Evaluation of confirmatory data following the Article 12 MRL review for picolinafen

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Abstract

The applicant BASF Agro B.V. submitted a request to the competent national authority in Germany to evaluate the confirmatory data that were identified for picolinafen in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps, a new validated analytical method for enforcement of the residue in dry/high starch-, high water content-, high acid content- and high oil content commodities and a new validated analytical method for enforcement of the residue in ruminant matrices were submitted. The data gaps were considered satisfactorily addressed. The new information provided may require a revision of the existing MRLs for barley, oat, rye and wheat and for products of animal origin. The risk assessment performed for picolinafen was updated. No consumer intake concerns were identified.

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Keywords: picolinafen, confirmatory data, pesticide, MRL review, risk assessment

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Summary

In 2013, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for picolinafen according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) an independent laboratory validation (ILV) for enforcement of the residue in dry commodities and straw (in process of evaluation for the renewal of the approval of picolinafen under Regulation (EC) No 1107/2009);

2) a validated analytical method (with confirmatory method and ILV) for enforcement of the residue in ruminants matrices (in process of evaluation for the renewal of the approval of picolinafen under Regulation (EC) No 1107/2009);

3) further investigation on the magnitude of residues in ruminants (ruminant feeding study).

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 1126/2014, including footnotes related to data gaps number 1, 2 and 3, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 24 October 2016.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, BASF Agro B.V. submitted an application to the competent national authority in Germany (rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 26 April 2018.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005. In view of future assessments of uses of picolinafen in crops that can be used as feed items, a risk management decision on the residue definitions for both enforcement and risk assessment purposes should be taken, considering the proposals derived in the previous assessments. EFSA derived MRL proposals for three different residue definitions (i.e. the current residue definition set in Regulation (EC) No 396/2005 and the two proposed residue definitions derived by EFSA in the framework of the MRL review and the renewal of the approval for picolinafen).

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------|----------------|--------------|---------------------------|
| **Enforcement residue definition in plants:** Picolinafen | | | |
| **Enforcement residue definition in animals:** | | | |
| **Option 1:** Current residue definition Regulation (EC) No 396/2005: Picolinafen | | | |
| **Option 2:** Proposed residue definition MRL review (EFSA, 2013): Sum of picolinafen and picolinic acid, expressed as picolinafen | | | |
| **Option 3:** Proposed residue definition Peer review (EFSA, 2015): Picolinic acid (CL 153815) expressed as picolinic acid | | | |
| 0500010 | Barley | 0.05* (ft1) | 0.05 | The data gap identified by EFSA concerning analytical methods has been addressed. The applicant submitted a new validated method with an LOQ of 0.01 mg/kg. Therefore it is proposed to delete the asterisk, indicating that the MRL is set at the LOQ of the analytical method available for enforcement purpose. Risk for consumers unlikely |
| 0500050 | Oats | 0.05* (ft1) | 0.05 | |
| 0500070 | Rye | 0.05* (ft1) | 0.05 | |
| 0500090 | Wheat | 0.05* (ft1) | 0.05 | |

(a) The code 05 identifies cereal grains as the commodity group (0500010 = Barley).

(b) The existing MRLs are set in Regulation (EC) No 396/2005.

www.efsa.europa.eu/efsajournal 3 EFSA Journal 2018;16(11):5489
| Code<sup>(a)</sup> | Commodity | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation |
|----------------|-----------|-----------------|-------------|--------------------------|
| 1012010 | Bovine (muscle) | 0.02* (ft 2) | Option 1: 0.01* Option 2: 0.02* Option 3: 0.01* | The submitted analytical method for animal origin products was sufficiently validated for quantifying picolinafen and its metabolite picolinic acid; the LOQ for picolinafen and picolinic acid is 0.01 mg/kg, respectively (combined LOQ for residue definition option 2: 0.02 mg/kg) |
| 10130101014010 | Sheep (muscle) Goat (muscle) | Option 1: 0.01* Option 2: 0.02* Option 3: 0.01* | | |
| 1012020 | Bovine (fat) | 0.02* (ft 2) | Option 1: 0.01* Option 2: 0.02* Option 3: 0.01* | No new livestock metabolism studies were submitted and, based on the agreement of experts derived in the framework of the peer review (EFSA, 2015), the available metabolism study is sufficient to derive MRL proposals for animal products |
| 1013020 | Sheep (fat) | Option 1: 0.01* Option 2: 0.02* Option 3: 0.01* | | |
| 1014020 | Goat (fat) | Option 1: 0.01* Option 2: 0.02* Option 3: 0.01* | | |
| 1012030 | Bovine (liver) | 0.02* (ft 2) | Option 1: 0.01* Option 2: 0.02* Option 3: 0.01* | | |
| 1013030 | Sheep (liver) | Option 1: 0.01* Option 2: 0.02* Option 3: 0.01* | | |
| 1014030 | Goat (liver) | Option 1: 0.01* Option 2: 0.02* Option 3: 0.01* | | |
| 1012040 | Bovine (kidney) | 0.02* (ft 2) | Option 1: 0.01* Option 2: 0.05 Option 3: 0.04 | | |
| 1013040 | Sheep (kidney) | Option 1: 0.01* Option 2: 0.05 Option 3: 0.04 | | |
| 1014040 | Goat (kidney) | Option 1: 0.01* Option 2: 0.05 Option 3: 0.04 | | |
| 1020010 | Milk (cattle, sheep, goat) | 0.01* (ft 2) | Option 1: 0.01* Option 2: 0.02* Option 3: 0.01* | | |
| 1020020 | | | | | |
| 1020030 | | | | | |

MRL: maximum residue level; LOQ: limit of quantification.

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

(b): Existing EU MRL and corresponding footnote on confirmatory data.

ft 1: The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 24 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1).

ft 2: The European Food Safety Authority identified some information on analytical methods and feeding study for ruminants as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 24 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gaps No 2 and 3).
# Table of contents

Abstract .......................................................................................................................................................... 1  
Summary .................................................................................................................................................... 3  
Assessment .................................................................................................................................................. 6  
1.  Residues in plants .................................................................................................................................... 6  
   1.1. Nature of residues and methods of analysis in plants ..................................................................... 6  
   1.1.1. Nature of residues in primary crops .......................................................................................... 6  
   1.1.2. Nature of residues in rotational crops ....................................................................................... 6  
   1.1.3. Nature of residues in processed commodities ......................................................................... 7  
   1.1.4. Methods of analysis in plants ................................................................................................... 7  
   1.1.5. Stability of residues in plants ..................................................................................................... 7  
   1.1.6. Proposed residue definitions ..................................................................................................... 7  
   1.2. Magnitude of residues in plants .................................................................................................... 7  
2.  Residues in livestock ............................................................................................................................... 7  
   2.1. Nature of residues .......................................................................................................................... 7  
   2.2. Methods of analysis in livestock ................................................................................................... 8  
   2.3. Magnitude of residues in livestock ............................................................................................... 8  
3.  Consumer risk assessment .................................................................................................................... 8  
4.  Conclusion and Recommendations .................................................................................................... 8  
References ................................................................................................................................................... 9  
Abbreviations .............................................................................................................................................. 9  
Appendix A – List of end points ................................................................................................................ 10  
Appendix B – Pesticide Residue Intake Model (PRIMo) ........................................................................ 16  
Appendix C – Input values for the exposure calculations ..................................................................... 18  
Appendix D – Used compound codes .................................................................................................... 19
Assessment

The review of existing maximum residue levels (MRLs) for picolinafen according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed in 2013 (EFSA, 2013). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 1126/2014, including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 24 October 2016. In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016), the applicant, BASF Agro B.V., submitted an application to the competent national authority in Germany (designated rapporteur Member State (RMS)) for the evaluation of confirmatory data. To address the data gaps identified by EFSA, the applicant provided (i) a new validated analytical method for enforcement of the residue in dry/high starch-, high water content-, high acid content- and high oil content commodities, and (ii) a new validated analytical method for enforcement of the residue in ruminant matrices which allows quantification of parent picolinafen and its metabolite picolinic acid (CL 153815).

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 26 April 2018 (Germany, 2018). EFSA assessed the application as requested by the European Commission in accordance with Article 9 of Regulation (EC) No 396/2005.

EFSA based its assessment on the evaluation report submitted by the RMS (Germany, 2018), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2013) and took into account the European Union (EU) peer review for the renewal of the approval of the active substance (EFSA, 2015).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 1126/2014 are applicable. 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.

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix A.

The evaluation report submitted by the RMS (Germany, 2018) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document 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

Not relevant for the current assessment.

1.1.2. Nature of residues in rotational crops

Not relevant for the current assessment.

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1 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.

2 Commission Regulation (EU) No 1126/2014 of 17 October 2014 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for asulam, cyanamide, dicrotan, flumioxazin, flupyrsulfuron-methyl, picolinafen and propisochlor in or on certain products. OJ L 305, 24.10.2014, p. 3–46.

3 Chemical structure of active substance and metabolite is provided in REF _Ref526936162 \h Appendix D.

4 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.

5 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.
1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Methods of analysis in plants

In order to address data gap number 1, the applicant provided a validated analytical method, including independent laboratory validation, for the determination of picolinafen in plant commodities. The method was assessed during the EU pesticides peer review (EFSA, 2015) and was considered sufficiently validated; the method is suitable to be used by enforcement laboratories to check compliance with the existing MRLs of picolinafen in commodities with high water content, commodities with high acid content, commodities with high oil content and dry crops with a limit of quantification (LOQ) of 0.01 mg/kg for all matrices.

Details on the analytical method are presented in Appendix A.1.1.1.

EFSA concluded that the data gap identified in the framework of the MRL review was sufficiently addressed.

1.1.5. Stability of residues in plants

Not relevant for the current assessment.

1.1.6. Proposed residue definitions

The previously derived residue definitions are still applicable (EFSA, 2013, 2015).

1.2. Magnitude of residues in plants

Not relevant for the current assessment.

2. Residues in livestock

In the framework of the MRL review (EFSA, 2013), the need to establish MRLs for food of animal origin was assessed. For that purpose, the dietary burden for livestock was calculated, taking into account the reported Good Agricultural Practices (GAPs) for crops that can be used for feed purpose. The calculation was performed according to the EU methodology applicable at the time (European Commission, 1997). Since the estimated dietary burden for ruminants exceeded the trigger value, EFSA derived residue definitions for food of animal origin, based on the results of a metabolism study in goats. Parent compound picolinafen was metabolised readily in lactating goats; hence, EFSA proposed to change the residue definition for enforcement by including also the carboxylic acid metabolite of picolinafen (proposed residue definition for risk assessment and enforcement: sum of picolinafen and 6-(3-trifluoromethylphenoxy)-pyridine-2-carboxylic acid, expressed as picolinafen). Considering that no sufficiently validated analytical method was available for the residue definition proposed by EFSA, a data gap was identified (see Section Assessment, data gap number 2). It is noted that the RMS Germany did not agree on the proposed residue definition, but was of the opinion that for picolinafen the setting of MRLs and the setting of a residue definition is not necessary (EFSA, 2013).

Risk managers decided not to implement the proposed residue definition in Regulation (EU) No 1126/2014, but to leave the default residue definition which comprises only the parent compound.

EFSA also noted that a feeding study would be required to estimate residues expected in food of animal origin (see Section Assessment, data gap number 3). Lacking a feeding study, EFSA derived tentative MRL proposals using the metabolism study in lactating ruminants (EFSA, 2013).

As regards the MRLs for animal products, risk managers decided to set the MRLs for all animal products at the LOQ of 0.02 mg/kg, including a footnote to the MRLs for certain animal commodities (ruminants muscle, fat, liver, kidney and milk) that highlighted that EFSA identified some information on analytical methods and a feeding study for ruminants as unavailable.

2.1. Nature of residues

The available metabolism study in lactating goats was assessed previously (EFSA, 2013, 2015). No new studies were submitted in the context of this application.

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6 Metabolite 6-(3-trifluoromethylphenoxy)-pyridine-2-carboxylic acid is also referred to as picolinic acid or CL 153815.
In view of future assessments of uses of picolinafen in crops that can be used as feed items, a risk management decision on the residue definitions for both enforcement and risk assessment purposes has to be taken, considering the proposals derived in the previous assessments:

- Option 1: Current residue definition for enforcement set in Regulation (EC) No 396/2005: Picolinafen;
- Option 2: Residue definition for enforcement and risk assessment proposed in the framework of the MRL review (EFSA, 2013): Sum of picolinafen and 6-(3-trifluoromethylphenoxy)-pyridine-2-carboxylic acid (CL 153815), expressed as picolinafen;
- Option 3: Residue definitions derived in the framework of the renewal of the active substance (EFSA, 2015).
  — enforcement residue definition: CL 153815, expressed as CL 153815;
  — risk assessment residue definition: Picolinafen and CL 153845 (expressed as picolinafen).

Depending on the decision taken for the enforcement residue definition, the current MRLs for animal products may need to be reconsidered (see Section 2.3).

2.2. Methods of analysis in livestock

In order to address data gap number 2, the applicant provided a validated analytical method, including independent laboratory validation, for the determination of picolinafen and its metabolite picolinic acid in animal commodities. The method was previously assessed during the EU pesticides peer review (EFSA, 2015) and was considered sufficiently validated to control residues of picolinafen and picolinic acid in milk, eggs, bovine meat, bovine fat, bovine kidney, bovine liver with a LOQ of 0.01 mg/kg for picolinafen and its metabolite CL 153815, respectively, in all animal matrices.

Details on the analytical method are presented in Appendix A.2.1.1. EFSA concluded that the data gap (2) identified in the framework of the MRL review was addressed.

2.3. Magnitude of residues in livestock

The applicant did not provide a feeding study in ruminants.

In the framework of the renewal of the approval for picolinafen the need to set MRLs for animal products was discussed. The experts agreed that the metabolism study in lactating goats would be sufficient to estimate the expected residues in animal products, and thus, a feeding study was not considered necessary (EFSA, 2015). Acknowledging this agreement, EFSA concluded that the data gap number 3 identified in the framework of the MRL review is sufficiently addressed.

Depending on the decision on the residue definition for animal products, the existing MRLs for animal products may need to be reconsidered, taking into account the expected occurrence of parent picolinafen and its metabolite as well as the LOQ of the analytical method available for MRL enforcement.

It should also be highlighted that in the framework of the renewal of the approval for picolinafen (EFSA, 2015) additional residue trials on barley and wheat were submitted which have an influence on the dietary burden for livestock. Thus, EFSA recalculated the dietary burden for ruminants, using the current OECD methodology (OECD, 2013). The input values and the calculated dietary burden are presented in Appendices C and A, respectively.

Based on the revised dietary burden, EFSA derived MRL proposals for the three options of the residue definition for enforcement (see Appendix A.4).

3. Consumer risk assessment

The submitted confirmatory data did not trigger a modification of risk assessment performed in the framework of the MRL review of picolinafen (EFSA, 2013) and the conclusions derived are still valid.

4. Conclusion and Recommendations

To address data gaps identified in the framework of the MRL review (EFSA, 2013), a validated analytical method, including independent laboratory validation, for the determination of picolinafen in plant commodities and a validated analytical method, including independent laboratory validation, for the determination of picolinafen and its metabolite 6-(3-trifluoromethylphenoxy)-pyridine-2-carboxylic acid (also referred to as picolinic acid or CL 153815) in animal commodities were submitted by the applicant. Thus, data gaps number 1 and 2 are fully addressed.
Acknowledging the agreement of experts derived in the framework of the peer review (EFSA, 2015) that the available metabolism study is sufficient to derive MRL proposals for animal products, and that therefore a feeding study is not required, the data gap number 3 asking for further investigation on the magnitude of residues in ruminants (ruminant feeding study) is also sufficiently addressed.

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix A.4.

References

EFSA (European Food Safety Authority), 2013. Reasoned opinion on the review of the existing maximum residue levels for picolinafen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(5):3222, 34 pp. https://doi.org/10.2903/j.efsa.2013.3222

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance picolinafen. EFSA Journal 2015;13(11):4279, 66 pp. https://doi.org/10.2903/j.efsa.2015.4279

European Commission, 1997. Appendix I. Calculation of maximum residue level and safety intervals.7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2016. Commission staff working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 17 June 2016. SANTE/E4/VW 10235/2016 - Rev. 2, 3pp., Brussels, 17 June 2016.

Germany, 2018. Evaluation report on the evaluation of confirmatory data for the review of the existing MRLs for picolinafen according to Article 12 of Regulation (EC) No 396/2005. February 2018, 19 pp.

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.

Abbreviations

**ADI** acceptable daily intake  
**AR** applied radioactivity  
**ARfd** acute reference dose  
**bw** body weight  
**CF** conversion factor for enforcement to risk assessment residue definition  
**DAR** draft assessment report  
**DM** dry matter  
**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  
**IEEDI** international estimated daily intake  
**IEESTI** international estimated short-term intake  
**ILV** independent laboratory validation  
**InChiKey** International Chemical Identifier Key.  
**ISO** International Organisation for Standardisation  
**IUPAC** International Union of Pure and Applied Chemistry  
**LOQ** limit of quantification  
**MRL** maximum residue level  
**OECD** Organisation for Economic Co-operation and Development  
**PF** processing factor  
**PRIMo** (EFSA) Pesticide Residues Intake Model  
**QuEChERS** Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)  
**RA** risk assessment  
**RD** residue definition  
**RMS** rapporteur Member State  
**SANCO** Directorate-General for Health and Consumers  
**SMILES** simplified molecular-input line-entry system  
**STMR** supervised trials median residue  
**TAR** total applied radioactivity
Appendix A – List of end points

A.1. Residues in plants

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

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

No additional studies provided under the current application except analytical methods. For metabolism studies and residue definitions, see previous assessments (EFSA, 2013, 2015).

| Can a general residue definition be proposed for primary crops? |
|---|
| Yes | EFSA (2015) |

| Rotational crop and primary crop metabolism similar? |
|---|
| Yes | EFSA (2015) |

| Residue pattern in processed commodities similar to residue pattern in raw commodities? |
|---|
| Not triggered | EFSA (2015) |

| Plant residue definition for monitoring (RD-Mo) |
|---|
| Picolinafen (EFSA, 2013; 2015) |

| Plant residue definition for risk assessment (RD-RA) |
|---|
| Picolinafen (EFSA, 2013; 2015) |

| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) |
|---|
| HPLC–MS/MS method based on the QuEChERS multiresidue method validated in commodities with high water content, commodities with high acid content, commodities with high oil content and dry crops with a LOQ of 0.01 mg/kg for all matrices. ILV available (EFSA 2015, Germany 2018) |

HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; LOQ: limit of quantification; ILV: independent laboratory validation.

A.1.1.2. Stability of residues in plants

No additional studies provided under the current application. See previous assessments (EFSA, 2013, 2015).

A.1.2. Magnitude of residues in plants

No additional studies provided under the current application. See previous assessments (EFSA, 2013, 2015).
### A.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day Median | Maximum | mg/kg DM Median | Maximum | Most critical subgroup<sup>(a)</sup> | Most critical commodity<sup>(b)</sup> | Trigger exceeded (Y/N) |
|---------------------------|--------------------------------|---------|----------------|---------|--------------------------------|--------------------------------|---------------------|
| Cattle (all)              | 0.003                          | 0.016   | 0.08           | 0.40    | Dairy cattle                    | Barley straw                   | Y                   |
| Cattle (dairy only)       | 0.003                          | 0.016   | 0.08           | 0.40    | Dairy cattle                    | Barley straw                   | Y                   |
| Sheep (all)               | 0.005                          | 0.032   | 0.11           | 0.75    | Lamb                            | Barley straw                   | Y                   |
| Sheep (ewe only)          | 0.004                          | 0.025   | 0.11           | 0.75    | Ram/Ewe                         | Barley straw                   | Y                   |
| Swine (all)               | 0.002                          | 0.002   | 0.08           | 0.08    | Swine (finishing)               | Distiller’s grain dried        | N                   |
| Poultry (all)             | 0.005                          | 0.010   | 0.07           | 0.15    | Poultry layer                   | Wheat straw                    | Y                   |
| Poultry (layer only)      | 0.005                          | 0.010   | 0.07           | 0.15    | Poultry layer                   | Wheat straw                    | Y                   |
| 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’.
A.2.1. Nature of residues and methods of analysis in livestock

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

No additional studies provided under the current application. See previous assessment of the metabolism in goats (EFSA, 2013, 2015).

| Time needed to reach a plateau concentration in milk and eggs (days) | Milk                          | Not relevant for the current assessment. Refer to EFSA (2015) |
|---------------------------------------------------------------------|-------------------------------|---------------------------------------------------------------|
|                                                                     | Eggs                          | Not relevant for the current assessment. Refer to EFSA (2015) |
| Metabolism in rat and ruminant similar                              | Yes                           | EFSA (2015)                                                   |
| Can a general residue definition be proposed for animals?           | Yes                           | EFSA (2015)                                                   |
| Animal residue definition for monitoring (RD-Mo)                    | **Option 1**: Picolinafen (current definition set in Regulation (EC) No 396/2005) |
|                                                                     | **Option 2**: Sum of picolinafen and 6-(3-trifluoromethylphenoxy)-pyridine-2-carboxylic acid (CL 153815), expressed as picolinafen (EFSA, 2013) |
|                                                                     | **Option 3**: Picolinic acid (CL 153815) expressed as CL 153815 (EFSA, 2015) |
| Animal residue definition for risk assessment (RD-RA)               | Sum of picolinafen and picolinic acid expressed as picolinafen (EFSA 2013, 2015) |
|                                                                     | For option 3: A conversion factor of 1.4 from monitoring to risk assessment is proposed to account for molecular weight differences of picolinic acid and picolinafen (EFSA 2015) |
| Fat soluble residues                                                | No                            | EFSA 2015                                                     |
| Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs) | HPLC–MS/MS method based on QuEChERS multiresidue method validated in milk, eggs, bovine meat, bovine fat, bovine kidney, bovine liver is available for the determination of picolinafen and picolinic acid with LOQs of 0.01 mg/kg for each compound in all animal matrices. ILV available (EFSA 2015, Germany, 2018) |

HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; LOQ: limit of quantification; ILV: independent laboratory validation.

A.2.1.2. Stability of residues in livestock

No additional studies provided under the current application. See previous assessments (EFSA, 2013, 2015).

A.2.2. Magnitude of residues in livestock

No additional studies provided under the current application. See previous assessments (EFSA, 2013, 2015).

A.2.2.1. Summary of the residue data from livestock feeding studies

Based on the revised dietary burden, EFSA derived MRL proposals for the **3 options of the residue definition for enforcement**.
**Residue definition for risk assessment** in all three options: Sum of picolinafen and 6-(3-trifluoromethylphenoxy)-pyridine-2-carboxylic acid (CL 153815), expressed as picolinafen (EFSA, 2013, 2015).

**Option 1:** RD for enforcement: Picolinafen (current definition set in Regulation (EC) No 396/2005)
RD for risk assessment: Sum of picolinafen and 6-(3-trifluoromethylphenoxy)-pyridine-2-carboxylic acid (CL 153815), expressed as picolinafen (EFSA, 2013, 2015)

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF |
|------------------|---------------------------------------------|-----------------------|----------------------|----|
|                  | Mean | Highest | STMR\(^{(a)}\) (mg/kg) | HR\(^{(b)}\) (mg/kg) |    |
| Cattle (all)     |      |         |                         |                      |    |
| Closest feeding level (0.28 mg/kg bw; 18.0 N rate)
| Muscle           | 0.01 | 0.01    | 0.00                    | 0.00                | 0.01* |
| Fat              | 0.00 | 0.00    | 0.00                    | 0.00                | 0.01* |
| Liver            | 0.17 | 0.17    | 0.00                    | 0.01                | 0.01* |
| Kidney           | 0.80 | 0.80    | 0.01                    | 0.04                | 0.01* |
| Milk             | 0.04 | 0.04    | 0.00                    | 0.00                | 0.01* |

**Option 2:** RD for enforcement: Sum of picolinafen and 6-(3-trifluoromethylphenoxy)-pyridine-2-carboxylic acid (CL 153815), expressed as picolinafen (EFSA, 2013)
RD for risk assessment: Sum of picolinafen and 6-(3-trifluoromethylphenoxy)-pyridine-2-carboxylic acid (CL 153815), expressed as picolinafen (EFSA, 2013, 2015)

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF |
|------------------|---------------------------------------------|-----------------------|----------------------|----|
|                  | Mean | Highest | STMR\(^{(a)}\) (mg/kg) | HR\(^{(b)}\) (mg/kg) |    |
| Cattle (all)     |      |         |                         |                      |    |
| Closest feeding level (0.28 mg/kg bw; 18.0 N rate)
| Muscle           | 0.01 | 0.01    | 0.00                    | 0.00                | 0.01* |
| Fat              | 0.00 | 0.00    | 0.00                    | 0.00                | 0.01* |
| Liver            | 0.17 | 0.17    | 0.00                    | 0.01                | 0.01* |
| Kidney           | 0.80 | 0.80    | 0.01                    | 0.04                | 0.05  |
| Milk             | 0.04 | 0.04    | 0.00                    | 0.00                | 0.01* |

**Option 3:** RD for enforcement: Picolinic acid (CL 153815) expressed as CL 153815 (EFSA, 2015)
RD for risk assessment: Sum of picolinafen and 6-(3-trifluoromethylphenoxy)-pyridine-2-carboxylic acid (CL 153815), expressed as picolinafen (EFSA, 2013, 2015)

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF |
|------------------|---------------------------------------------|-----------------------|----------------------|----|
|                  | Mean | Highest | STMR\(^{(a)}\) (mg/kg) | HR\(^{(b)}\) (mg/kg) |    |
| Cattle (all)     |      |         |                         |                      |    |
| Closest feeding level (0.28 mg/kg bw; 18.0 N rate)
| Muscle           | 0.01 | 0.01    | 0.00                    | 0.00                | 0.01* |
| Fat              | 0.00 | 0.00    | 0.00                    | 0.00                | 0.01* |
| Liver            | 0.12 | 0.12    | 0.00                    | 0.01                | 0.01* |
| Kidney           | 0.57 | 0.57    | 0.01                    | 0.03                | 0.04  |
| Milk             | 0.04 | 0.04    | 0.00                    | 0.00                | 0.01* |

RD: residue definition; MRL: maximum residue level; bw: body weight; STMR: supervised trials median residue; HR: highest residue.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): Mean 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.
A.3. Consumer risk assessment

**ARfD**

Highest IESTI, according to EFSA PRIMo

| Commodity   | ARfD (mg/kg bw) |
|-------------|-----------------|
| Wheat       | 0.05            |
| Rye         | 0.05            |
| Oats        | 0.05            |

Assumptions made for the calculations

The risk assessment for cereals was performed on the basis of the median residue. For animal commodities, the calculation is based on the highest residue levels expected in ruminant meat, fat, liver and kidney and the median residue expected in milk which are expressed as the sum of picolinafen and picolinic acid based on the residue definition for risk assessment (EFSA 2015).

**ADI**

Highest IEDI, according to EFSA PRIMo

| Commodity   | ADI (mg/kg bw per day) |
|-------------|------------------------|
|             | 0.014                  |

Assumptions made for the calculations

The calculation is based on the median residue levels derived for raw agricultural commodities (barley, oat, rye and wheat). For animal commodities, calculation is based on the median residue levels which are expressed as the sum of picolinafen and picolinic acid based on the residue definition for risk assessment (EFSA 2015).

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.

A.4. Recommended MRLs

| Code(a)  | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                 |
|----------|-----------|-----------------|--------------|------------------------------------------------------------------------------------------|
| 0500010  | Barley    | 0.05* (0)       | 0.05         | The data gap identified by EFSA concerning analytical methods has been addressed. The applicant submitted a new validated method with an LOQ of 0.01 mg/kg. Therefore it is proposed to delete the asterisk, indicating that the MRL is set at the LOQ of the analytical method available for enforcement purpose. Risk for consumers unlikely |
| 0500050  | Oats      | 0.05* (0)       | 0.05         |                                                                                          |
| 0500070  | Rye       | 0.05* (0)       | 0.05         |                                                                                          |
| 0500090  | Wheat     | 0.05* (0)       | 0.05         |                                                                                          |

**Enforcement residue definition in plants:** Picolinafen

**Enforcement residue definition in animals:**

- **Option 1:** Current residue definition Regulation (EC) No 396/2005: Picolinafen
- **Option 2:** Proposed residue definition MRL review (EFSA, 2013): Sum of picolinafen and picolinic acid, expressed as picolinafen
- **Option 3:** Proposed residue definition Peer review (EFSA, 2015): Picolinic acid (CL 153815) expressed as picolinic acid

www.efsa.europa.eu/efsajournal 14  EFSA Journal 2018;16(11):5489
| Code<sup>a</sup> | Commodity | Existing MRL<sup>b</sup> | Proposed MRL | Conclusion/recommendation |
|-----------------|-----------|------------------------|--------------|---------------------------|
| 1012010         | Bovine (muscle) | 0.02* (ft 2) | Option 1: 0.01* | The submitted analytical method for animal origin products was sufficiently validated for quantifying picolinafen and its metabolite picolinic acid; the LOQ for picolinafen and picolinic acid is 0.01 mg/kg, respectively (combined LOQ for residue definition option 2: 0.02 mg/kg) |
| 10130101014010  | Sheep (muscle) | 0.02* (ft 2) | Option 1: 0.01* | |
| 1012020         | Bovine (fat) | 0.02* (ft 2) | Option 1: 0.01* | |
| 1013020         | Sheep (fat) | 0.02* (ft 2) | Option 1: 0.01* | |
| 1014020         | Goat (fat) | 0.02* (ft 2) | Option 1: 0.02* | |
| 1012030         | Bovine (liver) | 0.02* (ft 2) | Option 1: 0.01* | No new livestock metabolism studies were submitted and, based on the agreement of experts derived in the framework of the peer review (EFSA, 2015), the available metabolism study is sufficient to derive MRL proposals for animal products |
| 1013030         | Sheep (liver) | 0.02* (ft 2) | Option 1: 0.02* | |
| 1014030         | Goat (liver) | 0.02* (ft 2) | Option 1: 0.01* | |
| 1012040         | Bovine (kidney) | 0.02* (ft 2) | Option 1: 0.01* | |
| 1013040         | Sheep (kidney) | 0.05 | Option 2: 0.05 | |
| 1014040         | Goat (kidney) | 0.04 | Option 3: 0.04 | |
| 1020010         | Milk (cattle, sheep, goat) | 0.01* (ft2) | Option 1: 0.01* | |
| 1020020         | 0.02 | Option 2: 0.02* | |
| 1020030         | 0.01 | Option 3: 0.01* | |

MRL: maximum residue level; LOQ: limit of quantification.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.

ft 1: The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 24 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1).

ft 2: The European Food Safety Authority identified some information on analytical methods and feeding study for ruminants as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 24 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 2 and 3).
### Appendix B – Pesticide Residue Intake Model (PRIMo)

#### Picolinafen

| Toxicological end points | ADI (mg/kg bw per day): | Proposed ADI: | ARfD (mg/kg bw): | Proposed ARfD: |
|-------------------------|-------------------------|---------------|------------------|---------------|
|                         | 0.014                   | 0.06          |                  |               |

Source of ADI: Source of ARfD:

| Year of evaluation: | Year of evaluation: |
|---------------------|---------------------|
|                     |                     |

| No of diets exceeding ADI: | --- |
|---------------------------|-----|

#### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI values in % of ADI | No of diets exceeding ADI: |
|--------------------------------|--------------------------|----------------------------|
| Wheat                          | 3.7 DK child             | 2.0                         |
|                                 | 2.6 WHO Cluster diet B   | 2.3                         |
|                                 | 1.9 WHO Cluster diet D   | 2.4                         |
|                                 | 1.8 DE child             | 1.4                         |
|                                 | 1.6 NL 50%               | 1.5                         |
|                                 | 1.5 IT adult             | 1.6                         |
|                                 | 1.4 UK Toddler           | 1.4                         |
|                                 | 1.4 IE adult             | 0.8                         |
|                                 | 1.2 SE general population 50th percentiles | 1.1 |
|                                 | 1.2 WHO regional European diet | 1.2 |
|                                 | 1.0 FR all population    | 1.2                         |
|                                 | 1.0 UK Infant            | 0.9                         |
|                                 | 1.0 ES adult             | 0.8                         |
|                                 | 1.0 DK adult             | 0.7                         |
|                                 | 0.9 FR toddler           | 0.9                         |
|                                 | 0.9 NL general           | 0.7                         |
|                                 | 0.8 LT adult             | 0.4                         |
|                                 | 0.8 UK vegetarian        | 0.7                         |
|                                 | 0.6 FI adult             | 0.4                         |
|                                 | 0.6 UK Adult             | 0.6                         |
|                                 | 0.3 FR infant            | 0.3                         |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Picolinafen is unlikely to present a public health concern.
### Acute risk assessment/children – refined calculations

The acute risk assessment is based on the ARfD. 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 ARfD.

| Unprocessed commodities | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|-------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|
|                         | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) |
| 1.4 Wheat                | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   |
| 0.6 Rye                  | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   |
| 0.4 Oats                 | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   |
| 0.3 Bovine: Kidney       | 0.04 / -                                                   | 0.04 / -                                                   | 0.04 / -                                                   | 0.04 / -                                                   |
| 0.2 Barley               | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   |

| Processed commodities    | No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|--------------------------|--------------------------------------------------|--------------------------------------------------|
|                         | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) |
| 1.2 Wheat flour          | 0.05 / -                                                   | 0.05 / -                                                   |
| 0.4 Bread/pizza          | 0.05 / -                                                   | 0.05 / -                                                   |

| No of critical MRLs (IESTI 1): | --- | --- |
| No of critical MRLs (IESTI 2): | --- | --- |

### Acute risk assessment/adults/general population – refined calculations

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

| Unprocessed commodities | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|-------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|
|                         | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) |
| 1.4 Wheat               | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   |
| 0.6 Rye                 | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   |
| 0.4 Oats                | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   |
| 0.3 Bovine: Kidney      | 0.04 / -                                                   | 0.04 / -                                                   | 0.04 / -                                                   | 0.04 / -                                                   |
| 0.2 Barley              | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   | 0.05 / -                                                   |

| Processed commodities   | No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|--------------------------|--------------------------------------------------|--------------------------------------------------|
|                         | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities pTMRL/ threshold MRL (mg/kg) |
| 1.2 Wheat flour          | 0.05 / -                                                   | 0.05 / -                                                   |
| 0.4 Bread/pizza          | 0.05 / -                                                   | 0.05 / -                                                   |

### Evaluation of confirmatory data for picolinafen to address data gaps identified in the MRL review

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

***) pTMRL: provisional temporary MRL for unprocessed commodity.
****) pTMRL: provisional temporary MRL for processed commodity.

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

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

### Conclusion:

For Picolinafen 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.

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

***) pTMRL: provisional temporary MRL for unprocessed commodity.
****) pTMRL: provisional temporary MRL for processed commodity.

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

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

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.
### Appendix C – Input values for the exposure calculations

#### C.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 plants: picolinafen
| Barley straw            | 0.05 STMR (EFSA, 2015) | 1 HR (EFSA, 2015)      |
| Oat straw               | 0.05 STMR (EFSA, 2013) | 0.53 HR (EFSA, 2013)   |
| Rye straw               | 0.05 STMR (EFSA, 2013) | 0.53 HR (EFSA, 2013)   |
| Triticale straw         | 0.05 STMR (EFSA, 2015) | 0.69 HR (EFSA, 2015)   |
| Wheat straw             | 0.05 STMR (EFSA, 2015) | 0.69 HR (EFSA, 2015)   |
| Barley grain            | 0.05 STMR (EFSA, 2015) | 0.05 STMR (EFSA, 2015) |
| Oat grain               | 0.05 STMR (EFSA, 2013) | 0.05 STMR (EFSA, 2013) |
| Rye grain               | 0.05 STMR (EFSA, 2013) | 0.05 STMR (EFSA, 2013) |
| Triticale grain         | 0.05 STMR (EFSA, 2015) | 0.05 STMR (EFSA, 2015) |
| Wheat grain             | 0.05 STMR (EFSA, 2015) | 0.05 STMR (EFSA, 2015) |
| Brewer's grain dried    | 0.17 0.05 STMR × 3.3 PF(a) (EFSA, 2015) | 0.17 0.05 STMR × 3.3 PF(a) (EFSA, 2015) |
| Distiller's grain dried | 0.17 0.05 STMR × 3.3 PF(a) (EFSA, 2015) | 0.17 0.05 STMR × 3.3 PF(a) (EFSA, 2015) |
| Wheat gluten meal       | 0.09 0.05 STMR × 1.8 PF(a) (EFSA, 2015) | 0.09 0.05 STMR × 1.8 PF(a) (EFSA, 2015) |
| Wheat milled by-products| 0.05 STMR (EFSA, 2015) | 0.05 STMR (EFSA, 2015) |

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

(a): For brewer's grain dried, distiller's grain dried, wheat gluten meal, in the absence of processing factors supported by data, default processing factors of 3.3, 3.3 and 1.8 were respectively included in the calculation to consider the potential concentration of residues in these commodities.

#### C.2. Consumer risk assessment

| Commodity           | Chronic risk assessment | Acute risk assessment |
|---------------------|-------------------------|-----------------------|
|                     | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Barley grain        | 0.05 STMR (EFSA, 2015)  | 0.05 STMR (EFSA, 2015) |
| Oat grain           | 0.05 STMR (EFSA, 2013)  | 0.05 STMR (EFSA, 2013) |
| Rye grain           | 0.05 STMR (EFSA, 2013)  | 0.05 STMR (EFSA, 2013) |
| Wheat grain         | 0.05 STMR (EFSA, 2015)  | 0.05 STMR (EFSA, 2015) |
| Bovine, Sheep, Goat: kidney | 0.01 STMR               | 0.04 HR               |
| Bovine, Sheep, Goat: liver | 0.00 STMR              | 0.01 HR               |
| Milk (cattle, sheep, goat) | 0.00 STMR             | 0.00 STMR             |

STMR: supervised trials median residue; HR: highest residue.
## Appendix D – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|-------------------|-----------------------------------------------|----------------------------------|
| Picolinafen       | 4′-fluoro-6-(α,α,α-trifluoro-m-tolyloxy)pyridine-2-carboxanilide | ![Structural formula](image) |
|                   | Fc1ccc(cc1)NC(=O)c1ccccc(Oc2cccc(c2)C(F)(F)F)n1              | ![Structural formula](image) |
|                   | CWKFPEBMTGKLX-UHFFFAOYSA-N                           | ![Structural formula](image) |
| Picolinic acid (CL 153815) | 6-[(3-trifluoromethyl)phenoxy]-2-pyridinecarboxylic acid | ![Structural formula](image) |
|                   | FC(F)(F)c1ccccc(Oc1cccc(n1)C(=O)O                     | ![Structural formula](image) |
|                   | LFRASJXUIQMIMC-UHFFFAOYSA-N                         | ![Structural formula](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.  
<sup>(a)</sup>: ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).  
<sup>(b)</sup>: ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).