on common pasture grasses, most of the radioactive residues were extracted (90–99% of the total radioactive residues; TRR). In fresh grass, residue levels ranged from 19 to 37 mg eq/kg 7 days after treatment (DAT), decreasing to 5–7 mg eq/kg 42 DAT. In hay 42 DAT, residues were higher ranging from 13 to 23 mg eq/kg. In all three varieties, the major component identified in fresh grass was parent aminopyralid, accounting for 48–68% TRR 7 days after treatment and decreasing to 22–31% TRR (up to 35% TRR in hay) after 42 days. The decrease of the parent, unconjugated aminopyralid, was balanced with a constant increase of the conjugated fraction mostly composed of glucose conjugates, from 19–39% TRR to 50–60% TRR (EFSA, 2013b).

In a second study, wheat was treated with one foliar application of 40 g a.s./ha (4N the application rate of the GAP on cereals) and 80 g a.s./ha (8N rate). Total residue levels of aminopyralid in grain were 0.039 to 0.084 mg eq/kg (at 4N rate and 8N rate, respectively), while total radioactive residues were higher in forage (up to 0.87 mg eq/kg), hay (up to 0.69 mg eq/kg) and straw (up to 0.62 mg eq/kg). A similar profile as in grass was observed in wheat, with a steady decrease of unconjugated aminopyralid, from 87–90% TRR in forage (0 DAT) to 8–11% TRR in straw (86 DAT), compensated by an increase of the conjugated fractions, similarly composed of glucose conjugates of aminopyralid, from 7–9% TRR to 63–70% TRR (EFSA, 2013b).

The metabolism of aminopyralid was also investigated in oilseeds and assessed in the framework of a previous MRL application but not peer reviewed (France, 2011; EFSA, 2012). After one foliar treatment on rapeseed with 14 g a.s./ha of aminopyralid radiolabelled in the positions 2 and 6 of the pyridine ring, total residue levels from successive sampling decreased from 0.08 mg eq/kg to 0.04 mg eq/kg in immature seeds and were 0.003 mg eq/kg in mature seeds. The major components identified were also unconjugated aminopyralid (up to 78% TRR just after application) and its conjugates (up to 60% TRR at harvest) which were released as aminopyralid upon hydrolytic extraction conditions (France, 2011; EFSA, 2012). As it was observed in the wheat and grass studies, residue levels of the unconjugated aminopyralid declined while at longer harvest intervals the levels of conjugates increased.

The metabolic pathway of aminopyralid was similar in cereals, grass and oilseeds.

1.1.2. Nature of residues in rotational crops

Aminopyralid is authorised on crops that may be grown in rotation. The field DT90 reported in the soil degradation studies evaluated in the framework of the peer review was 116 days (EFSA, 2013b). Therefore, the possible occurrence of residues in rotational crops needs to be assessed.

One confined rotational crop study with aminopyralid radiolabelled in the positions 2 and 6 of the pyridine ring of the molecule was available for this review (EFSA, 2013b; United Kingdom, 2013). In this study, aminopyralid was applied at a low rate of 10 g a.s./ha onto bare soil. Crops were planted at nominal plant-back intervals (PBI) of 90 and 120 DAT. Crops planted at each interval consisted of leafy vegetables (lettuce), roots (turnip) and cereals (sorghum). Residues in all crops were generally low, ranging from < 0.001 to 0.006 mg eq/kg in edible parts of the crops and reaching up to 0.03 mg eq/kg in feed items (sorghum forage and stover). The major compounds further characterised were aminopyralid (free or conjugated) and it was concluded that the metabolic pathway was similar as in primary crops. However, this study performed at a dose rate equivalent to 0.2N the application of the most critical GAP for grass and considering two PBI only, was not considered sufficient to conclude on the residues in rotational crops.

Thus, an additional confined rotational crop study was recently submitted and assessed in the framework of a previous MRL application, however not peer reviewed (United Kingdom, 2017; EFSA, 2019b). In this study, aminopyralid radiolabelled in the positions 2 and 6 of the pyridine ring was applied at 63.9 g a.s./ha to bare soil (just above 1N rate for grass, a 6N rate for cereals). Leafy
vegetables (lettuce), roots (turnip) and cereals (wheat) were planted at PBIs of 30, 120 and 365 days. Leafy vegetables were also planted 180 and 300 DAT. However, due to phytotoxic effects, lettuce did not grow and was replaced with mustard planted at PBIs of 300 and 365 days. The major compound characterised in all samples was aminopyralid (free or conjugated), accounting for 35–95% TRR, with residue levels ranging from 0.01 mg eq/kg (wheat grain, 30 DAT) to 0.66 mg eq/kg (wheat hay, 120 DAT), and highest levels observed in wheat hay and straw. In turnips and wheat, residues generally increased between PBIs of 30 and 120 DAT, before decreasing significantly 365 DAT, while in mustard greens residues increased between 300 and 365 DAT. In turnip roots and wheat grain at a PBI of 365 days, residues were too low to be characterised (United Kingdom, 2017; EFSA, 2019b).

Based on the available data, it can be concluded that the metabolism and distribution of aminopyralid in rotational crops is similar to the metabolic pathway observed in primary crops.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of aminopyralid residues in processed commodities were assessed in the framework of a previous application to modify MRLs in cereals (United Kingdom, 2017; EFSA, 2019b), however, not peer reviewed. These studies were conducted with radiolabelled aminopyralid in the positions 2 and 6 of the pyridine ring simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). Aminopyralid was stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/baking and sterilisation.

1.1.4. Methods of analysis in plants

During the peer review, a hyphenated analytical method based on high-performance liquid chromatography (HPLC) coupled to tandem mass spectrometry (MS/MS) detection was validated for the determination of aminopyralid free and conjugated (measured as aminopyralid) in all four crop matrices (high water, high acid, high oil content and dry commodities), with a limit of quantification (LOQ) of 0.01 mg/kg. The method includes hydrolytic conditions that release free aminopyralid from its conjugates. It is supported by an independent laboratory validation (ILV).

During the completeness check, the EURLs provided a QuEChERS multi-residue analytical method using HPLC-MS/MS with an LOQ of 0.05 mg/kg for the routine analysis of free aminopyralid in high water content, high acid content and dry commodities. During the Member State consultation, the EURLs provided an updated evaluation report and additional validation data for high oil content commodities with the same LOQ of 0.05 mg/kg. However, this method does not cover the default LOQ of 0.01 mg/kg, neither the proposed residue definition for enforcement since aminopyralid conjugates are not analysed. According to the EURLs, aminopyralid is stable under alkaline hydrolysis and as the conjugates residues of aminopyralid are mostly glucosides (easy to breakup), it is confirmed that a modified QuEChERS method including an alkaline hydrolysis step would be suitable for the determination of aminopyralid (free and conjugated) (EURLs, 2019). However, validation data for this method were not provided by the EURLs.

1.1.5. Stability of residues in plants

The storage stability of aminopyralid residues was investigated in wheat (grain, forage, hay and straw) and grass (forage) in the framework of the peer review (EFSA, 2013b; United Kingdom, 2013) and in rapeseed (forage, seeds, rape oil) in a new study submitted under this review, however not peer reviewed (Finland, 2020).

In high water content and dry commodities, the available studies demonstrated storage stability for aminopyralid for a period of 16 months when stored at −20°C, while in high oil content matrices, the new study reported by Finland demonstrates the storage stability for up to 25 months.

1.1.6. Proposed residue definitions

The metabolism of aminopyralid was similar in all crops assessed. The metabolism in rotational crops is similar to the metabolism observed in primary crops and the processing of aminopyralid is not expected to modify the nature of residues.

Based on the metabolism studies, unconjugated aminopyralid is not a sufficient marker as its conjugates were found to represent a major part of the radioactive residues. Both parent and its conjugated are toxicologically relevant and thus should be considered in the consumer exposure.
Therefore, the residue definition for enforcement and risk assessment in cereals/grass and oilseeds is proposed as the sum of aminopyralid and its conjugates, expressed as aminopyralid. This residue definition was already proposed during the peer review (in cereals only) and supported in all assessments performed in the framework of previous MRL applications. It is noted that the residue definition for enforcement currently established in the Regulation (EC) 396/2005 is limited to the parent only.

Considering that an analytical method involving an alkaline hydrolysis step for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all matrices is available (EFSA, 2013b), and that conjugates were analysed for in all the supervised residue trials, this residue definition derived during the peer review is still considered appropriate and relevant under the current review.

According to the EURs, the LOQ of 0.05 mg/kg is achievable in high water content, high oil content, high acid content and dry commodities by using the QuEChERS method for the routine analysis of free aminopyralid. A modified QuEChERS method releasing conjugates would be suitable to cover the proposed enforcement residue definition (see Section 1.1.4). Considering the reasons mentioned above and that such conjugates are not easy to address through conversion factors, the EURs also support the proposal that the residue definition should include the conjugates (EURs, 2019).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of aminopyralid residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Finland, 2020) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2013b) or in the framework of previous MRL applications (EFSA, 2012, 2016, 2019b). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017). It should be noted that according to these European guidelines, residue trials both in barley and in wheat could have been used by extrapolation to derive MRL and risk assessment values for oat and rye. Under the last MRL application, both options were proposed, and risk managers supported the extrapolation from barley to set MRLs for oat and rye. Nevertheless, considering that residues in wheat straw represented a more critical situation compared to barley, residue levels in wheat straw were extrapolated to oat and rye straw (EFSA, 2019b). The same approach was followed for this Article 12 review (see Appendix B.1.2.1).

The available residue trials are sufficient to derive MRL and risk assessment values for all crops under assessment.

1.2.2. Magnitude of residues in rotational crops

There were no studies investigating the magnitude of residues in rotational crops available for this review.

Based on the available confined rotational crop studies (see Section 1.1.2), the occurrence of residues in rotational crops above 0.01 mg/kg, could not be fully excluded when aminopyralid is applied following the GAPs reported in Appendix A.

Consequently, to avoid the presence of aminopyralid residues in rotational crops, Member States should consider the need of defining plant-back restrictions when granting authorisations for plant protection products containing aminopyralid. Alternatively, setting MRLs for rotational crops might be considered, but would require rotational crop residue trials covering the most critical GAP currently authorised (data gap).

Several Member States already reported in their GAPs that mitigation measures (90-day PBI and label restrictions) were implemented, while granting authorisations. Nevertheless, considering the results of the confined study performed at 60 g a.s./ha, this 90-day PBI may not be sufficient.
1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was first assessed on studies conducted in wheat in the framework of the peer review (United Kingdom, 2006; EFSA, 2013b). An additional study performed in wheat and barley was assessed in the framework of a recent MRL application (United Kingdom, 2017; EFSA, 2019b), however not peer reviewed. An overview of all available processing studies is available in Appendix B.1.2.3.

A robust processing factor (based on a sufficient number of studies) could be derived for wheat bran, while tentative processing factors (not fully supported by data) were derived for all other processed products of wheat (fine and coarse bran, flour, wholemeal flour and wholemeal bread) and of barley (brewing malt, spent grains, brewer’s yeast and beer) (EFSA, 2019b).

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

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation.

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

Specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures (e.g. define plant-back interval) in order to avoid significant residues to occur in rotational crops.

2. Residues in livestock

Aminopyralid is authorised for use on cereals, grass and rapeseed that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for cattle, sheep and swine were found to exceed the trigger value of 0.1 mg/kg dry matter (DM).

2.1. Nature of residues and methods of analysis in livestock

The metabolism of aminopyralid residues in livestock was investigated in lactating goats and laying hens at dose rates covering or approximating the maximum dietary burdens calculated in this review (Finland, 2020). These studies, assessed in the framework of the peer review (United Kingdom, 2006, 2013; EFSA, 2013b), sufficiently address the metabolism in livestock.

In all studies, aminopyralid was radiolabelled in the positions 2 and 6 of the pyridine ring of the molecule. The study performed on lactating goats (at ca. 1N the dietary burden calculated for ruminants) indicates that transfer of residues is insignificant, as aminopyralid is intensively excreted and no more than 0.07% of the administered dose was recovered in milk and edible matrices. TRRs were below 0.01 mg eq/kg in all matrices (from 0.001 to 0.008 mg eq/kg), except in kidney (0.07 mg eq/kg) where residues were characterised and 80% TRR was identified as aminopyralid (EFSA, 2013b).

Although not required under the current review, a study on laying hens (131N the dietary burden calculated for poultry) was available in which, as for ruminants, aminopyralid was almost totally excreted and TRRs in all matrices were significantly lower than 0.01 mg eq/kg (representing less than 0.05% of the administered dose). Residues were thus, not characterised.

The storage stability of aminopyralid was not demonstrated, however all samples analysed were stored for less than 30 days.

EFSA concludes that the metabolism of aminopyralid in livestock is adequately elucidated. As aminopyralid is not significantly metabolised or conjugated and is the most relevant compound in livestock commodities, the residue definition for enforcement and risk assessment in livestock commodities is proposed as aminopyralid only.

An analytical method for the enforcement of the proposed residue definition using HPLC-MS/MS was fully validated in all animal matrices with an LOQ of 0.01 mg/kg, and supported by an ILV (EFSA, 2013b). During the Member State consultation, EURLs provided additional validation data for food of animal origin, concluding that aminopyralid can be monitored in milk and liver with an LOQ of...
0.05 mg/kg. According to the EURLs, judging from the analytical behaviour of aminopyralid, an LOQ of 0.05 mg/kg should be also achievable in eggs, fat, kidney and muscle (EURLs, 2019).

2.2. Magnitude of residues in livestock

In the framework of the peer review, a feeding study was performed with dairy cows (United Kingdom, 2006). In these studies, aminopyralid was administered using different dosing levels ranging from 32.8 mg/kg DM (equivalent to 1.26 mg/kg body weight (bw) per day) to 644.7 mg/kg DM (equivalent to 24.8 mg/kg bw per day), corresponding to 3.2N to 62.9N the maximum dietary burden calculated for dairy cattle. In this study, samples of tissues and milk were analysed for aminopyralid and the results confirmed the intensive excretion of aminopyralid observed in the metabolism study.

The study performed on dairy cows was used to derive MRL and risk assessment values for all commodities of ruminants, in compliance with the latest recommendations on this matter (FAO, 2009). Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. Significant levels of aminopyralid are only expected in kidney, where the mean levels were 0.07 and 0.15 mg/kg for the two lowest dose rates. For milk and all other tissues of ruminants, no residues were found above the LOQ at any dosing levels and MRLs can be proposed at the LOQ (0.01 mg/kg). All the samples analysed were stored for less than 30 days, thus decline of residues during storage of the trial samples is not expected.

No study was available for poultry; however MRLs are not required since poultry are not expected to be exposed to significant levels of aminopyralid residues.

3. Consumer risk assessment

In the framework of this review, only the uses of aminopyralid reported by the RMS in Appendix A were considered; however, the use of aminopyralid was previously also assessed by the JMPR (FAO, 2006, 2007). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

3.1. Consumer risk assessment without consideration of the existing CXLs

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

The exposure values calculated were compared with the toxicological reference values for aminopyralid, derived by EFSA (2013b). The highest chronic exposure was calculated for NL toddler, representing 0.3% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for milk from cattle, representing 0.5% of the acute reference dose (ARfD). These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health.

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is also provided in Appendix D.

The CXLs established by JMPR were derived following a different enforcement residue definition (aminopyralid and its conjugates that can be hydrolysed, expressed as aminopyralid) both for plants and animal commodities, that does not fully comply with the ones proposed under this review. Although JMPR included aminopyralid conjugates in its residue definition for enforcement of animal commodities, this difference is of no relevance in practice as under the EU evaluation the conjugates...
are not found in significant amount in livestock (EFSA, 2013a). Thus, it can be concluded that CXLs and MRL proposals are comparable. It is to note that risk managers already agreed to take over the CXLs derived for commodities of ruminants in the European regulation (see Table 1).

Although a CXL is not set for fat, considering that the CXLs derived for all livestock commodities are higher than the ones derived from the European uses, EFSA calculated the CXLs for fat, based on the data available in the JMPR report (FAO, 2006).

Chronic and acute exposure calculations were also performed using revision 3.1 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference values derived for aminopyralid. The highest chronic exposure was calculated for NL toddler, representing 0.3% of the ADI, and the highest acute exposure was calculated for bovine kidney, representing 1% of the ARfD. Based on these calculations, EFSA concludes that the CXLs are not expected to be of concern for European consumers.

Conclusions

The metabolism of aminopyralid in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as the sum of aminopyralid and its conjugates, expressed as aminopyralid. This residue definition is also applicable to processed commodities. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all four crop matrices at the LOQ of 0.01 mg/kg. According to the EURLs the LOQ of 0.05 mg/kg is achievable by using the QuEChERS method (QuOil for high oil content commodities) for the routine analysis of free aminopyralid in all matrices. A modified QuEChERS method including an alkaline hydrolysis step to release the conjugated residues of aminopyralid would be suitable to cover the proposed enforcement residue definition for food of plant origin.

Available residue trials data were sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. To avoid the occurrence of significant residues in succeeding crops, Member States should consider taking adequate risk mitigation measures. Alternatively, setting specific MRLs for rotational crops might be considered; in that case rotational crop residue trials would be required.

Aminopyralid is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for cattle, sheep and swine were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in these groups of livestock.

The metabolism of aminopyralid residues in livestock was investigated in lactating goats and laying hens at dose rates covering or approximating the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement and risk assessment in livestock commodities was proposed as aminopyralid only. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all animal matrices is available. According to the EURLs, aminopyralid can be monitored in milk and liver with an LOQ of 0.05 mg/kg, and the same LOQ of 0.05 mg/kg should be also achievable in eggs, fat, kidney and muscle.

A livestock feeding study on dairy cows was used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of this livestock feeding study were relied upon to derive the MRL and risk assessment values in pigs. Poultry are not expected to be significantly exposed to aminopyralid residues, thus no MRLs are required for this group.

Chronic and acute 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 0.3% of the ADI (NL toddler) and the highest acute exposure amounted to 0.5% of the ARfD (cattle milk).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for aminopyralid. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 0.3% of the ADI (NL toddler) and the highest acute exposure amounted to 1% of the ARfD (bovine kidney).

These calculations indicate that the uses assessed under this review and the CXLs currently established are not expected to be of concern for European consumers.
Recommendations

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

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

- a representative field rotational crop study covering the most critical GAP currently authorised.

Pending the submission of this study, Member States granting authorisations for aminopyralid should take the appropriate risk mitigation measures or modify the relevant authorisations in order to avoid the presence of significant residues in rotational crops.

Table 2: Summary table

| Code number | Commodity       | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------------|-------------------------|----------------------|-----------------------|---------|
| 401060      | Rapeseed        | 0.03                    | –                    | 0.03                  | Recommended<sup>(a)</sup> |
| 5000010     | Barley grain    | 0.15                    | 0.1                  | 0.15                  | Recommended<sup>(b)</sup> |
| 500030      | Maize grain     | 0.05                    | –                    | 0.05                  | Recommended<sup>(a)</sup> |
| 500040      | Oats grain      | 0.15                    | 0.1                  | 0.15                  | Recommended<sup>(b)</sup> |
| 500070      | Rye grain       | 0.15                    | –                    | 0.15                  | Recommended<sup>(b)</sup> |
| 500080      | Sorghum grain   | 0.05                    | –                    | 0.05                  | Recommended<sup>(a)</sup> |
| 500090      | Wheat grain     | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(a)</sup> |

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

**Enforcement residue definition (proposed):** sum of aminopyralid and its conjugates, expressed as aminopyralid

| Code number | Commodity       | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------------|-------------------------|----------------------|-----------------------|---------|
| 1011010     | Swine meat      | 0.01*                   | 0.1                  | 0.1                   | Recommended<sup>(c)</sup> |
| 1011020     | Swine fat (free of lean meat) | 0.02 | 0.1 | 0.1 | Recommended<sup>(c)</sup> |
| 1011030     | Swine liver     | 0.02                    | 0.05                 | 0.05                  | Recommended<sup>(c)</sup> |
| 1011040     | Swine kidney    | 0.3                     | 1                    | 1                     | Recommended<sup>(c)</sup> |
| 1012010     | Bovine meat     | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(c)</sup> |
| 1012020     | Bovine fat      | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(c)</sup> |
| 1012030     | Bovine liver    | 0.05                    | 0.05                 | 0.05                  | Recommended<sup>(c)</sup> |
| 1012040     | Bovine kidney   | 1                       | 1                    | 1                     | Recommended<sup>(c)</sup> |
| 1013010     | Sheep meat      | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(c)</sup> |
| 1013020     | Sheep fat       | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(c)</sup> |
| 1013030     | Sheep liver     | 0.05                    | 0.05                 | 0.05                  | Recommended<sup>(c)</sup> |
| 1013040     | Sheep kidney    | 1                       | 1                    | 1                     | Recommended<sup>(c)</sup> |
| 1014010     | Goat meat       | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(c)</sup> |
| 1014020     | Goat fat        | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(c)</sup> |
| 1014030     | Goat liver      | 0.05                    | 0.05                 | 0.05                  | Recommended<sup>(c)</sup> |
| 1014040     | Goat kidney     | 1                       | 1                    | 1                     | Recommended<sup>(c)</sup> |
| 1015010     | Horse meat      | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(c)</sup> |
| 1015020     | Horse fat       | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(c)</sup> |
| 1015030     | Horse liver     | 0.05                    | 0.05                 | 0.05                  | Recommended<sup>(c)</sup> |
| 1015040     | Horse kidney    | 1                       | 1                    | 1                     | Recommended<sup>(c)</sup> |
| 1016010     | Poultry meat    | 0.01*                   | 0.01*                | 0.01*                 | Recommended<sup>(c)</sup> |
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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
| Abbreviation | Definition |
|--------------|------------|
| CF           | conversion factor for enforcement residue definition to risk assessment residue definition |
| cGAP         | critical GAP |
| CXL          | codex maximum residue limit |
| DAR          | draft assessment report |
| DAT          | days after treatment |
| DB           | dietary burden |
| DM           | dry matter |
| DT<sub>90</sub> | period required for 90% dissipation (define method of estimation) |
| EMS          | evaluating Member State |
| eq           | residue expressed as a.s. equivalent |
| EU RLs       | European Union Reference Laboratories for Pesticide Residues (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 |
| 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) |
| LOQ          | limit of quantification |
| Mo           | monitoring |
| MRL          | maximum residue level |
| MS           | Member States |
| NEDI         | national estimated daily intake |
| NESTI        | national estimated short-term intake |
| NEU          | northern European Union |
| NTMDI        | national theoretical maximum daily intake |
| 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 |
| 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 |
| SMILES       | simplified molecular-input line-entry system |
| SL           | soluble concentrate |
| STMR         | supervised trials median residue |
| TMDI         | theoretical maximum daily intake |
| TRR          | total radioactive residue |
| WG           | water-dispersible granule |
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 Y(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|--------------|-------------|-----------------------------------|-------------|------------|--------------------------------|---------------|---------|
|                       |              |             |                                   | Type(6)     | Conc. a.s. | Method kind                      | Range of growth stages & season(c) | Number min-max | Minimum interval (days) | a.s./hl-min max | Water L/ha-min max | Rate and unit | |
| Rapeseeds             | HU           | F           | Broadleaved weeds                 | SL          | 40 g/L     | Foliar treatment – spraying      | 12–31                      | 1              | n.a.                  | –              | –               | 12 g a.s/ha | n.a. – |
| Barley                | CZ, DK, EE, FI, HU, LT, NO, SE | F           | Broadleaved weeds                 | Foliar treatment – spraying           | 32         | 1              | n.a.                  | –              | –               | 10 g a.s/ha | n.a.             | Also reported as an SE (10 g/L) or a WG (300 g/kg) formulation. Application from BBCH 13–30 to BBCH 32 |
| Maize                 | HU, RO       | F           | Broadleaved weeds                 | SE          | 300 g/L    | Foliar treatment – spraying      | 12–16                      | 1              | n.a.                  | –              | –               | 10 g a.s/ha | n.a.             | Also reported as an SE formulation (11.8 g/L), with tractor mounted broadcast spray |
| Common millet         | HU, RO       | F           | Broadleaved weeds                 | SE          | 300 g/L    | Foliar treatment – spraying      | 12–16                      | 1              | n.a.                  | –              | –               | 10 g a.s/ha | n.a.             | Also reported as an SE formulation (11.8 g/L), with tractor mounted broadcast spray |
| Oat                   | DK, EE, FI, LT, SE | F           | Broadleaved weeds                 | Foliar treatment – spraying           | 32         | 1              | n.a.                  | –              | –               | 10 g a.s/ha | n.a.             | Registered as an SE (10 g/L) or a WG (300 g/kg) formulation. Application from BBCH 13–30 to BBCH 32 |
| Rye                   | CZ, DK, EE, HU, LT, NO, PL, SE | F           | Broadleaved weeds                 | Foliar treatment – spraying           | 32         | 1              | n.a.                  | –              | –               | 10 g a.s/ha | n.a.             | Registered as an SE (10 g/L) or a WG (50 or 300 g/kg) formulation. Application from BBCH 13–30 to BBCH 32 |
| Crop and/or situation | MS or country | F or G or I(a) | Pests or group of pests controlled | Preparation Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Minimum interval (days) | Application rate per treatment a.s./hL min-max | Water L/ha min-max | Rate and unit | PHI (days)(d) | Remarks |
|-----------------------|--------------|---------------|------------------------------------|---------------------|-----------|-------------|------------------------------------|---------------|------------------------|---------------------------------------------|------------------|-------------|-------------|---------|
| Sorghum HU, RO        | F            | Broadleaved weeds | SE 300 g/L Foliar treatment – spraying | 12–16               | 1          | n.a.        | – –                               | 10 g a.s./ha  | n.a.                   | Also reported as an SE formulation (11.8 g/L), with tractor mounted broadcast spray |
| Wheat CZ, DK, EE, FI, HU, LT, NO, PL, SE | F            | Broadleaved weeds | Foliar treatment – spraying | 32                   | 1          | n.a.        | – –                               | 10 g a.s./ha  | n.a.                   | Authorised also for triticale and spelt |
| Grass (for forage) AT, BE, IE, FR, DE, UK | F            | Broadleaved weeds | EW 30 g/L Foliar treatment – spraying | 29–32               | 1          | n.a.        | – –                               | 60 g a.s./ha  | 7                      | Registered as an ME formulation (30 g/L) in AT and DE, and as an SL formulation (30 g/L) in FR |

MS: Member State; a.s.: active substance; n.a: not applicable; MRL: maximum residue level; SL: soluble concentrate; SE: Suspo-emulsion; EW: Emulsion, oil in water; WG: water-dispersible granule; ME: Micro-emulsion.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
## A.2. Authorised outdoor uses in southern EU

| Crop and/or situation       | MS or country | FG or T | Pests or group of pests controlled | Preparation | Method | Application | Application rate per treatment | PHI (days) | Remarks                                                                 |
|-----------------------------|---------------|---------|------------------------------------|-------------|--------|-------------|-------------------------------|-------------|-------------------------------------------------------------------------|
| Rapeseeds                   | BG, FR        | F       | Broadleaved weeds                  | SL          | 40 g/L | Foliar treatment – spraying | 8 g a.s./ha                  | n.a.         | Registered in FR as an SC formulation (5,3 g/L): 1 × 7.95 g as/ha, BBCH 14-18, PHI n.a. |
| Barley                      | ES            | F       | Broadleaved weeds                  | WG          | 30% (w/w) | Foliar treatment – spraying | 11.8 g a.s./ha               | n.a.         |                                                                         |
| Maize                       | EL            | F       | Broadleaved weeds                  | WG          | 300 g/kg | Foliar treatment – spraying | 9.9 g a.s./ha                | n.a.         |                                                                         |
| Common millet               | BG, EL        | F       | Broadleaved weeds                  | SE          | 300 g/L | Foliar treatment – spraying | 10 g a.s./ha                 | n.a.         |                                                                         |
| Oat                         | BG, EL        | F       | Broadleaved weeds                  | SE          | 300 g/L | Foliar treatment – spraying | 10 g a.s./ha                 | n.a.         |                                                                         |
| Rye                         | BG, EL        | F       | Broadleaved weeds                  | SE          | 300 g/L | Foliar treatment – spraying | 10 g a.s./ha                 | n.a.         | Registered also as a WG formulation (50 g/kg) in FR (1 × 7.5 g a.s./ha, BBCH 21-32) |
| Sorghum                     | BG, EL        | F       | Broadleaved weeds                  | SE          | 300 g/L | Foliar treatment – spraying | 10 g a.s./ha                 | n.a.         |                                                                         |
| Wheat                       | ES            | F       | Broadleaved weeds                  | WG          | 30% (w/w) | Foliar treatment – spraying | 11.8 g a.s./ha               | n.a.         | Authorised also for triticale and spelt                                 |
| Crop and/or situation | MS or country | F G or I \(^{(a)}\) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) \(^{(d)}\) | Remarks |
|-----------------------|--------------|----------------|----------------------------------|-------------|----------------|-----------------------------|----------------|---------|
| Grass (for forage)    | FR           | F              | Broadleaved weeds                | SL          | 30 g/L | Foliar treatment – spraying | 29–32 | 1 | n.a. | – | – | 60 g a.s./ha | 7 | – |

MS: Member State; a.s.: active substance; n.a.: not applicable; SL: soluble concentrate; SC: suspension concentrate; SE: Suspo-emulsion; WG: water-dispersible granule.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Cereals/grass                     | Grass       | Foliar, 1 x 360 g a.s./ha | 0, 7, 14, 21 (fresh) 42 (fresh and hay) | Study on three varieties of grass, with 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring. Portions of the 42 DAT fresh samples were allowed to air dry for 2 days to provide hay samples (United Kingdom 2006; EFSA, 2013b) |
|                                  | Wheat       | Foliar, 1 x 40 g a.s./ha at BBCH 26-28 | 0, 14 (forage) 35 (hay) 86 (straw and grain) | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (United Kingdom 2006; EFSA, 2013b) |
|                                  | Rapeseed    | Foliar, 1 x 14 g a.s./ha at BBCH 51 | 0, 7, 14, 28 (immature) 62 (mature seeds and rest of the plant) | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (France, 2011; EFSA, 2012) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|----------|----------------|
| Root/tuber crops                     | Turnip      | Bare soil, 1 x 10 g a.s./ha | 90, 120 | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (United Kingdom 2006; EFSA, 2013b) |
|                                     | Turnip      | Bare soil, 1 x 63.9 g a.s./ha | 30, 120, 365 | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (United Kingdom, 2017; EFSA, 2019b) |
| Leafy crops                          | Lettuce     | Bare soil, 1 x 10 g a.s./ha | 90, 120 | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (United Kingdom 2006; EFSA, 2013b) |
|                                     | Lettuce     | Bare soil, 1 x 63.9 g a.s./ha | 30, 120, 180, 300, 365 | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring. Lettuces did not grow due to phytotoxic effects and was then replaced with mustard at PBIs 300 and 365 days (United Kingdom, 2017; EFSA, 2019b) |
|                                     | Green mustard | Bare soil, 1 x 63.9 g a.s./ha | 300, 365 | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (United Kingdom, 2017; EFSA, 2019b) |
| Cereal (small grain)                 | Sorghum     | Bare soil, 1 x 10 g a.s./ha | 90, 120 | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (United Kingdom 2006; EFSA, 2013b) |
|                                     | Wheat       | Bare soil, 1 x 63.9 g a.s./ha | 30, 120, 365 | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (United Kingdom, 2017; EFSA, 2019b) |
### Processed commodities (hydrolysis study)

| Conditions                          | Stable? | Comment/Source                                                                 |
|------------------------------------|---------|-------------------------------------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4) | Yes     | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (United Kingdom, 2017; EFSA, 2019b) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (United Kingdom, 2017; EFSA, 2019b) |
| Sterilisation (20 min, 120°C, pH 6)   | Yes     | 14C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring (United Kingdom, 2017; EFSA, 2019b) |

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**Can a general residue definition be proposed for primary crops?**

|                            | No                      | Metabolic pathway was investigated only in two groups: cereals/grass and oilseeds |
|---------------------------|-------------------------|----------------------------------------------------------------------------------|

**Rotational crop and primary crop metabolism similar?**

|                            | Yes | – |
|---------------------------|-----|---|

**Residue pattern in processed commodities similar to residue pattern in raw commodities?**

|                            | Yes | – |
|---------------------------|-----|---|

**Plant residue definition for monitoring (RD-Mo)**

|                            | Cereals/grass and oilseeds: sum of aminopyralid and its conjugates, expressed as aminopyralid |
|---------------------------|---------------------------------------------------------------------------------------------|

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

|                            | Cereals/grass and oilseeds: sum of aminopyralid and its conjugates, expressed as aminopyralid |
|---------------------------|---------------------------------------------------------------------------------------------|

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

|                            | High water content, high oil content, high acid content and dry matrices (United Kingdom, 2013; EFSA, 2013b): |
|---------------------------|---------------------------------------------------------------------------------------------------------------|
|                           | - HPLC–MS/MS, LOQ 0.01 mg/kg                                                                                 |
|                           |   Method validated for aminopyralid and its conjugates (measured as aminopyralid)                             |
|                           |   ILV available for high water content and dry matrices                                                       |
|                           | High water content, high oil content, high acid content, and dry matrices (EURLs, 2019):                 |
|                           | - QuEChERS (HPLC–MS/MS) for enforcement in routine analysis of free aminopyralid, LOQ 0.05 mg/kg |
|                           |   A modified QuEChERS method including an alkaline hydrolysis step to release conjugated residues of aminopyralid would be suitable to cover the proposed enforcement residue definition |

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*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.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|-----------------|------------------|----------------|
|                                   | High water content | Wheat forage, grass forage | −20°C | 16 Months | Aminopyralid and its conjugates | United Kingdom (2013), EFSA (2013b) |
|                                   | High oil content | Rapeseed | −20°C | 25 Months | Aminopyralid and its conjugates | Finland (2020) (study from the Registration Report assessed by Poland in 2016) |
|                                   | Dry/High starch content | Wheat grain, wheat hay | −20°C | 16 Months | Aminopyralid and its conjugates | United Kingdom (2013), EFSA (2013b) |
|                                   | Others | Wheat straw | −20°C | 16 Months | Aminopyralid and its conjugates | United Kingdom (2013), EFSA (2013b) |
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) | CF(d) |
|-----------|------------------|---------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|---------------|----------------|-------|
| Rapeseeds/canola seeds | NEU | 11 × < 0.01; 0.02 | 8 GAP-compliant trials and 4 overdosed trials deemed acceptable since residues from these trials < LOQ (EFSA, 2012) MRL\text{OECD} = 0.02 Demonstrated stability: Yes | 0.03 | 0.02 | 0.01 | 1.00 |
|                     | SEU | 6 × < 0.01; 4 × 0.01; 0.02 | Overdosed trials (performed at 1.4 to 1.6 N) deemed acceptable since calculated MRLs and risk assessment values are covered by the ones from the northern dataset (EFSA, 2012) MRL\text{OECD} = 0.02 Demonstrated stability: Yes | 0.03 | 0.02 | 0.01 | 1.00 |
| Barley grains | NEU | < 0.01; 0.02; 4 × 0.03; 2 × 0.04; 4 × 0.05; 0.06; 2 × 0.08 | Trials on barley compliant with the GAP. Northern and southern data were combined to derive MRLs and risk assessment values (United Kingdom, 2017; EFSA, 2019b) Extrapolation to oat and rye is acceptable MRL\text{OECD} = 0.14 Demonstrated stability: Yes | 0.15 | 0.09 | 0.04 | 1.00 |
| Oat grains       | NEU | < 0.01; 2 × 0.02; 0.03; 2 × 0.04; 2 × 0.06; 2 × 0.09 | Trials on barley compliant with the GAP. Northern and southern data were combined to derive MRLs and risk assessment values (United Kingdom, 2017; EFSA, 2019b) Extrapolation to oat and rye is acceptable MRL\text{OECD} = 0.14 Demonstrated stability: Yes | 0.15 | 0.09 | 0.04 | 1.00 |
| Rye grains       | SEU | < 0.01; 0.01; 0.04 | Trials on maize compliant with GAP. Northern and southern data were combined to derive MRLs and risk assessment values (EFSA, 2016; Hungary, 2016) Extrapolation to millet and sorghum is acceptable MRL\text{OECD} = 0.04 Demonstrated stability: Yes | 0.05(e) | 0.04 | 0.01 | 1.00 |
| Maize/corn grains | NEU | 10 × < 0.01; 0.01; 0.04 | | 0.05(e) | 0.04 | 0.01 | 1.00 |
| Common millet/proso millet grains | SEU | 8 × < 0.01 | | 0.05(e) | 0.04 | 0.01 | 1.00 |
| Maize/corn grains | SEU | 12 × < 0.01; 5 × 0.01; 4 × 0.02; 0.03; 0.04 | Trials on wheat compliant with GAP. Northern and southern data were combined to derive MRLs and risk assessment values (United Kingdom, 2017; EFSA, 2019b) MRL\text{OECD} = 0.04 Demonstrated stability: Yes | 0.04 | 0.04 | 0.01 | 1.00 |
| Wheat grains     | NEU | 7 × < 0.01; 5 × 0.01; 0.02 | | 0.04 | 0.04 | 0.01 | 1.00 |
| Commodity                | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|--------------------------|------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|---------------|-----------------|-------|
| Grass forage             | NEU: 0.78; 0.82; 0.98; 1.00; 2 × 1.03; 2 × 1.05; 1.09; 1.18; 1.19; 1.26; 1.35; 1.37; 1.76; 1.84; 1.87; 1.93; 2.79; 2.97 | Trials on grass (forage) compliant with GAP. Northern and southern data were combined to derive MRLs and risk assessment values (EFSA, 2013b; United Kingdom, 2013) | 6.00 | 4.26 | 1.19 | 1.00 |
| Barley straw             | NEU: 3 × 0.01; 4 × 0.02; 2 × 0.03; 2 × 0.04; 3 × 0.05; 0.06 | Trials on barley compliant with the GAP. Northern and southern data were combined to derive MRLs and risk assessment values (United Kingdom, 2017; EFSA, 2019b) | 0.15 | 0.13 | 0.04 | 1.00 |
| Maize/corn stover        | Common millet straw                                               | Trials on maize compliant with GAP. Northern and southern data were combined to derive MRL and risk assessment values (EFSA, 2016; Hungary, 2016) | 0.15 | 0.12 | 0.01 | 1.00 |
| Sorghum stover           | NEU: 7 × < 0.01; 2 × 0.01; 2 × 0.02; 0.12                        | Extrapolation to millet and sorghum is acceptable MRL(OECD) = 0.12 Demonstrated stability: Yes | 0.30 | 0.27 | 0.05 | 1.00 |
| Wheat straw              | Oat straw Rye straw                                               | Trials on wheat compliant with GAP. Northern and southern data were combined to derive MRLs and risk assessment values. Extrapolation to oat straw and rye straw is acceptable (considering that the wheat straw represents a more critical situation than barley) (United Kingdom, 2017; EFSA, 2019b) MRL(OECD) = 0.27 Demonstrated stability: Yes | 0.30 | 0.27 | 0.05 | 1.00 |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. (e): The calculated MRL would be 0.04 mg/kg, however, considering the highest residue of 0.04 mg/kg, an MRL of 0.05 mg/kg was proposed (EFSA, 2016).
B.1.2.2. Residues in rotational crops

Overall summary

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

In the first confined rotational crop study assessed during the peer review (performed at 10 g a.s./ha), low residues were detected in the sorghum forage samples and residues in crops for human consumption were all ≤ 0.01 mg/kg. However, this dose rate does not cover the most cGAP (60 g a.s./ha) assessed under the current review.

In the second study available performed at 63.4 a.s./ha (just above the most cGAP, and 6N the GAPs of cereals), residues above 0.01 mg/kg cannot be excluded.

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

No field study was available. As, from the available confined studies, the occurrence of residues in rotational crops cannot be fully excluded, EFSA recommends that Member States should consider the need of implementing mitigation measures (as defining plant-back restrictions) when granting authorisations for plant protection products containing aminopyralid. Alternatively, setting MRLs for rotational crops might be considered, but would require field trials covering the most critical GAP currently authorised.

cGAP: critical Good Agricultural Practice; GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing factor (PF) | Comment/Source |
|---------------------|---------------------------|------------------------|----------------|
|                     |                           | Individual values      | Median PF      |
|                     |                           | n.r.                   | 2.4(b)         | EFSA (2013b, 2019b) |
| Wheat, bran         | 1                         | 4; 4.6                 | 4.3(c)         | EFSA (2013b, 2019b) |
| Wheat, coarse bran  | 1                         | 1.1; 1.3               | 1.2(b)         | EFSA (2013b, 2019b) |
| Wheat, fine bran    | 1                         | 1; 1.2                 | 1.1(c)         | United Kingdom (2017); EFSA, 2019b |
| Wheat, flour        | 1                         | n.r.                   | 0.2(c)         | United Kingdom (2017); EFSA, 2019b |
| Wheat, wholemeal flour | 1                         | 0.8; 0.8               | 0.8(c)         | United Kingdom, 2017; EFSA, 2019b |
| Wheat, wholemeal bread | 1                         | 1.47                   | 1.47(c)        | United Kingdom, 2017; EFSA, 2019b |
| Barley, brewing malt | 1                         | 0.75                   | 0.75(c)        | United Kingdom, 2017; EFSA, 2019b |
| Barley, spent grain | 1                         | 0.31                   | 0.31(c)        | United Kingdom, 2017; EFSA, 2019b |
| Barley, brewer’s yeast | 1                         | 0.31                   | 0.31(c)        | United Kingdom, 2017; EFSA, 2019b |
| Barley, beer        | 1                         | 0.31                   | 0.31(c)        | United Kingdom, 2017; EFSA, 2019b |
PF: Processing factor (Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); n.r.: not reported.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): For wheat bran, EFSA calculated the median PF of 2.4 considering the 3 available individual processing values.
(c): A tentative PF is derived based on a limited dataset.

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup (a) | Most critical commodity (b) | Trigger exceeded (Yes/No) | Comments |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|--------------------------|----------|
|                             | mg/kg bw per day | mg/kg DM | Median | Maximum | Median | Maximum |                        |                        |                      |
| Cattle (all)                | 0.11 (0.39) | 2.89 (10.3) | Dairy cattle | Grass, forage (fresh) | Yes | – |
| Cattle (dairy only)         | 0.11 (0.39) | 2.89 (10.3) | Dairy cattle | Grass, forage (fresh) | Yes | – |
| Sheep (all)                 | 0.15 (0.54) | 4.53 (16.2) | Ram/Ewe | Grass, forage (fresh) | Yes | – |
| Sheep (ewe only)            | 0.15 (0.54) | 4.53 (16.2) | Ram/Ewe | Grass, forage (fresh) | Yes | – |
| Swine (all)                 | 0.02 (0.08) | 1.00 (3.45) | Swine (breeding) | Grass, silage | Yes | – |
| Poultry (all)               | 0.004 (0.006) | 0.06 (0.08) | Poultry layer | Wheat straw | No | – |
| Poultry (layer only)        | 0.004 (0.006) | 0.06 (0.08) | Poultry layer | Wheat straw | No | – |

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

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

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

| Livestock (available studies) | Animal       | Dose (mg/kg bw/day) | Duration (days) | Comment/Source |
|-------------------------------|--------------|---------------------|-----------------|---------------|
| Laying hen                    | 0.79         | 7                   | Study performed with $^{14}$C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring. Dose rate recalculated assuming body weight of 1.9 kg and feed intake of 0.13 kg per day (United Kingdom, 2006; EFSA, 2013b) |
| Lactating ruminants           | 0.50         | 6                   | Study performed on goats with $^{14}$C-aminopyralid labelled in the positions 2 and 6 of the pyridine ring. Dose rate recalculated assuming body weight of 70 kg and feed intake of 2 kg per day (United Kingdom, 2006; EFSA, 2013b) |
Time needed to reach a plateau concentration in milk and eggs (days)

|                | Milk: 1-2 days | Eggs: 5-7 days |
|----------------|----------------|----------------|
| Metabolism     |                |                |
| in rat and     | yes            |                |
| ruminant       |                |                |
| similar        | yes            |                |
|                |                |                |
| Can a general  | yes            |                |
| residue        |                |                |
| definition be  |                |                |
| proposed for   |                |                |
| animals?       |                |                |
| Animal residue | Aminopyralid.   |                |
| definition for |                |                |
| monitoring (RD-Mo) | Aminopyralid. |                |
| Animal residue |                |                |
| definition for |                |                |
| risk assessment (RD-RA) | Aminopyralid. |                |
| Fat soluble   |                |                |
| residues      |                |                |
| Methods of     |                |                |
| analysis for   |                |                |
| monitoring of  |                |                |
| residues       |                |                |
| (analytical    |                |                |
| technique,     |                |                |
| matrix groups, |                |                |
| LOQs)          |                |                |

**bw:** body weight; **Pow:** partition coefficient between n-octanol and water; **HPLC–MS/MS:** high-performance liquid chromatography with tandem mass spectrometry; **LOQ:** limit of quantification; **ILV:** independent laboratory validation.

### B.2.1.2. Stability of residues in livestock

No studies are available, however not needed, as all livestock samples were stored for less than 30 days.
## B.2.2. Magnitude of residues in livestock

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

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|--------------------------------------------|----------------------|
|                  | Mean | Highest | STMR<sub>Mo</sub><sup>(a)</sup> (mg/kg) | HR<sub>Mo</sub><sup>(b)</sup> (mg/kg) |             |
| Cattle (all)     |      |         |                                         |                      |             |
| Muscle           | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Fat              | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Liver            | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Kidney           | 0.07  | 0.10    | 0.01                                      | 0.03                 | 0.04        |
| Cattle (dairy only) |      |         |                                         |                      |             |
| Milk             | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Sheep (all)      |      |         |                                         |                      |             |
| Muscle           | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Fat              | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Liver            | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Kidney           | 0.07  | 0.10    | 0.01                                      | 0.04                 | 0.05        |
| Sheep (ewe only) |      |         |                                         |                      |             |
| Milk             | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Swine (all)      |      |         |                                         |                      |             |
| Muscle           | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Fat              | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Liver            | < 0.01 | < 0.01 | 0.01                                      | 0.01                 | 0.01*       |
| Kidney           | 0.07  | 0.10    | 0.01                                      | 0.01                 | 0.01*       |
| Poultry (all)    |      |         |                                         |                      |             |
| Muscle           | –     | –       | –                                         | –                    | –           |
| Fat              | –     | –       | –                                         | –                    | –           |
| Liver            | –     | –       | –                                         | –                    | –           |
| Poultry (layer only) |      |         |                                         |                      |             |
| Eggs             | –     | –       | –                                         | –                    | –           |

*: Indicates that the MRL is proposed at the limit of quantification.
(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.
(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): For milk, mean was derived from samplings performed from day 2 to day 28 (daily mean of 3 cows).
(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
### B.3. Consumer risk assessment

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

| ARfD | 0.26 mg/kg bw (EFSA, 2013b) |
|------|----------------------------|
| Highest IESTI, according to EFSA PRIMo (rev.3.1) | **Scenario EU:**
| Milk (cattle): 0.5% of ARfD |
| Rye: 0.1% of ARfD |
| Milk (goat)/barley: 0.09% of ARfD |
| NESTI (% ARfD) | Not assessed in this review |
| Assumptions made for the calculations |

**ADI:** acceptable daily intake; **bw:** body weight; **NESTI:** national estimated short-term intake; **PRIMo:** (EFSA) Pesticide Residues Intake Model; **ESTI:** international estimated short-term intake.

| ADI | 0.26 mg/kg bw per day (EFSA, 2013b) |
|-----|------------------------------------|
| 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) | **Scenario EU:**
| 0.3% ADI (NL toddler) |
| NEDI (% ADI) | Not assessed in this review |
| Assumptions made for the calculations |

**ADI:** acceptable daily intake; **bw:** body weight; **NEDI:** national estimated daily intake; **PRIMo:** (EFSA) Pesticide Residues Intake Model; **EDI:** international estimated daily intake.

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

| Metabolite(s) | Not assessed in this review |
|---------------|----------------------------|
| ADI (mg/kg bw per day) | Not assessed in this review |
| Intake of groundwater metabolites (% ADI) | Not assessed in this review |
### B.3.2. Consumer risk assessment with consideration of the existing CXLs

| ARfD | 0.26 mg/kg bw (EFSA, 2013b) |
|------|----------------------------|
| Highest IESTI, according to EFSA PRIMo (rev.3.1) | **Scenario CX:** Bovine kidney: 1% of ARfD Milk (cattle): 0.5% of ARfD Swine kidney: 0.4% of ARfD |
| Not assessed in this review | **Scenario CX:** The calculation is based on the median residue levels (STMR) derived for raw agricultural commodities according to the GAPs reported in this review. For wheat, having a CXL higher than the EU MRL proposal, the median residue level (STMR) derived by JMPR was considered |

| NESTI (% ARfD) | Assumptions made for the calculations |
|----------------|--------------------------------------|
| **Scenario CX:** | The calculation is based on the median residue levels (STMR) derived for raw agricultural commodities according to the GAPs reported in this review. For wheat, having a CXL higher than the EU MRL proposal, the median residue level (STMR) derived by JMPR was considered |

| ADI | 0.26 mg/kg bw per day (EFSA, 2013b) |
|-----|-----------------------------------|
| 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) | **Scenario CX:** 0.3% ADI (NL toddler) |
| NEDI (% ADI) | Not assessed in this review |

| **Scenario CX:** | The calculation is based on the median residue levels (STMR) derived for raw agricultural commodities according to the GAPs reported in this review. For wheat, having a CXL higher than the EU MRL proposal, the median residue level (STMR) derived by JMPR was considered. 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; IEDI: international estimated daily intake; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; GAP: Good Agricultural Practice; CXL: codex maximum residue limit.
### B.4. Proposed MRLs

| Code number | Commodity          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment                  |
|-------------|--------------------|-------------------------|----------------------|-----------------------|--------------------------|
| 401060      | Rapeseed           | 0.03                    | –                    | 0.03                  | Recommended<sup>(a)</sup> |
| 500010      | Barley grain       | 0.15                    | 0.1                  | 0.15                  | Recommended<sup>(b)</sup> |
| 500030      | Maize grain        | 0.05                    | –                    | 0.05                  | Recommended<sup>(a)</sup> |
| 500040      | Millet grain       | 0.05                    | –                    | 0.05                  | Recommended<sup>(a)</sup> |
| 500050      | Oats grain         | 0.15                    | 0.1                  | 0.15                  | Recommended<sup>(b)</sup> |
| 500070      | Rye grain          | 0.15                    | –                    | 0.15                  | Recommended<sup>(a)</sup> |
| 500080      | Sorghum grain      | 0.05                    | –                    | 0.05                  | Recommended<sup>(a)</sup> |
| 500090      | Wheat grain        | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(c)</sup> |

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

**Enforcement residue definition (proposed):** sum of aminopyralid and its conjugates, expressed as aminopyralid

| Code number | Commodity          | Enforcement residue definition 2: aminopyralid |
|-------------|--------------------|-----------------------------------------------|
| 1011010     | Swine meat         | 0.01*                                         |
| 1011020     | Swine fat (free of lean meat) | 0.02                                         |
| 1011030     | Swine liver        | 0.02                                          |
| 1011040     | Swine kidney       | 0.3                                           |
| 1012010     | Bovine meat        | 0.1                                           |
| 1012020     | Bovine fat         | 0.1                                           |
| 1012030     | Bovine liver       | 0.05                                          |
| 1012040     | Bovine kidney      | 1                                             |
| 1013010     | Sheep meat         | 0.1                                           |
| 1013020     | Sheep fat          | 0.1                                           |
| 1013030     | Sheep liver        | 0.05                                          |
| 1013040     | Sheep kidney       | 1                                             |
| 1014010     | Goat meat          | 0.1                                           |
| 1014020     | Goat fat           | 0.1                                           |
| 1014030     | Goat liver         | 0.05                                          |
| 1014040     | Goat kidney        | 1                                             |
| 1015010     | Horse meat         | 0.1                                           |
| 1015020     | Horse fat          | 0.1                                           |
| 1015030     | Horse liver        | 0.05                                          |
| 1015040     | Horse kidney       | 1                                             |
| 1016010     | Poultry meat       | 0.01*                                         |
| 1016020     | Poultry fat        | 0.02                                          |
| 1016030     | Poultry liver      | 0.02                                          |
| 1020010     | Cattle milk        | 0.02                                          |
| 1020020     | Sheep milk         | 0.02                                          |
| 1020030     | Goat milk          | 0.02                                          |
| 1020040     | Horse milk         | 0.02                                          |
| 1030000     | Birds’ eggs        | 0.01*                                         |

**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).

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(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; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).

(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-VII in Appendix E).

(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).

(e): 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).
## Aminopyralid

### Toxicological reference values

| LOQ (mg/kg) | EU (mg/kg) | Year of evaluation |
|-------------|------------|-------------------|
| 0.01        | 0.01       | 2013              |

#### Source of ADI
EFSA

#### Source of ARfD
EFSA

### PRIMo(EU)

#### LOQs (mg/kg)
- Range from 0.01 to 0.01

#### ADI (mg/kg bw per day)
- 0.26

#### ARfD (mg/kg bw)
- 0.26

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

### No of diets exceeding the ADI
---

### Calculated exposure (% of ADI)

#### MS Diet

| Commodity/group of commodities | Highest contributor to MS diet (% of ADI) | 2nd contributor to MS diet (% of ADI) | 3rd contributor to MS diet (% of ADI) |
|-------------------------------|------------------------------------------|---------------------------------------|---------------------------------------|
| Wheat                         | 0.3%                                     | 0.77                                  | 0.2%                                  |
| Bovine: Muscle/meat           | 0.2%                                     | 1.0%                                  |                                        |
| Wheat                         | 0.2%                                     | 0.0%                                  |                                        |
| Bovine: Muscle/meat           | 0.2%                                     | 0.0%                                  |                                        |
| Swine: Muscle/meat            | 0.1%                                     | 0.4%                                  |                                        |
| Rye                           | 0.0%                                     | 0.0%                                  |                                        |
| Bovine: Muscle/meat           | 0.1%                                     | 0.0%                                  |                                        |
| Swine: Muscle/meat            | 0.0%                                     | 0.0%                                  |                                        |
| Rye                           | 0.0%                                     | 0.0%                                  |                                        |

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

### Conclusion
The estimated long-term intake of Aminopyralid is unlikely to present a public health concern.

### Details – chronic risk assessment
- Chronic risk assessment: JMPR methodology (IEDI/TMDI)
- The chronic risk assessment was performed using the JMPR methodology (IEDI/TMDI).

### Details – acute risk assessment/children
- The acute risk assessment was performed using the JMPR methodology (IEDI/TMDI).

### Details – acute risk assessment/adults
- The acute risk assessment was performed using the JMPR methodology (IEDI/TMDI).

### Supplementary results – chronic risk assessment
- The supplementary results of the chronic risk assessment are available on the EFSA website.

### Input values
- Toxicological reference values
- Exposure resulting from consumption

### Normal mode
- The Normal mode of the PRIMo model uses default input values.

### Supplementary results – acute risk assessment/adults
- The supplementary results of the acute risk assessment for adults are available on the EFSA website.

### Supplementary results – acute risk assessment/children
- The supplementary results of the acute risk assessment for children are available on the EFSA website.

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

### Acute risk assessment/children

### Acute risk assessment/adults/general population

**Details – acute risk assessment/children**

**Details – acute risk assessment/adults**

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

### Show results for all crops

#### Unprocessed commodities

| Highest % of ARID/ADI | Commodities                          | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARID/ADI | Commodities                          | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|----------------------|--------------------------------------|---------------------------|---------------------|----------------------|--------------------------------------|---------------------------|---------------------|
| 0.5%                 | Milk: Cattle                         | 0.01/0.01                 | 0.01                 | 0.1%                 | Milk: Cattle                         | 0.01/0.01                 | 0.01                |
| 0.1%                 | Rye                                  | 0.15/0.04                 | 0.15                 | 0.07%                | Rye                                  | 0.15/0.04                 | 0.15                |
| 0.09%                | Milk: Goat                           | 0.01/0.01                 | 0.01                 | 0.07%                | Milk: Goat                           | 0.01/0.01                 | 0.01                |
| 0.06%                | Barley                               | 0.15/0.04                 | 0.15                 | 0.07%                | Barley                               | 0.15/0.04                 | 0.15                |
| 0.05%                | Wheat                                | 0.04/0.01                 | 0.04                 | 0.07%                | Wheat                                | 0.04/0.01                 | 0.04                |
| 0.05%                | Swine: Muscle/meat                   | 0.01/0.01                 | 0.01                 | 0.07%                | Swine: Muscle/meat                   | 0.01/0.01                 | 0.01                |
| 0.05%                | Bovine: Kidney                       | 0.04/0.03                 | 0.04                 | 0.07%                | Bovine: Kidney                       | 0.04/0.03                 | 0.04                |
| 0.03%                | Bovine: Liver                        | 0.01/0.01                 | 0.01                 | 0.07%                | Bovine: Liver                        | 0.01/0.01                 | 0.01                |
| 0.03%                | Bovine: Muscle/meat                  | 0.01/0.01                 | 0.01                 | 0.07%                | Bovine: Muscle/meat                  | 0.01/0.01                 | 0.01                |
| 0.03%                | Mazza/corn                           | 0.05/0.01                 | 0.05                 | 0.07%                | Mazza/corn                           | 0.05/0.01                 | 0.05                |
| 0.02%                | Equine: Muscle/meat                  | 0.01/0.01                 | 0.01                 | 0.07%                | Equine: Muscle/meat                  | 0.01/0.01                 | 0.01                |
| 0.02%                | Sheep: Muscle/meat                   | 0.01/0.01                 | 0.01                 | 0.07%                | Sheep: Muscle/meat                   | 0.01/0.01                 | 0.01                |
| 0.02%                | Oat                                  | 0.15/0.04                 | 0.15                 | 0.07%                | Oat                                  | 0.15/0.04                 | 0.15                |
| 0.01%                | Milk: Sheep                          | 0.01/0.01                 | 0.01                 | 0.07%                | Milk: Sheep                          | 0.01/0.01                 | 0.01                |
| 0.01%                | Sorghum                              | 0.05/0.01                 | 0.05                 | 0.07%                | Sorghum                              | 0.05/0.01                 | 0.05                |

#### Processed commodities

| Highest % of ARID/ADI | Processed commodities       | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARID/ADI | Processed commodities       | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|----------------------|----------------------------|---------------------------|---------------------|----------------------|----------------------------|---------------------------|---------------------|
| 0.1%                 | Maize/oil                  | 0.05/0.25                 | 0.05                 | 0.2%                 | Barley/beer                | 0.15/0.01                 | 0.15                |
| 0.1%                 | Rye boiled                 | 0.15/0.04                 | 0.15                 | 0.05%                | Maize/oil                  | 0.05/0.25                 | 0.05                |
| 0.1%                 | Oat boiled                 | 0.15/0.04                 | 0.15                 | 0.05%                | Oat boiled                 | 0.15/0.04                 | 0.15                |
| 0.1%                 | barley cooked              | 0.15/0.04                 | 0.15                 | 0.05%                | barley boiled              | 0.15/0.04                 | 0.15                |
| 0.1%                 | Rye milling (wholesale)    | 0.15/0.04                 | 0.15                 | 0.05%                | Rye milling (wholesale)    | 0.15/0.04                 | 0.15                |
| 0.0%                 | Oat milling (flakes)       | 0.15/0.04                 | 0.15                 | 0.05%                | Oat milling (flakes)       | 0.15/0.04                 | 0.15                |
| 0.0%                 | barley milling (flour)     | 0.15/0.04                 | 0.15                 | 0.05%                | barley milling (flour)     | 0.15/0.04                 | 0.15                |
| 0.0%                 | Wheat milling              | 0.04/0.01                 | 0.04                 | 0.05%                | Wheat milling              | 0.04/0.01                 | 0.04                |
| 0.0%                 | Milled/bread               | 0.04/0.01                 | 0.04                 | 0.05%                | Milled/bread               | 0.04/0.01                 | 0.04                |
| 0.0%                 | Wheat milling (flour)      | 0.04/0.01                 | 0.04                 | 0.05%                | Wheat milling (flour)      | 0.04/0.01                 | 0.04                |
| 0.0%                 | Milled/bread (flakes)      | 0.04/0.01                 | 0.04                 | 0.05%                | Milled/bread (flakes)      | 0.04/0.01                 | 0.04                |
| #NUM!                | #NUM!                      | #NUM!                     | #NUM!               | #NUM!                | #NUM!                      | #NUM!                     | #NUM!               |

### Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short-term intake of residues of Aminopyralid is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARID/ADI was identified.

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**No exceedance of the toxicological reference value was identified for any unprocessed commodity.**

**A short-term intake of residues of Aminopyralid is unlikely to present a public health risk.**

**For processed commodities, no exceedance of the ARID/ADI was identified.**
### Aminopyralid

**Toxicological reference values**

| Value          | Source   | Year of evaluation | Year of evaluation |
|----------------|----------|--------------------|--------------------|
| ADI (mg/kg bw per day) | EFSA     | 2013               | 2013               |
| ARfD (mg/kg bw)    | EFSA     |                    |                    |

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

**MRLs set at the LOQ (in % of ADI)**

| Commodity/group of commodities | Exposure resulting from the ADI (in % of ADI) | Commodity/group of commodities |
|--------------------------------|---------------------------------------------|--------------------------------|
| Wheat                          | 0.2%                                        | Eggs: Chicken                  |
| Wheat                          | 0.2%                                        | Bovine: Muscle/meat            |
| Wheat                          | 0.1%                                        | Swine: Muscle/meat             |
| Wheat                          | 0.1%                                        | Bovine: Muscle/meat            |
| Wheat                          | 0.1%                                        | Rye                            |
| Wheat                          | 0.1%                                        | Bovine: Muscle/meat            |
| Wheat                          | 0.1%                                        | Wheat                          |
| Wheat                          | 0.1%                                        | Barley                         |
| Wheat                          | 0.1%                                        | Swine: Muscle/meat             |
| Wheat                          | 0.1%                                        | Barley                         |
| Wheat                          | 0.1%                                        | Barley                         |
| Wheat                          | 0.1%                                        | Barley                         |
| Wheat                          | 0.1%                                        | Maize/corn                     |
| Wheat                          | 0.0%                                        | Barley                         |
| Wheat                          | 0.0%                                        | Wheat                          |
| Wheat                          | 0.0%                                        | Oat                            |
| Wheat                          | 0.0%                                        | Swine: Muscle/meat             |
| Wheat                          | 0.0%                                        | Maize/corn                     |
| Wheat                          | 0.0%                                        | Wheat                          |
| Wheat                          | 0.0%                                        | Maize/corn                     |
| Wheat                          | 0.0%                                        | Wheat                          |
| Wheat                          | 0.0%                                        | Maize/corn                     |
| Wheat                          | 0.0%                                        | Wheat                          |
| Wheat                          | 0.0%                                        | Maize/corn                     |
| Wheat                          | 0.0%                                        | Wheat                          |
| Wheat                          | 0.0%                                        | Maize/corn                     |
| Wheat                          | 0.0%                                        | Wheat                          |
| Wheat                          | 0.0%                                        | Maize/corn                     |
| Wheat                          | 0.0%                                        | Wheat                          |

**Comments:**

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

**Conclusion:**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Aminopyralid is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Unprocessed commodities

| % | Commodity      | MRL/input (mg/kg) | Exposure (µg/kg bw) | % | Commodity      | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|---|----------------|-------------------|--------------------|---|----------------|-------------------|--------------------|
| 1% | Bovine: Kidney | 1/0.87            | 3.3                | 0.7% | Swine: Kidney | 1/0.87            | 1.9                |
| 0.5% | Milk: Cattle | 0.02/0.01         | 1.2                | 0.7% | Bovine: Kidney | 1/0.87            | 1.8                |
| 0.4% | Swine: Kidney | 1/0.87            | 1.1                | 0.1% | Milk: Cattle | 0.02/0.01         | 0.39               |
| 0.1% | Swine: Muscle/meat | 0.1/0.03 | 0.31               | 0.07% | Rye          | 0.15/0.04         | 0.19               |
| 0.10% | Rye | 0.15/0.04         | 0.25               | 0.07% | Barley        | 0.15/0.04         | 0.19               |
| 0.10% | Bovine: Liver | 0.05/0.03         | 0.25               | 0.07% | Milk: Goat   | 0.02/0.01         | 0.18               |
| 0.09% | Milk: Goat | 0.02/0.01         | 0.24               | 0.06% | Milk: Sheep  | 0.02/0.01         | 0.15               |
| 0.09% | Barley | 0.15/0.04         | 0.22               | 0.06% | Bovine: Muscle | 0.10/0.03         | 0.15               |
| 0.07% | Bovine: Muscle/meat | 0.1/0.03 | 0.19               | 0.05% | Swine: Muscle/meat | 0.10/0.03 | 0.13               |
| 0.07% | Poultry: Muscle/meat | 0.01/0.01 | 0.17               | 0.05% | Equine: Muscle/meat | 0.10/0.03 | 0.12               |
| 0.06% | Equine: Muscle/meat | 0.1/0.03         | 0.16               | 0.05% | Bovine: Liver | 0.05/0.03         | 0.12               |
| 0.05% | Wheat | 0.1/0.01         | 0.14               | 0.05% | Sheep: Muscle/meat | 0.10/0.03         | 0.12               |
| 0.05% | Sheep: Muscle/meat | 0.1/0.03         | 0.14               | 0.05% | Poultry: Muscle | 0.01/0.01         | 0.12               |
| 0.05% | Eggs: Chicken | 0.01/0.01         | 0.12               | 0.04% | Swine: Fat tissue | 0.1/0.05         | 0.11               |
| 0.04% | Bovine: Fat tissue | 0.1/0.05         | 0.11               | 0.03% | Swine: Kidney | 1/0.87            | 0.09               |

Expand/collapse list

### Processed commodities

| % | Processed commodities | MRL/input (mg/kg) | Exposure (µg/kg bw) | % | Processed commodities | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|---|----------------------|-------------------|--------------------|---|----------------------|-------------------|--------------------|
| 0.1% | Maize/oil | 0.05/0.25         | 0.23               | 0.2% | Barley/beer | 0.15/0.01         | 0.45               |
| 0.1% | Rye/boiled | 0.15/0.04         | 0.15               | 0.05% | Maize/oil | 0.05/0.25         | 0.13               |
| 0.1% | Oat/boiled | 0.15/0.04         | 0.15               | 0.02% | Oat/boiled | 0.15/0.04         | 0.06               |
| 0.1% | Barley/cooked | 0.15/0.04         | 0.15               | 0.02% | Wheat/brad/pizza | 0.1/0.01         | 0.04               |
| 0.1% | Rye/boiled (wholemeal)-bak | 0.15/0.04 | 0.14               | 0.01% | Wheat/pasta | 0.1/0.01         | 0.04               |
| 0.0% | Oat/milling (flakes) | 0.15/0.04         | 0.12               | 0.01% | Wheat/brad (wholemeal) | 0.1/0.01 | 0.03               |
| 0.0% | Barley/milling (flour) | 0.15/0.04         | 0.07               | 0.01% | Millet/boiled | 0.05/0.0           | 0.02               |
| 0.0% | Wheat/milling | 0.1/0.01         | 0.06               | #NUM! | #NUM! | #NUM! | #NUM! |
| 0.0% | Oat/boiled | 0.05/0.0          | 0.05               | #NUM! | #NUM! | #NUM! | #NUM! |
| 0.0% | Wheat/milling (flour) | 0.1/0.02         | 0.02               | #NUM! | #NUM! | #NUM! | #NUM! |
| 0.0% | Maize/processed (not specif | 0.05/0.02         | 0.02               | #NUM! | #NUM! | #NUM! | #NUM! |
| 0.0% | Rapeseeds/olds | 0.03/0.02         | 0.01               | #NUM! | #NUM! | #NUM! | #NUM! |

Expand/collapse list

### Conclusion:

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

D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
|                                 | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment |
| Barley straw                    | 0.04 STMR            | 0.13 HR                |                       |         |
| Corn, field stover (fodder)     | 0.01* STMR           | 0.12 HR                |                       |         |
| Corn, pop stover (fodder)       | 0.01* STMR           | 0.12 HR                |                       |         |
| Grass forage (fresh)            | 1.19 STMR            | 4.26 HR                |                       |         |
| Grass hay                       | 4.17 STMR × default PF (3.5)(a) | 14.91 HR × default PF (3.5)(a) |                       |         |
| Grass silage                    | 1.9 STMR × default PF (1.6)(a) | 6.82 HR × default PF (1.6)(a) |                       |         |
| Millet straw (fodder, dry)      | 0.01* STMR           | 0.12 HR                |                       |         |
| Oat straw                       | 0.05 STMR            | 0.27 HR                |                       |         |
| Rye straw                       | 0.05 STMR            | 0.27 HR                |                       |         |
| Sorghum, grain stover           | 0.01* STMR           | 0.12 HR                |                       |         |
| Triticale straw                 | 0.05 STMR            | 0.27 HR                |                       |         |
| Wheat straw                     | 0.05 STMR            | 0.27 HR                |                       |         |
| Barley grain                    | 0.04 STMR            | 0.04 STMR              |                       |         |
| Corn, field (Maize) grain       | 0.01* STMR           | 0.01* STMR             |                       |         |
| Corn, pop grain                 | 0.01* STMR           | 0.01* STMR             |                       |         |
| Millet grain                    | 0.01* STMR           | 0.01* STMR             |                       |         |
| Oat grain                       | 0.04 STMR            | 0.04 STMR              |                       |         |
| Rye grain                       | 0.04 STMR            | 0.04 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             |                       |         |
| Brewer’s grain dried            | 0.13 STMR × default PF (3.3)(a) | 0.13 STMR × default PF (3.3)(a) |                       |         |
| Canola (Rapeseed) meal          | 0.02 STMR × default PF (2)(a) | 0.02 STMR × default PF (2)(a) |                       |         |
| Corn, field milled by-pdts      | 0.01* STMR           | 0.01* STMR             |                       |         |
| Corn, field hominy meal         | 0.06 STMR × default PF (6)(a) | 0.06 STMR × default PF (6)(a) |                       |         |
| Corn, field gluten feed         | 0.03 STMR × default PF (2.5)(a) | 0.03 STMR × default PF (2.5)(a) |                       |         |
| Corn, field gluten, meal        | 0.01* STMR           | 0.01* STMR             |                       |         |
| Distiller’s grain dried         | 0.03 STMR × default PF (3.3)(a) | 0.03 STMR × default PF (3.3)(a) |                       |         |
| Rape meal                       | 0.02 STMR × default PF (2)(a) | 0.02 STMR × default PF (2)(a) |                       |         |
| Wheat gluten meal               | 0.02 STMR × default PF (1.8)(a) | 0.02 STMR × default PF (1.8)(a) |                       |         |
| Wheat milled by-pdts            | 0.02 STMR × PF (2.4) | 0.02 STMR × PF (2.4)   |                       |         |

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

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

(a): In the absence of processing factors supported by data, a default processing factor was included in the calculation to consider the potential concentration of residues in these commodities.
### D.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| **Risk assessment residue definition 1:** sum of aminopyralid and its conjugates, expressed as aminopyralid | | | |
| Rapeseeds/canola seeds     | 0.01* STMR              |                       | 0.01* STMR          |         |
| Barley                     | 0.04 STMR               |                       | 0.04 STMR           |         |
| Maize/corn                 | 0.01* STMR              |                       | 0.01* STMR          |         |
| Common millet/proso millet | 0.01* STMR              |                       | 0.01* STMR          |         |
| Oat                        | 0.04 STMR               |                       | 0.04 STMR           |         |
| Rye                        | 0.04 STMR               |                       | 0.04 STMR           |         |
| Sorghum                    | 0.01* STMR              |                       | 0.01* STMR          |         |
| Wheat                      | 0.01* STMR              |                       | 0.01* STMR          |         |
| **Risk assessment residue definition 2:** aminopyralid | | | |
| Swine: Muscle/meat         | 0.01* STMR              |                       | 0.01* HR            |         |
| Swine: Fat tissue          | 0.01* STMR              |                       | 0.01* HR            |         |
| Swine: Liver               | 0.01* STMR              |                       | 0.01* HR            |         |
| Swine: Kidney              | 0.01* STMR              |                       | 0.01* HR            |         |
| Bovine: Muscle/meat        | 0.01* STMR              |                       | 0.01* HR            |         |
| Bovine: Fat tissue         | 0.01* STMR              |                       | 0.01* HR            |         |
| Bovine: Liver              | 0.01* STMR              |                       | 0.01* HR            |         |
| Bovine: Kidney             | 0.01* STMR              |                       | 0.03 HR             |         |
| Sheep: Muscle/meat         | 0.01* STMR              |                       | 0.01* HR            |         |
| Sheep: Fat tissue          | 0.01* STMR              |                       | 0.01* HR            |         |
| Sheep: Liver               | 0.01* STMR              |                       | 0.01* HR            |         |
| Sheep: Kidney              | 0.01* STMR              |                       | 0.04 HR             |         |
| Goat: Muscle/meat          | 0.01* STMR              |                       | 0.01* HR            |         |
| Goat: Fat tissue           | 0.01* STMR              |                       | 0.01* HR            |         |
| Goat: Liver                | 0.01* STMR              |                       | 0.01* HR            |         |
| Goat: Kidney               | 0.01* STMR              |                       | 0.04 HR             |         |
| Equine: Muscle/meat        | 0.01* STMR              |                       | 0.01* HR            |         |
| Equine: Fat tissue         | 0.01* STMR              |                       | 0.01* HR            |         |
| Equine: Liver              | 0.01* STMR              |                       | 0.01* HR            |         |
| Equine: Kidney             | 0.01* STMR              |                       | 0.03 HR             |         |
| Milk: Cattle               | 0.01* STMR              |                       | 0.01* STMR          |         |
| Milk: Sheep                | 0.01* STMR              |                       | 0.01* STMR          |         |
| Milk: Goat                 | 0.01* STMR              |                       | 0.01* STMR          |         |
| Milk: Horse                | 0.01* STMR              |                       | 0.01* STMR          |         |

STMR: supervised trials median residue; HR: highest residue.  
*: Indicates that the input value is proposed at the limit of quantification.
D.3. Consumer risk assessment with consideration of the existing CXLs

| Commodity               | Chronic risk assessment | Acute risk assessment |
|-------------------------|-------------------------|-----------------------|
|                         | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Rapeseeds/canola seeds  | 0.01* STMR              | 0.01* STMR            |                      |                      |
| Barley                  | 0.04 STMR               | 0.04 STMR             |                      |                      |
| Maize/corn              | 0.01* STMR              | 0.01* STMR            |                      |                      |
| Common millet/proso millet | 0.01* STMR        | 0.01* STMR            |                      |                      |
| Oat                     | 0.04 STMR               | 0.04 STMR             |                      |                      |
| Rye                     | 0.04 STMR               | 0.04 STMR             |                      |                      |
| Sorghum                 | 0.01* STMR              | 0.01* STMR            |                      |                      |
| Wheat                   | 0.01* STMR (CXL)        | 0.01* STMR (CXL)      |                      |                      |

**Risk assessment residue definition 1:** sum of aminopyralid and its conjugates, expressed as aminopyralid

**Risk assessment residue definition 2:** aminopyralid

Swine: Meat 0.01* STMR (CXL) 0.03 HR (CXL)
Swine: Fat tissue 0.01* STMR (CXL) 0.05 HR (CXL)
Swine: Liver 0.01* STMR (CXL) 0.03 HR (CXL)
Swine: Kidney 0.1 STMR (CXL) 0.87 HR (CXL)
Bovine: Meat 0.01* STMR (CXL) 0.03 HR (CXL)
Bovine: Fat tissue 0.01* STMR (CXL) 0.05 HR (CXL)
Bovine: Liver 0.01* STMR (CXL) 0.03 HR (CXL)
Bovine: Kidney 0.1 STMR (CXL) 0.87 HR (CXL)
Sheep: Meat 0.01* STMR (CXL) 0.03 HR (CXL)
Sheep: Fat tissue 0.01* STMR (CXL) 0.05 HR (CXL)
Sheep: Liver 0.01* STMR (CXL) 0.03 HR (CXL)
Sheep: Kidney 0.1 STMR (CXL) 0.87 HR (CXL)
Goat: Meat 0.01* STMR (CXL) 0.03 HR (CXL)
Goat: Fat tissue 0.01* STMR (CXL) 0.05 HR (CXL)
Goat: Liver 0.01* STMR (CXL) 0.03 HR (CXL)
Goat: Kidney 0.1 STMR (CXL) 0.87 HR (CXL)
Equine: Meat 0.01* STMR (CXL) 0.03 HR (CXL)
Equine: Fat tissue 0.01* STMR (CXL) 0.05 HR (CXL)
Equine: Liver 0.01* STMR (CXL) 0.03 HR (CXL)
Equine: Kidney 0.1 STMR (CXL) 0.87 HR (CXL)
Poultry: Meat 0.01* STMR (CXL) 0.01* HR (CXL)
Poultry: Fat 0.01* STMR (CXL) 0.01* HR (CXL)
Poultry: Liver 0.01* STMR (CXL) 0.01* HR (CXL)
Milk: Cattle 0.01* STMR (CXL) 0.01* HR (CXL)
Milk: Sheep 0.01* STMR (CXL) 0.01* HR (CXL)
Milk: Goat 0.01* STMR (CXL) 0.01* HR (CXL)
Milk: Horse 0.01* STMR (CXL) 0.01* HR (CXL)
Eggs: Chicken 0.01* STMR (CXL) 0.01* HR (CXL)

STMR: supervised trials median residue; HR: highest residue; CXL: Codex maximum residue limits.
* indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations
Comparison of the EU recommendation with the existing CXL

1. CXL available?
   - Yes
   - RD comparable?
     - Yes
     - CXL higher?
       - Yes
       - Codex median/highest residues are included in the RA.
       - Risk identified?
         - Yes
         - CXL is included in the RA.
         - Input values for the RA remain unchanged.
         - Yes
         - No
     - No
   - No

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

Recommendations with consideration of the existing CXL

- (I) Maintain EU recommendation indicating that no CXL is available.
- (II) Maintain EU recommendation indicating CXL is not compatible.
- (III) Maintain EU recommendation indicating that CXL is covered.
- (IV) Maintain current CXL or EU recommendation?
  - No
  - CXL higher?
    - Yes
    - CXL is included in the RA.
    - Input values for the RA remain unchanged.
    - Yes
    - No
  - No
  - Risk identified?
    - Yes
    - CXL is included in the RA.
    - Input values for the RA remain unchanged.
    - Yes
    - No
  - No
- (V) Maintain EU recommendation; higher CXL is not safe for consumer.
- (VI) Maintain EU recommendation; higher CXL is not safe for consumer.
- (VII) CXL is recommended; EU recommendation is covered as well.
## Appendix F – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-----------------------------------------------|----------------------------------|
| Aminopyralid                    | 4-amino-3,6-dichloropyridine-2-carboxylic acid or 4-amino-3,6-dichloropicolinic acid NIXXQNOQHKNPEJ-UHFFFAOYSA-N | ![Aminopyralid Structure](image) |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 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).