Modification of the existing maximum residue levels for aminopyralid in certain cereals

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Dow AgroSciences Denmark submitted a request to the competent national authority in the United Kingdom to modify the existing maximum residue levels (MRLs) for the active substance aminopyralid in cereals. The data submitted in support of the request were found to be sufficient to derive MRL proposals for barley, rye, sorghum, millet and oats. A modification of the existing MRL of aminopyralid in wheat has been considered unnecessary. Adequate analytical methods for enforcement are available to control the residues of aminopyralid and its conjugates in plant matrices and on the commodities under assessment at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of aminopyralid according to the intended agricultural practices is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Dow AgroSciences Denmark submitted an application to the competent national authority in the United Kingdom (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance aminopyralid in certain cereals: barley, oats, rye, wheat, millet and sorghum. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 1 June 2018. To accommodate for the intended uses of aminopyralid, the EMS proposed to raise the existing MRLs for barley, oat, rye and wheat (including triticale and spelt) from 0.1 to 0.15 mg/kg; and for millet and sorghum, from the limit of quantification (LOQ) of 0.01 to 0.05 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

The metabolism of aminopyralid in primary crops was investigated following a foliar application on cereals/grass crop group (wheat, grass). Additionally, studies investigating the effect of processing on the nature of aminopyralid (hydrolysis studies) demonstrated that the active substance is stable under standard hydrolysis conditions. In rotational crops, the major residue identified was the parent compound.

Based on the metabolic pattern identified in metabolism studies and the standard hydrolysis studies, the peer review derived residue definitions for monitoring and risk assessment, i.e. ‘sum of aminopyralid and its conjugates expressed as aminopyralid’; these residue definitions are considered valid in the framework of the current MRL application and are applicable to primary crops, rotational crops and processed products. It is noted that current residue definition reported in Regulation (EC) No 396/2005 does not include the conjugates and is limited to aminopyralid only. It is, however, expected that the residue definition will be reconsidered in the upcoming review of the existing MRLs, taking into account the recommended residue definition derived in the peer review.

The available residue trials are sufficient to derive MRL proposals of 0.15 mg/kg for barley, oat and rye and of 0.05 mg/kg for millet and sorghum. The MRL proposals were derived based on the extended residue definition including also aminopyralid conjugates, thus are likely to be higher than required for the current residue definition established in Regulation (EC) No 396/2005.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition, including the conjugates. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

A limited number of processing studies are available which allow deriving indicative processing factors (PF) for different processed products derived from barley and wheat. The processing factor of 2.4 for wheat bran, which is based on a sufficient number of studies, is recommended to be included in Annex VI of Regulation (EC) No 396/2005.

The occurrence of aminopyralid residues in rotational crops was investigated in the framework of the European Union (EU) pesticides peer-review and further information has been made available in the current MRL application. Based on the available information, EFSA could not exclude that the use of aminopyralid according to the proposed good agricultural practice (GAP) will result in quantifiable residues in rotational corps. Therefore, Member States should consider the need to set specific risk mitigation measures to avoid the presence of aminopyralid residues in rotational crops.

As the crops under consideration and their by-products are used as feed products, a potential carry-over into food of animal origin was assessed. However, since the contribution of aminopyralid residues in the crops under consideration in this MRL application to the total livestock exposure did not have a significant impact on the overall dietary burden for livestock, a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

For performing the consumer risk assessment, the estimated consumers exposures were compared with the toxicological reference values derived for aminopyralid. The toxicological profile of aminopyralid was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.26 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.26 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The estimated long-term intake accounted for less than 1% of the ADI (Dutch children) and the contribution of the residues in cereals to the total exposure accounting for a maximum of 0.07% (rye, Danish children). The expected short-term intake of aminopyralid residues in the crops assessed under this application accounted for less than 1% of the ARfD.
EFSA concluded that the intended uses of aminopyralid on cereals will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a health risk to consumers.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D. EFSA proposes to amend the existing MRLs as reported in the summary table below.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/Justification |
|---------|-----------|------------------------|-------------------------|------------------------|
| 0500010 | Barley    | 0.1                    | 0.15                    | Residues trials supporting the NEU and SEU intended uses performed on barley and according to the risk assessment residue definition(b) No risk to consumers identified |
| 0500040 | Millet    | 0.01*                  | 0.05                    | MRL was derived from residues trials in maize (NEU and SEU)(b) by extrapolation to millet No risk to consumers identified |
| 0500050 | Oats      | 0.1                    | Option 1: no change (0.1) or Option 2: 0.15 | Two MRL proposals were derived by EFSA for further risk management consideration: Option 1: MRL derived by extrapolation from residue trials in wheat (b) which did not provide evidence that the existing MRL has to be modified. Option 2: MRL was derived by extrapolation from residue trials in barley. Both extrapolation options are in accordance with the EU guidance. No risk to consumers identified has been identified |
| 0500070 | Rye       | 0.1                    | Option 1: no change (0.1) or Option 2: 0.15 | Two MRL proposals were derived by EFSA for further risk management consideration: Option 1: MRL derived by extrapolation from residue trials in wheat (b) which did not provide evidence that the existing MRL has to be modified. Option 2: MRL was derived by extrapolation from residue trials in barley. Both extrapolation options are in accordance with the EU guidance. No risk to consumers identified has been identified |
| 0500080 | Sorghum   | 0.01*                  | 0.05                    | MRL was derived from residues trials in maize (NEU and SEU)(b) by extrapolation to sorghum. No risk to consumers has been identified |
| 0500090 | Wheat     | 0.1                    | No change              | Residues trials(b) supporting the NEU and SEU intended uses in wheat suggested an MRL of 0.04 mg/kg; therefore, it is deemed unnecessary to modify the existing MRL |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.

(*) Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(b): Residues determined only according to the residue definition for risk assessment as 'sum of aminopyralid and its conjugates expressed as aminopyralid'.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for certain cereals. The detailed description of the intended uses of aminopyralid which are the basis for the current MRL application is reported in Appendix A.

Aminopyralid was evaluated in the framework of Directive 91/414/EEC\(^1\) with the United Kingdom designated as rapporteur Member State (RMS); the representative use assessed was the use on grassland (application in spring and summer). The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2013b). On 1 January 2015, aminopyralid was approved in accordance with the provisions of Regulation (EC) No 1107/2009\(^2\) for being used as a herbicide.

The European Union (EU) MRLs for aminopyralid are established in Annex III of Regulation (EC) No 396/2005\(^3\). The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been initiated. EFSA has previously issued several reasoned opinions on the modification of MRLs for aminopyralid which have been considered in the MRL legislation.\(^4\) In 2014, certain Codex MRLs (CXLs) established by Codex Alimentarius Commission (CAC) have been taken over in the EU legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, Dow AgroSciences Denmark submitted an application to the competent national authority in the United Kingdom (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for aminopyralid in various crops: barley, oats, rye, wheat, millet and sorghum. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 1 June 2018. To accommodate for the intended uses of aminopyralid, the EMS proposed to raise the existing MRLs for barley, oat, rye and wheat (including tritcale and spelt) from 0.1 to 0.15 mg/kg; and for millet and sorghum, from the limit of quantification (LOQ) of 0.01 to 0.05 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (United Kingdom, 2017), the DAR (and its addendum) (United Kingdom, 2006, 2013) prepared under Council Directive 91/414/EEC, the Commission review report on aminopyralid (European Commission, 2014), the conclusion on the peer review of the pesticide risk assessment of the active substance aminopyralid (EFSA, 2013b) as well as the conclusions from previous EFSA opinions on aminopyralid (EFSA, 2012, 2013a, 2016).

For this application, the data requirements established in Regulation (EU) No 544/2011\(^5\) and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011\(^6\).

As the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL review.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, submitted in support of the current MRL application, are presented in Appendix B.

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\(^1\) 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.

\(^2\) 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.

\(^3\) Regulation (EC) No 396/2005 of the 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.

\(^4\) For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

\(^5\) Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

\(^6\) Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
The evaluation report submitted by the EMS (United Kingdom, 2017) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

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 in primary crops (foliar application on wheat and grass) was assessed in the framework of the peer review under Regulation (EC) No 1107/2009 (EFSA, 2013b). The major part of the extracted radioactivity was composed of the free and conjugated form of aminopyralid. Furthermore, a metabolism study on oilseed rape has been assessed in an EFSA reasoned opinion (EFSA, 2012). The results of this metabolism study are comparable with the results of the previously assessed studies in cereals and grass.

For the uses in cereals, EFSA concludes that the metabolism of aminopyralid is sufficiently addressed.

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

Cereals can be grown in rotation with other plants and since the maximum DT$_{90}$ value measured in soil degradation field studies exceeded the trigger value of 100 days (DT$_{90}$ aminopyralid: 116 days (EFSA, 2013b)), the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed as required according to the applicable EU guidance document (European Commission, 1997c).

Studies on the nature and magnitude of aminopyralid residues in rotational crops were assessed in the framework of the peer review where it was concluded that the residue definitions set for primary crops are also applicable to rotational crops (EFSA, 2013b).

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

The effect of processing on the nature and magnitude of aminopyralid residues in cereals has not been previously investigated. Considering that the expected exposure exceeds the trigger value defined in the EU guidance document (i.e. residue in the raw agricultural commodity (RAC) assessed is greater than 0.1 mg/kg), a standard hydrolysis study simulating the processing conditions of pasteurization, boiling, brewing, baking and sterilization has been submitted in the framework of the current application (United Kingdom, 2017). The results of the study suggest that aminopyralid is stable under standard processing conditions.

1.1.4. **Methods of analysis in plants**

The peer review under Regulation (EC) No 1107/2009 concluded that a sufficiently validated analytical method based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) quantification is available to quantify residues of aminopyralid and its conjugates (measured as aminopyralid) in high water, high acid, high oil content and dry commodities with a LOQ of 0.01 mg/kg (EFSA, 2013b). The method includes hydrolytic conditions that release free aminopyralid from its conjugates.

1.1.5. **Stability of residues in plants**

The stability of aminopyralid residues in plant matrices under storage conditions prior to analysis was assessed during the peer-review process under Regulation (EC) No 1107/2009. Residues of aminopyralid were found to be stable in high water content commodities (forage, grass) and dry/starch matrices (wheat grain, wheat straw and wheat hay) at –20°C for at least 16 months (EFSA, 2013b).

1.1.6. **Proposed residue definitions**

Considering the results of metabolism studies (primary and rotational crop studies), the results of hydrolysis studies and the capabilities of enforcement analytical methods, the peer review proposed
the following residue definitions for enforcement and risk assessment: ‘sum of aminopyralid and its conjugates expressed as aminopyralid’.

These residue definitions are also appropriate for the crops assessed in the framework of this application.

It is noted that the existing residue definition set in Regulation (EC) No 396/2005 is different as it comprises the parent compound only. It is expected that in the framework of the MRL review the residue definition for enforcement will be reconsidered, taking into account the residue definition derived in the peer review process.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, 25 good agricultural practice (GAP)-compliant residue trials conducted on barley and 36 GAP-compliant residue trials conducted on wheat in both northern Europe (NEU) and southern Europe (SEU) were submitted. The samples were analysed with a method that measures the sum of aminopyralid and its conjugate, which was according to the EMS sufficiently validated.

As the samples of the residue trials were stored for a maximum period of 15 months under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

Wheat grain:

In total, 36 GAP-compliant residue trials (23 NEU trials and 13 SEU trials) were submitted in support of the MRL application. Since the statistical assessment (Mann–Whitney (U-test)) demonstrated that the NEU and SEU data belong to a similar population, the data sets were merged to calculate the MRL proposal for wheat.7

Barley grain:

In total, 25 GAP-compliant residue trials (15 NEU trials and 10 SEU trials) were submitted in support of the MRL application. Since the statistical assessment (Mann–Whitney (U-test)) demonstrated that the NEU and SEU data belong to a similar population, the data sets were merged to calculate the MRL proposal for barley.8

Oats and rye grain:

No specific residue trials in oats or rye are available. However, MRL proposals can be derived by extrapolation. According to the EU extrapolation rules (European Commission, 2017), extrapolation from wheat grain to oats and rye is possible; alternatively, residue trials in barley could be used265(670,795),(857,828)(670,828),(857,862)(670,862),(857,895) to derive a MRL proposal for oats and rye grain. Thus, EFSA derived to MRL proposals for further risk management consideration.

Maize, sorghum and millet:

As regards the MRL application for millet and sorghum, the applicant proposed to derive the MRL proposal by extrapolation from maize, which is acceptable according to the EU extrapolation rules. The data set for maize has been assessed previously in an EFSA reasoned opinion (EFSA, 2016; Hungary, 2016). EFSA has re-assessed the residue data in maize and concluded that the data were appropriate for deriving a MRL proposal and risk assessment input values for millet and sorghum.

Wheat straw:

In total, 36 GAP-compliant residue trials (23 NEU trials and 13 SEU trials) where residues in wheat straw were analysed have been submitted. Since the statistical assessment (Mann–Whitney (U-test)) demonstrated that the NEU and SEU data belong to a similar population, the data sets were merged for deriving risk assessment input values for assessing the contribution of wheat straw to the animal dietary burden.8

7 Data sets for barley (NEU and SEU) and wheat (NEU and SEU) (both grain and straw) were found to be statistically significant different (Kruskal–Wallis H-test (p > 0.05) rejecting the possibility of merging the whole dataset of barley and wheat in order to derive a single MRL/risk assessment input values for both commodities.

8 See footnote 7.
Barley straw:

In total, 25 GAP-compliant residue trials (15 NEU trials and 10 SEU trials) where residues in barley straw were analysed have been submitted. Since the statistical assessment (Mann–Whitney (U-test)) demonstrated that the NEU and SEU data belong to a similar population, the data sets were merged for deriving risk assessment input values for assessing the contribution of barley straw to the animal dietary burden.8

A summary of the available residue trials including residue values for MRL setting, for risk assessment and for animal intake exposure calculations is available in Appendix B, Table B.1.2.1.

1.2.2. Magnitude of residues in rotational crops

Studies on the magnitude of aminopyralid residues in rotational crops were assessed in the framework of the peer review. After application of 10 g/ha, leafy (lettuce), root (turnip) and cereal (wheat) crops were planted at two plant-back intervals (PBI) of 90 and 120 days. Significant residues were not observed in the mature edible parts of the plants. The study did not investigate the 30-day PBI scenario which is relevant for crop failure. Therefore, further rotational crop data covering the rotational crop scenario covering the PBI of 30 days has been considered necessary. In addition, it was noted that the application rate tested in the rotational crop study did not cover the representative use assessed in the peer review. Thus, it was requested to perform studies with an application rate reflecting the critical representative use (EFSA, 2013b).

With the current application, a new confined rotational crop study has been submitted. Lettuce, turnips and sorghum were planted 30, 120 and 365 days after the application of 63.9 g/ha of aminopyralid in bare soil. Due to phytotoxic effects, lettuce did not grow at the tested plant back intervals of 30, 120 or 180 days; thus, the study design was modified, replacing lettuce with mustard, which was planted at PBI 300 and 365 days. Residues in green mustard (mature and immature) were found at 0.024–0.027 mg eq/kg at PBI 300 days and 0.084–0.088 mg/kg at PBI 365 days. Residues of aminopyralid were determined in turnip leaves at 0.270 mg eq/kg and 0.334 mg eq/kg at PBI 30 and 120 days, respectively, and 0.038 mg eq/kg and 0.034 mg eq/kg at PBI 30 and 120 days, respectively, in turnip roots. In wheat (forage, straw, hay and grain), the highest residues found in all crop products at 120 days PBI (0.095 mg eq/kg in wheat forage; 0.658 mg eq/kg in wheat hay; 0.555 mg eq/kg in wheat straw; 0.033 mg eq/kg in wheat grain). The level of details reported in the ER (United Kingdom, 2017) was limited. For example, information regarding the characterization of the residues of aminopyralid in rotated crops was considered insufficient to draw a robust conclusion. However, considering that this study is overdosed in comparison with the GAPs under assessment by a factor of 6 (6N rate), it is concluded that this study gives an indication that residues in crops growing in rotational may occur at more than 0.01 mg/kg if the application is performed following the GAPs under assessment.

Based on the available information on the nature and magnitude of the residues, EFSA concludes that the occurrence of residues in rotational crops cannot be fully excluded. Thus, it is recommended that Member States should consider the need of defining plant back restrictions when granting authorizations for the use of aminopyralid in crops assessed under this application. Alternatively, an application for setting MRLs for rotational crops might be considered appropriate.

1.2.3. Magnitude of residues in processed commodities

Two processing studies were submitted in the framework of the current application which allow deriving indicative processing factor for processed wheat products and for certain fractions of brewery process (see Appendix B.1.2.3). A sufficiently robust processing factor of 2.4 was obtained for wheat bran which is recommended to be included in Annex VI of Regulation (EC) No 396/2005. This value has been used for the dietary burden calculations of livestock (see Appendix D).

1.2.4. Proposed MRLs

The MRL proposals are based on residue trials analysed with an analytical method that covers also the conjugates of aminopyralid. Thus, the results are likely to be higher than required for the current residue definition established in Regulation (EC) No 396/2005, which comprises only parent aminopyralid. In Appendix B, Section B.4 of the current reasoned opinion, more information on the recommend MRLs is presented.
2. Residues in livestock

As the crops under assessment and their by-products are normally fed to livestock, the magnitude of aminopyralid residues in livestock was assessed in the framework of this application.

The nature of residues in livestock was assessed previously (EFSA, 2013b); for animal products it was agreed to set the residue definitions for risk assessment and enforcement purpose as the parent compound.

EFSA has updated the previous dietary burden calculation for livestock (EFSA, 2016) by using the animal model 2017 (OECD, 2013) and considering the expected residue levels resulting from the intended uses of aminopyralid on cereals assessed in the current application. The input values used for the animal intake calculations are reported in Appendix D. The results of the updated animal dietary intake estimation are reported in Appendix B.2. The maximum dietary burden was 16.20 mg/kg (dry matter (DM)) for ruminants, being ram/ewe the most critical diet; for swine, 3.5 mg/kg (DM) and less than 0.1 mg/kg (DM) for poultry (poultry layer).

The existing EU MRLs for animal products (mammals) are Codex MRLs (CXLs) that were taken over in the EU MRL legislation by Regulation (EU) No 36/2014.9,10 These CXLs were derived from feeding studies based on the dietary burden calculated at international level by JMPR that was significantly higher than the dietary burden calculated for the EU zone (maximum dietary burden for ruminants: 103 mg/kg DM, pigs: 7.2 mg/kg DM). For poultry, the existing EU MRLs are higher than the CXLs which were derived based on a dietary burden calculation of JMPR which was also significantly higher than the result obtained by EFSA in the updated dietary burden calculation (i.e. 10.4 mg/kg DM (FAO, 2006)).

Thus, overall, EFSA concludes that a modification of the existing MRLs for commodities of animal origin is not necessary.

3. Consumer risk assessment

The toxicological profile of the active substance aminopyralid was assessed in the framework of the peer review under Regulation (EC) No 1107/2009 (EFSA, 2013b; European Commission, 2014). The following toxicological reference values were derived: acute reference dose (ARfD) 0.26 mg/kg body weight (bw) and acceptable daily intake (ADI) 0.26 mg/kg bw per day.

For performing the consumer risk assessment, the consumer exposure was estimated using EFSA PRIMo rev. 2. The calculated exposure was then compared with the toxicological reference values derived for aminopyralid.

For the calculation of the chronic exposure, EFSA used the supervised trials median residue (STMR) derived from the residue trials on the cereals assessed in the framework of this MRL application, the STMR derived for rape seeds and maize from previous EFSA reasoned opinions (EFSA, 2013a, 2016) and the existing MRLs set in Regulation (EU) 2017/171.11

The acute exposure assessment was performed only with regard to the commodities assessed under the current MRL application in accordance with the internationally agreed methodology assuming the consumption of a large portion of the food item as reported in the national food surveys and that these items contained residues at the STMR level as observed in supervised field trials. The input values used for the dietary exposure calculation are summarised in Appendix D, Table D.2.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The calculated total chronic intake accounted for less than 1% of the ADI (Dutch children diet) and the highest contributor of the residues in cereals under assessment to the total exposure accounting for a maximum of 0.07% (rye, Danish children diet).

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9 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, cyflufenamid, meipiquat, metalaxyl-M, propamocarb, pyriofenone and quinoxyfen in or on certain products, OJ L 17, 21.1.2014, p. 1-41

10 Risk managers agreed to take over Codex MRLs in the EU legislation although the residue definition derived at Codex level did not fully comply with the EU residue definition for enforcement; the Codex residue definition is set for aminopyralid and its conjugates that can be hydrolysed, expressed as aminopyralid.

11 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, cytantraniliprole, cyflufenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxyfop, isofetamid, metalaxyl, prohexadione, propaquizafop, pyrimethanil, Trichoderma atroviride strain SC1 and zoxamide in or on certain products (Text with EEA relevance.) OJ L 30, 3.2.2017, p. 45-111.
No acute consumer risk was identified in relation to the MRL proposals for cereals, the highest calculated acute exposure being less than 1% of the ARfD. Further information on the results of the consumer risk assessment are available in Appendix B, Section B.3.

EFSA concludes that the proposed use of aminopyralid on cereals will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a health risk to consumers.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for barley, oats, rye, millet, sorghum and wheat.

The MRL proposals are based on residue trials analysed with an analytical method that covers also the conjugates of aminopyralid. Thus, the results are likely to be higher than required for the current residue definition established in Regulation (EC) No 396/2005, which comprises only parent aminopyralid. EFSA is of the opinion that this deviation is acceptable, taking into account that the MRL review under Article 12 of the MRL regulation will be initiated soon and it is likely that the MRL recommendations will be aligned with the proposed residue definition derived in the peer review (sum of aminopyralid and its conjugates, expressed as aminopyralid). In previous MRL applications, a similar approach was agreed by risk managers, accepting to set the MRLs for rape seeds and maize, based on residue trials where the residue concentration measured was the sum of aminopyralid and its conjugates, expressed as aminopyralid (EFSA, 2012, 2016).

EFSA concludes that the intended uses of aminopyralid on cereals will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a concern for public health.

The MRL recommendations are summarised in Appendix B, Section B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CAS Chemical Abstract Service
CF conversion factor for enforcement to risk assessment residue definition
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DM dry matter
DT$_{90}$ period required for 90% dissipation (define method of estimation)
EC emulsifiable concentrate
EMS evaluating Member State
eq residue expressed as a.s. equivalent
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
InChiKey International Chemical Identifier Key
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
| Abbreviation | Description |
|--------------|-------------|
| LC-MS/MS     | liquid chromatography with tandem mass spectrometry |
| LOQ          | limit of quantification |
| MRL          | maximum residue level |
| NEU          | northern Europe |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant-back interval |
| PF           | processing factor |
| PHI          | preharvest interval |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SE           | suspoemulsion |
| SEU          | southern Europe |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TRR          | total radioactive residue |
| WHO          | World Health Organization |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Type(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|---------|-----------------------------------|-------------|------------|--------------------------------|----------------|---------|
| **Winter cereals**    |                         | F       | Broadleaf weeds                   | SE          | Overall, Broadcast foliar spray | BBCH 21–32 (1 Feb–31 May) | 1 na           | 3.33–10 | 100–300 | 10 g a.s./ha na |          |
| (wheat, triticale, rye, barley, oat) |                         |         |                                   |             |                         |                                |                |         |
|                      | NEU (Denmark, Sweden, Norway, Finland, Lithuania, Latvia, Estonia, Czech Rep., Hungary, Poland, Romania, Slovakia, Slovenia) |         |                                   |             |                         |                                |                |         |
|                      | SEU (Bulgaria, Greece)  | F       | Broadleaf weeds                   | SE          | Overall, Broadcast foliar spray | BBCH 21-32 (1 Feb–31st May) | 1 na           | 3.33–10 | 100–300 | 10 g a.s./ha na |          |
|                      |                         |         |                                   |             |                         |                                |                |         |
|                      | NEU (Denmark, Sweden, Norway, Finland, Lithuania, Latvia, Estonia, Czech Rep., Hungary, Poland, Romania, Slovakia, Slovenia) |         |                                   |             |                         |                                |                |         |
| **Spring cereal**     |                         | F       | Broadleaf weeds                   | SE          | Overall, Broadcast foliar spray | BBCH 13-32 (1 March–31 May) | 1 na           | 2.5–7.5 | 100–300 | 7.5 g a.s./ha na |          |
| (wheat, triticale, rye, barley, oat) |                         |         |                                   |             |                         |                                |                |         |
|                      |                         |         |                                   |             |                         |                                |                |         |
### Crop and/or situation

| Crop and/or situation | NEU, SEU, MS or country | FG OR T(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|--------------------------|------------|------------------------------------|-------------|------------|-------------------------------|--------------|---------|
|                       |                          |            |                                    | Type(b) | Conc a.s. | Method kind | Range of growth stages & season(c) | Number min–max | Interval between appl. (min) | g a.s./L/ha | Water L/ha | Rate | Unit |             |
| Spring cereal (wheat, triticale, rye, barley, oat) | SEU (Bulgaria, Greece) | F | Broadleaf weeds | SE | 300 g/L | Overall, Broadcast foliar spray | BBCH 21–32 (1 Feb–31 May) | 1 | na | 2.5–7.5 | 100–300 | 7.5 | g a.s./ha | na | |
| Maize(e), Millet, Sorghum | NEU (Hungary, Romania) | F | Broadleaf weeds | SE | 300 g/L | Overall, Broadcast foliar spray | BBCH 12–16 April–June | 1 | na | 5–10 | 100–400 | 10 | g a.s./ha | Not relevant | |
| Maize(e), Millet, Sorghum | SEU (Bulgaria, Greece) | F | Broadleaf weeds | SE | 300 g/L | Overall, Broadcast foliar spray | BBCH 12–16 April–June | 1 | na | 2.5–5 | 200–400 | 10 | g a.s./ha | Not relevant | |
| Maize(e), Millet, Sorghum | (Hungary, Romania) | F | Broadleaf weeds | SE | 11.8 g/L | Tractor mounted broadcast spray | BBCH 12–16 April–June | 1 | na | 1.475–11.8 | 100–400 | 5.9–11.8 | g a.s./ha | Not relevant | |

**NEU:** northern European Union; **SEU:** southern European Union; **MS:** Member State; **a.s.:** active substance; **SE:** suspoemulsion.

(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 formulation types and international coding system.

(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.

(e): The GAP in maize has been previously assessed (EFSA, 2016). No change in the MRL for maize has been requested.
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       | Spray, 1 x 360 g/ha, 12-14 cm high | 0, 7, 14, 21, 42 | Three varieties of grass 14C-aminopyralid labelled in positions 2 and 6 of the pyridine ring. EFSA (2013b) |
| Cereals/grass                    | Wheat       | Spray, 1 x 40 and 80 g/ha, BBCH 26-28 | 0, 14, 35, 86 | Three varieties of grass 14C-aminopyralid labelled in positions 2 and 6 of the pyridine ring. EFSA (2013b) |
| Pulses/Oilseeds                  | Oilseed rape | Spray, 1 x 14 g/ha, BBCH 51 | 28, 62 | Not peer-reviewed study EFSA (2012) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|--------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                    | Turnip      | 10 g/ha | 90, 120        | EFSA (2013b) |
| Root/tuber crops                    | Turnip      | 63.9 g/ha | 30, 120, 365 | 14C-aminopyralid labelled in the pyridine ring. United Kingdom (2017) |
| Leafy crops                         | Lettuce     | 10 g/ha | 90, 120        | EFSA (2013b) |
| Leafy crops                         | Lettuce     | 63.9 g/ha | 30, 120, 180 | 14C-aminopyralid labelled in the pyridine ring. Lettuce was planted at 30, 120, 180 PBI; however, crop failure does not allow to determine residues immature and immature lettuce. United Kingdom (2017) |
| Leafy crops                         | Mustard     | Mustard | 300, 365       | 14C-aminopyralid labelled in the pyridine ring. United Kingdom (2017) |
| Cereal (small grain)                | Sorghum     | 10 g/ha | 90, 120        | EFSA (2013b) |
| Cereal (small grain)                | Wheat       | 63.9 g/ha | 30, 120, 365 | 14C-aminopyralid labelled in the pyridine ring. United Kingdom (2017) |
| Other                               | --          | --      | --             | --         |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Yes        | United Kingdom (2017) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes        | United Kingdom (2017) |
| Sterilisation (20 min, 120°C, pH 6)      | Yes        | United Kingdom (2017) |
| Other processing conditions              | --         | --      |
Can a general residue definition be proposed for primary crops?

| Residue pattern in processed commodities similar to residue pattern in raw commodities? |
|-------------------------------------------------------------|
| Yes Aminopyralid is stable to the hydrolysis under the condition simulating processing (United Kingdom, 2017) |

Regulation (EC) No 396/2005: Aminopyralid Proposal derived in peer review: Sum of aminopyralid and its conjugates expressed as aminopyralid (EFSA, 2013b)

Method for enforcement residue definition derived in peer review: Matrices with high water content and high starch/dry matrices: LC–MS/MS, LOQ 0.01mg/kg (EFSA, 2013b)

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period Value | Unit | Compounds covered | Comment/| source |
|-----------------------------------|----------|-----------|--------|------------------------|------|-------------------|--------|
| High water content                | Wheat forage Grass | –20 | 16 | Months | Aminopyralid | EFSA (2013b) |
| Dry/High starch                   | Wheat grain Wheat straw Wheat hay | –20 | 16 | Months | Aminopyralid | EFSA (2013b) |

DAT: days after treatment; PBI: plant-back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.
### B.1.2. Magnitude of residues in plants

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

| 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\(^{(d)}\) |
|-----------|--------------------------|-------------------------------------------------------------|----------------|------------------------|------------------|------------------|----------|
| Wheat grain | NEU | Mo: – RA: 12 × < 0.01, 5 × 0.01, 4 × 0.02, 0.03, 0.04 | Residue trials on wheat compliant with NEU GAP. Calculated MRL based on results for risk assessment residue definition. | 0.04 | 0.04 | 0.02 | – |
| Wheat grain | SEU | Mo: – RA: 7 × < 0.01, 5 × 0.01, 0.02 | Residue trials on wheat compliant with SEU GAP. Calculated MRL based on results for risk assessment residue definition. | 0.04 | 0.02 | 0.01 | – |
| Wheat grain Oats grain (option 1), Rye grain (option 1) | NEU + SEU | Mo: – RA: 19 × < 0.01, 10 × 0.01, 5 × 0.02, 0.03, 0.04 | Combination of NEU and SEU data sets; population was demonstrated to be similar (Mann-Whitney (U-test)). MRL for wheat derived from the residue trials in wheat. Calculated MRL based on results for risk assessment residue definition. According to EU guidance document, residue trials in wheat grain (application before BBCH 51) can be used by extrapolation to derive MRL for barley, oat and rye. See also below assessment of trials in barley grain. | 0.04 | 0.04 | 0.01 | – |
| Barley grain | NEU | Mo: – RA: < 0.01, 0.02, 4 × 0.03, 2 × 0.04, 4 × 0.05, 0.06, 2 × 0.08 | Residue trials on barley compliant with NEU GAP. Calculated MRL based on results for risk assessment residue definition. | 0.15 | 0.08 | 0.04 | – |
| Barley grain | SEU | Mo: – RA: 1 × < 0.01, 2 × 0.02, 0.03, 2 × 0.04, 2 × 0.06, 2 × 0.09 | Residue trials on barley compliant with SEU GAP. Calculated MRL based on results for risk assessment residue definition. | 0.15 | 0.09 | 0.04 | – |

\(^{(a)}\) Commodity Region:
- NEU: Northern and Eastern Europe
- SEU: Southern and Eastern Europe

\(^{(b)}\) HR: Harmonised Reference Level

\(^{(c)}\) STMR: Scientifically derived MRL

\(^{(d)}\) CF: Conversion factor
| Commodity | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|------------------------|----------------------|------------------------|-----------|
| Barley grain, Oats grain (option 2), Rye grain (option 2) | NEU + SEU | Mo: – RA: 2 × < 0.01, 3 × 0.02, 5 × 0.03, 4 × 0.04, 4 × 0.05, 3 × 0.06, 2 × 0.08, 2 × 0.09 | Combination of NEU and SEU data sets since population was demonstrated to be similar following the Mann–Whitney (U-test) Calculated MRL based on results for risk assessment residue definition According to EU guidance document, residue trials in barley grain (application before BBCH 51) can be used by extrapolation to derive MRL for oat and rye. See also below assessment of trials in wheat grain | 0.15 | 0.09 | 0.04 | – |
| Sorghum, millet grain | NEU | Mo: – RA: 8 × < 0.01, 2 × < 0.01, 0.01, 0.04 | Residues trials on maize according to the intended GAP were previously validated (EFSA, 2016). Calculated MRL based on results for risk assessment residue definition | 0.04 | 0.04 | 0.01 | – |
| Sorghum, millet grain | SEU | Mo: – RA: 8 × < 0.01 | Residues trials on maize according to the intended GAP were previously validated (EFSA, 2016). Calculated MRL based on results for risk assessment residue definition | 0.01 | 0.01 | 0.01 | – |
| Sorghum, millet grain | NEU + SEU | Mo: – RA: 16 × < 0.01, 2 × < 0.01, 0.01, 0.04 | Combination of NEU and SEU data sets since populations were demonstrated to be similar following the Mann–Whitney (U-test). Calculated MRL based on results for risk assessment residue definition. Extrapolation from maize to millet and sorghum is appropriate | 0.05 | 0.04 | 0.01 | – |
### Modification of existing MRLs for aminopyralid in certain cereals

| 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\(^{(d)}\) |
|-----------|-------------------------|---------------------------------------------------------------|-----------------|------------------------|-------------------|------------------|-----|
| Wheat straw | NEU + SEU | **Mo:** –  
**RA:** 3 × < 0.01, 4 × 0.02, 5 × 0.03, 6 × 0.04, 5 × 0.05, 2 × 0.06, 2 × 0.07, 4 × 0.08, 0.09, 0.12, 2 × 0.13, 0.27  | NEU and SEU data sets for wheat straw were merged for deriving a single value to be used in dietary burden calculation. The values can be extrapolated to other cereal straw. Considering that the wheat straw represents a more critical situation; this residue situation has been also applied to oats and rye straw. | – | 0.27 | 0.04 | – |
| Barley straw | NEU + SEU | **Mo:** –  
**RA:** 3 × 0.01, 4 × 0.02, 5 × 0.03, 5 × 0.04, 4 × 0.05, 0.06, 0.08, 0.13  | NEU and SEU data sets for wheat straw were merged for deriving a single value to be used in dietary burden calculation. | – | 0.13 | 0.04 | – |
| Maize and sorghum stover | NEU + SEU | **Mo:** –  
**RA:** 13 × < 0.01, < 0.01, 2 × 0.01, 0.02, 2 × 0.02, 0.12  | NEU and SEU data sets on maize stover were merged for deriving single values to be used in dietary burden calculation. Since extrapolation from maize to millet is allowed, it was considered appropriate to extrapolate from maize stover to sorghum stover. | – | 0.12 | 0.01 | – |

MRL: maximum residue level; GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants.
\(^{(a)}\): 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 refers to the whole commodity and not to the edible portion.
\(^{(c)}\): Supervised trials median residue. The median residue for risk assessment 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.

Underlined values: where residue values after the PHI described in the GAP were higher than the values in the GAP for the intended use(s), these residues at higher PHI were used for deriving risk assessment values.
B.1.2.2. Residues in rotational crops

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

|          | Residues detected | Study description                                                                 |
|----------|-------------------|----------------------------------------------------------------------------------|
| No       | Low residues were detected in samples of sorghum forage and residues in crops for human consumption (all ≤0.01 mg/kg (EFSA, 2013b)) |

Study performed with an application rate of 63.9 g a.s./ha (6N compared to GAPs under assessment, residues > 0.01 mg/kg were observed (United Kingdom, 2017)

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

|          | Residues detected | Study description                                                                 |
|----------|-------------------|----------------------------------------------------------------------------------|
| Not triggered | Confined rotation crop studies were sufficient to conclude for the intended uses in cereals under assessment |

a.s.: active substance; GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

| Processed commodity       | Number of valid studies(a) | Processing factor (PF) | CF_F(b) | Comment/source                      |
|---------------------------|----------------------------|------------------------|---------|-------------------------------------|
| Wheat/Bran                | 1                          | –                      | 2.4     | EFSA (2013b)(c)                     |
| Wheat/Coarse bran         | 1                          | –                      | 4       | United Kingdom (2017)               |
| Wheat/Fine bran           | 1                          | –                      | 1.1     | United Kingdom (2017)               |
| Wheat/Flour               | 1                          | –                      | 0.2     | EFSA (2013b)                        |
| Wheat/Wholemeal flour     | 1                          | –                      | 1.2     | United Kingdom (2017)               |
| Wheat/Wholemeal bread     | 1                          | –                      | 0.8     | United Kingdom (2017)               |
| Barley/Brewing malt       | 1                          | –                      | 1.47    | Tentative(d) (United Kingdom, 2017) |
| Barley/Spent grains       | 1                          | –                      | 0.75    | Tentative(d) (United Kingdom, 2017) |
| Barley/Brewer’s yeast     | 1                          | –                      | 0.31    | Tentative(d) (United Kingdom, 2017) |
| Barley/Beer               | 1                          | –                      | 0.31    | Tentative(d) (United Kingdom, 2017) |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.
(c): For wheat bran, EFSA calculated the median PF of 2.4 considering the 3 available individual processing values.
(d): Tentative PF were derived based on a limited data set. Tentative processing factors are not recommended for inclusion in Annex VI of Regulation (EC) No 396/2005.
### B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup<sup>(a)</sup> | Most critical commodity<sup>(b)</sup> | Trigger exceeded<sup>(Y/N)</sup> |
|-----------------------------|---------------------------------------------|---------------------------------|---------------------------------|-----------------|
|                             | Median | Maximum | Median | Maximum |                               |                   |
| Cattle (all)                | 0.111  | 0.394   | 2.89   | 10.26   | Dairy cattle                     | Grass forage (fresh) | Y               |
| Cattle (dairy only)         | 0.111  | 0.394   | 2.88   | 10.26   | Dairy cattle                     | Grass forage (fresh) | Y               |
| Sheep (all)                 | 0.151  | 0.540   | 4.53   | 16.20   | Ram/Ewe                         | Grass forage (fresh) | Y               |
| Sheep (ewe only)            | 0.151  | 0.540   | 4.53   | 16.20   | Ram/Ewe                         | Grass forage (fresh) | Y               |
| Swine (all)                 | 0.023  | 0.080   | 1.00   | 3.45    | Swine (breeding)                 | Grass silage         | Y               |
| Poultry (all)               | 0.004  | 0.005   | 0.06   | 0.08    | Poultry layer                    | Wheat straw          | N               |
| Poultry (layer only)        | 0.004  | 0.005   | 0.06   | 0.08    | Poultry layer                    | Wheat straw          | N               |
| Fish                        | N/A    |         |        |         |                                |                    |                 |

bw: body weight; DM: dry matter.

(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

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

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

| Livestock (available studies) | Animal                | Dose (mg/kg bw per day) | Duration (days) | Comment/source                                                                 |
|-------------------------------|-----------------------|-------------------------|-----------------|--------------------------------------------------------------------------------|
|                               | Laying hen            | 11.6 mg/kg DM           | 7               | Aminopyralid was almost totally extracted and the characterization of residues was not performed in any of the samples (EFSA, 2013b) |
|                               | Lactating ruminants   | 17.6 mg/kg DM           | 6               | Metabolism study in lactating goat. Aminopyralid was extensively extracted in faeces and urine and the characterisation of residues was only attempted in kidney where 80% TRR was identified as aminopyralid (EFSA, 2013b) |
| Time needed to reach a plateau concentration in milk and eggs (days) | Milk: 2 days | EFSA (2013b) |
|------------------------|---------------|---------------|
|                        | Eggs: 5–7 days | EFSA (2013b) |
| Metabolism in rat and ruminant similar | Yes | EFSA (2013b) |
| Can a general residue definition be proposed for animals? | Not triggered | See dietary burden calculation (Appendix B, Section B.2) |
| Animal residue definition for monitoring (RD-Mo) | Aminopyralid | EFSA (2013b) |
| Animal residue definition for risk assessment (RD-RA) | Aminopyralid | EFSA (2013b) |
| Fat soluble residues | No | EFSA (2013b) |
| Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs) | Method for enforcement residue definition derived in peer review: Milk, eggs, muscle, kidney, fat and liver LC–MS/MS, LOQ 0.01 mg/kg (EFSA, 2013b) |

bw: body weight; DM: dry matter; TRR: total radioactive residue; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.

### B.2.2. Magnitude of residues in livestock

Not relevant for the current assessment.
B.3. Consumer risk assessment

ARfD

| Commodity   | IESTI          |
|-------------|----------------|
| Wheat       | 0.1% of ARfD  |
| Oat         | 0.1% of ARfD  |
| Sorghum     | 0.1% of ARfD  |
| Rye         | 0.1% of ARfD  |
| Millet      | < 0.1% of ARfD|
| Barley      | < 0.1% of ARfD|

Assumptions made for the calculations

The acute exposure calculations are based on the median residue levels expected in raw agricultural commodities that were determined according to the residue definition for risk assessment.

ADI

| Commodity   | IEDI          |
|-------------|---------------|
| Wheat       | < 0.1% of ADI |
| Oat         | < 0.1% of ADI |
| Rye         | < 0.1% of ADI |
| Sorghum     | < 0.1% of ADI |
| Millet      | < 0.1% of ADI |
| Barley      | < 0.1% of ADI |

Assumptions made for the calculations

The calculation is based on the median residue levels derived for raw agricultural commodities and the STMR values for the commodities previously assessed by EFSA (rapeseed, maize) (EFSA, 2012, 2016). For the commodities not previously assessed by EFSA, the MRLs set in the Regulation (Reg. (EU) 2017/171) have been used for exposure calculations.

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/Justification |
|---------|-----------|-------------------------|-------------------------|-----------------------|
| 0500010 | Barley    | 0.1                     | 0.15                    | Residues trials supporting the NEU and SEU intended uses performed on barley and according to the risk assessment residue definition(b) No risk to consumers identified |
| 0500040 | Millet    | 0.01*                   | 0.05                    | MRL was derived from residues trials in maize (NEU and SEU)(b) by extrapolation to millet No risk to consumers identified |
| 0500050 | Oats      | 0.1                     | Option 1: no change (0.1) or | Two MRL proposals were derived by EFSA for further risk management consideration: Option 1: MRL derived by extrapolation from residue trials in wheat (b) which did not provide evidence that the existing MRL has to be modified |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; STMR: supervised trials median residue.

(a) Code corresponds to the EU Index Code.

(b) The Index Code is provided for information purposes only and is not required for the use of the data in this document.
| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/Justification |
|-----------------|-----------|------------------------|------------------------|-----------------------|
| 0500070 | Rye | 0.1 | Option 1: no change (0.1) or Option 2: 0.15 | Two MRL proposals were derived by EFSA for further risk management consideration: Option 1: MRL derived by extrapolation from residue trials in wheat<sup>(b)</sup> which did not provide evidence that the existing MRL has to be modified Option 2: MRL was derived by extrapolation from residue trials in barley<sup>(b)</sup> Both extrapolation options are in accordance with the EU guidance No risk to consumers identified has been identified |
| 0500080 | Sorghum | 0.01<sup>*</sup> | 0.05 | MRL was derived from residues trials in maize (NEU and SEU)<sup>(b)</sup> by extrapolation to sorghum No risk to consumers has been identified |
| 0500090 | Wheat | 0.1 | No change | Residues trials<sup>(b)</sup> supporting the NEU and SEU intended uses in wheat suggested an MRL of 0.04 mg/kg; therefore, it is deemed unnecessary to modify the existing MRL |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.

<sup>(*)</sup>: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.

<sup>(b)</sup>: Residues determined only according to the residue definition for risk assessment as "sum of aminopyralid and its conjugates expressed as aminopyralid".
# Appendix C – Pesticide Residue Intake Model (PRiMo)

| Aminopyralid |  |
|--------------|---|
| Status of the active substance: | Approved |
| Code no. |  |
| LOQ (mg/kg bw): | Proposed LOQ |
| Toxicological end points |  |
| ADI (mg/kg bw per day): | ARfD (mg/kg bw): |  |
| Source of ADI: | EFSA | Source of ARfD: | EFSA |
| Year of evaluation: | 2013 | Year of evaluation: | 2013 |

## Chronic risk assessment–refined calculations

| Commodity/group of commodities | MS Diet | TMDI (range) in % of ADI | minimum–maximum |
|-------------------------------|---------|--------------------------|------------------|
| Milk and milk products: Cattle | 0.23 | 0.05–0.42 | Bovine: Meat |
| Milk and milk products: Cattle | 0.20 | 0.02–0.29 | Bovine: Meat |
| Milk and milk products: Cattle | 0.11 | 0.05–0.29 | Bovine: Kidney |
| Milk and milk products: Cattle | 0.03 | 0.03–0.27 | Bovine: Meat |
| Bovine: Meat | 0.10 | 0.02–0.25 | Bovine: Meat |
| Bovine: Meat | 0.02 | 0.02–0.18 | Bovine: Meat |
| Bovine: Meat | 0.02 | 0.02–0.15 | Bovine: Meat |
| Bovine: Meat | 0.02 | 0.01–0.05 | Bovine: Meat |
| Bovine: Meat | 0.02 | 0.01–0.02 | Bovine: Kidney |
| Bovine: Meat | 0.02 | 0.01–0.02 | Bovine: Kidney |
| Bovine: Meat | 0.02 | 0.01–0.01 | Bovine: Kidney |

## Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Aminopyralid is unlikely to present a public health concern.
The acute risk assessment is based on the ARID.

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

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

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

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

### Table: Highest % of ARfD/ADI Commodities

|                | Threshold MRL (mg/kg) |                | Threshold MRL (mg/kg) |                | Threshold MRL (mg/kg) |                | Threshold MRL (mg/kg) |                |
|----------------|-----------------------|----------------|-----------------------|----------------|-----------------------|----------------|-----------------------|----------------|
| Rye            | 0.10                  | 0.10           | Rye                   | 0.11           | Barley                | 0.11           | Barley                | 0.04/-         |
| Oats           | 0.04/-                | 0.04/-         | Oats                  | 0.04/-         | Oats                  | 0.04/-         | Oats                  | 0.04/-         |
| Wheat          | 0.01/-                | 0.01/-         | Wheat                 | 0.01/-         | Oats                  | 0.01/-         | Oats                  | 0.04/-         |
| Sorghum        | 0.04/-                | 0.04/-         | Sorghum               | 0.04/-         | Oats                  | 0.04/-         | Oats                  | 0.04/-         |
| Barley         | 0.04/-                | 0.04/-         | Barley                | 0.04/-         | Milet                 | 0.04/-         | Milet                 | 0.04/-         |
| Millet         | 0.04/-                | 0.04/-         | Millet                | 0.04/-         |                      |                |                       |                |

### Table: No of critical MRLs (IESTI 1)

|                |                |                |
|----------------|----------------|----------------|
|                |                |                |

### Table: No of critical MRLs (IESTI 2)

|                |                |                |
|----------------|----------------|----------------|
|                |                |                |

### Table: No of commodities for which ARfD/ADI is exceeded:

|                |                |
|----------------|----------------|
|                |                |

For Aminopyralid, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

**Note:**
--json: The results of the IESTI calculations are reported for at least 6 commodities. If the ARID is exceeded for more than 6 commodities, all IESTI values > 90% of ARID are reported.
- pTMRL: provisional temporary MRL for unprocessed commodity.
- pTMRL: provisional temporary MRL for processed commodity.

Conclusion:
- For Aminopyralid, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
- No exceedance of the ARfD/ADI was identified for any unprocessed commodity.
- 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                |
|                                          |                       |                        |                      |                        |
| **Risk assessment residue definition for plant commodities:** Sum aminopyralid and its conjugates expressed as aminopyralid (EFSA, 2013b) | | | | |
| Barley straw                            | 0.04                  | STMR (Table B.1.2.1)   | 0.13                 | HR (Table B.1.2.1)    |
| Corn, field forage/silage               | 0.01                  | STMR (Table B.1.2.1)   | 0.09                 | HR (Table B.1.2.1)    |
| Corn, field stover                      | 0.01                  | STMR (Table B.1.2.1)   | 0.12                 | HR (Table B.1.2.1)    |
| Corn, pop stover                        | 0.01                  | STMR (Table B.1.2.1)   | 0.12                 | HR (Table B.1.2.1)    |
| Grass forage (fresh) (a)                 | 1.19                  | STMR-p (EFSA, 2013b)   | 4.26                 | STMR-p (EFSA, 2013b)  |
| Grass hay (a)                           | 3.03                  | STMR-p (EFSA, 2013b)   | 10.86                | STMR-p (EFSA, 2013b)  |
| Grass silage (a)                        | 1.90                  | STMR-p (EFSA, 2013b)   | 6.82                 | STMR-p (EFSA, 2013b)  |
| Oat straw                               | 0.04                  | STMR (Table B.1.2.1)   | 0.27                 | HR (Table B.1.2.1)    |
| Rye straw                               | 0.04                  | STMR (Table B.1.2.1)   | 0.27                 | HR (Table B.1.2.1)    |
| Sorghum stover                          | 0.01                  | STMR (Table B.1.2.1)   | 0.12                 | HR (Table B.1.2.1)    |
| Triticale straw                         | 0.04                  | STMR (Table B.1.2.1)   | 0.27                 | HR (Table B.1.2.1)    |
| Wheat straw                             | 0.04                  | STMR (Table B.1.2.1)   | 0.27                 | HR (Table B.1.2.1)    |
| Barley grain                            | 0.04                  | STMR (Table B.1.2.1)   | 0.04                 | STMR (Table B.1.2.1)  |
| Corn, field (Maize) grain               | 0.01                  | STMR (Table B.1.2.1)   | 0.01                 | STMR (Table B.1.2.1)  |
| Corn, pop grain                         | 0.01                  | STMR (Table B.1.2.1)   | 0.01                 | STMR (Table B.1.2.1)  |
| Millet grain                            | 0.01                  | STMR (Table B.1.2.1)   | 0.01                 | STMR (Table B.1.2.1)  |
| Oat grain                               | 0.04                  | STMR (Table B.1.2.1)   | 0.04                 | STMR (Table B.1.2.1)  |
| Rye grain                               | 0.04                  | STMR (Table B.1.2.1)   | 0.04                 | STMR (Table B.1.2.1)  |
| Sorghum grain                           | 0.01                  | STMR (Table B.1.2.1)   | 0.01                 | STMR (Table B.1.2.1)  |
| Triticale grain                         | 0.04                  | STMR (Table B.1.2.1)   | 0.04                 | STMR (Table B.1.2.1)  |
| Wheat grain                             | 0.01                  | STMR (Table B.1.2.1)   | 0.01                 | STMR (Table B.1.2.1)  |
| Brewer’s grain                          | 0.13                  | STMR-p (PF 3.3)        | 0.13                 | STMR-p (PF 3.3)        |
| Corn, field (milled by-products)        | 0.01                  | STMR-p (PF 1)          | 0.01                 | STMR-p (PF 1)          |
| Corn, field (hominy meal)               | 0.06                  | STMR-p (PF 6)          | 0.06                 | STMR-p (PF 6)          |
| Corn, field (gluten feed)               | 0.03                  | STMR-p (PF 2.5)        | 0.03                 | STMR-p (PF 2.5)        |
| Corn, field (gluten meal)               | 0.01                  | STMR-p (PF 1)          | 0.01                 | STMR-p (PF 1)          |
| Distiller’s grain                       | 0.03                  | STMR-p (PF 3.3)        | 0.03                 | STMR-p (PF 3.3)        |
| Wheat gluten meal                       | 0.02                  | STMR-p (PF 1.8)        | 0.02                 | STMR-p (PF 1.8)        |
| Wheat, milled by-products               | 0.02                  | STMR-p (PF 2.4)        | 0.02                 | STMR-p (PF 2.4)        |

STMR: supervised trials median residue according to the risk assessment residue definition; HR: highest residue determined according to the risk assessment residue definition; PF: processing factor; in the absence of processing factors supported by data, default processing factors of were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

(a): Expected residues in grass silage and hay were calculated considering a dry matter content of 25% in grass, 40% in silage and 88% in hay as reported in the OECD feedstuff Table (OECD, 2009). Values retrieved from EFSA (2013b).
### D.2. Consumer risk assessment

| Commodity                        | Chronic exposure assessment | Acute exposure assessment |
|----------------------------------|-----------------------------|---------------------------|
|                                  | Input (mg/kg)               | Comment                   | Input (mg/kg) | Comment |
| Barley; Oat; Rye;                | 0.04                        | STMR (Table B.1.2.1)      | 0.04          | STMR (Table B.1.2.1) |
| Wheat                            | 0.01                        | STMR (Table B.1.2.1)      | 0.01          | STMR (Table B.1.2.1) |
| Maize; Millet; Sorghum           | 0.01                        | STMR (Table B.1.2.1)      | 0.01          | STMR (Table B.1.2.1) |
| Rape seeds                       | 0.01                        | STMR (EFSA, 2012)         |               |         |
| Other plant and animal commodities | MRL                        | Regulation (EU) 2017/171  |               |         |

**Risk assessment residue definition for plant commodities:** Sum aminopyralid and its conjugates expressed as aminopyralid (EFSA, 2013b).

Other plant and animal commodities: Acute risk assessment undertaken only for the commodities under assessment in the framework of the current MRL application.

STMR: supervised trials median residue; MRL: maximum residue level.
## Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| Aminopyralid          | 4-amino-3,6-dichloropyridine-2-carboxylic acid or 4-amino-3,6-dichloropicolinic acid Clc1c(nc(Cl)cc1N)C(=O)O | ![Structural formula](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 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).