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

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance pyridalyl. To assess the occurrence of pyridalyl residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011, as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. All information required by the regulatory framework was present and a risk to consumers was not identified.

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Summary

Pyridalyl was approved on 1 July 2014 by means of Commission Regulation (EU) No 143/2014/EU in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

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

As the basis for the MRL review, on 14 August 2018, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 14 September 2018 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State the Netherlands to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 2 November 2018. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations were provided by the RMS to EFSA on 13 December 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURL, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011, EFSA prepared in June 2019 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 16 July 2019 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of pyridalyl in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as ‘pyridalyl’. This residue definition is also applicable to processed commodities. Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water content matrices at the limit of quantification (LOQ) of 0.01 mg/kg and in high oil content commodities with an LOQ of 0.02 mg/kg. According to the EURLs the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses in all plant matrices.

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

Pyridalyl is not authorised for use on crops that might be fed to livestock. Further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3 of the EFSA PRIMo. The exposure values calculated were compared with the toxicological reference value for pyridalyl derived by EFSA. The highest chronic exposure was calculated for GEMS Food G06, representing 5% of the acceptable daily intake (ADI). This calculation indicates that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.
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Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC\(^2\) a reasoned opinion on the review of the existing MRLs for that active substance.

As pyridalyl was approved on 1 July 2014 by means of Commission Regulation (EU) No 143/2014/ EU\(^3\) in the framework of Regulation (EC) No 1107/2009\(^4\) as amended by Commission Implementing Regulations (EU) No 540/2011\(^5\) and 541/2011\(^6\), EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EU) No 188/2011\(^7\), pyridalyl was evaluated by the Netherlands designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA conclusion (EFSA, 2013). The approval of Pyridalyl is restricted to uses as insecticide in greenhouses with permanent structure.

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

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

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

As the basis for the MRL review, on 14 August 2018 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 14 September 2018 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, eight Member States provided feedback on their national authorisations of pyridalyl. Based on the GAP data submitted, the designated RMS the Netherlands was asked to identify the critical GAPs to be further considered in the assessment, in the

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

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

\(^3\) Commission Implementing Regulation (EU) No 143/2014 of 14 February 2014 approving the active substance pyridalyl, 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 45, 15.2.2014, p. 1–6.

\(^4\) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

\(^5\) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

\(^6\) Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

\(^7\) Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51–55.
format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the critical GAPs by 2 November 2018.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked The Netherlands to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations, were submitted to EFSA on 13 December 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, EFSA prepared in June 2019 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 16 July 2019 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Netherlands, 2018), taking into account also the information provided by Member States during the collection of data, and the EURL report on analytical methods (EURL, 2018) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2019a) and the Member States consultation report (EFSA, 2019b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile as well as the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

**Terms of Reference**

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

**The active substance and its use pattern**

Pyridalyl is the ISO common name for 2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl 3-[5-(trifluoromethyl)-2-pyridyloxy]propyl ether (IUPAC).

The chemical structure of the active substance and its main metabolites are reported in Appendix F.

The EU MRLs for pyridalyl are established in Annexes IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for pyridalyl are not available. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

| Procedure | Legal implementation | Remarks |
|-----------|----------------------|---------|
| MRL application | Commission Regulation (EC) No 1050/2009 (a) | Tomatoes, aubergines (egg plants), peppers, cucurbits (in edible peel), lettuce and cotton seed (EFSA, 2009) |

MRL: maximum residue level.

(a): Commission Regulation (EC) No 1050/2009 of 28 October 2009 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 azoxystrobin, acetamiprid, clomazone, cyflufenamid, emamectin benzoate, farnoxadone, fenbutatin oxide, flufenoxuron, flupicicloide, indoxacarb, kloxynil, mepanipyrim, prothioconazole, pyridalyl, thiacloprid and trifloxystrobin in or on certain products. OJ L 290, 6.11.2009, p. 7–55.

For the purpose of this MRL review, all the uses of pyridalyl currently authorised within the EU as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for pyridalyl are given in...
Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (The Netherlands, 2018);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (The Netherlands, 2012, 2013);
- the conclusion on the peer review of the pesticide risk assessment of the active substance pyridalyl (EFSA, 2013);
- the previous reasoned opinion on pyridalyl (EFSA, 2009).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a, 2017; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of pyridalyl was investigated after foliar treatment in fruits, leafy vegetables and pulses and oilseeds (Netherlands, 2012) and assessed in the framework of the peer review (EFSA, 2013). In all studies, pyridalyl was radiolabelled on the phenyl ring and propenyl moiety, while for cotton, a third labelling on the pyridyl ring was used.

After four applications of 225 g a.s./ha on tomatoes, the major component of the total radioactive residues (TRR) was pyridalyl, representing 68–87% at preharvest interval (PHI) 1 and 69.9–84.8% TRR at PHI 7, in a range of 0.047–0.149 mg/kg (Netherlands, 2012; EFSA, 2013). After four applications of 225 g a.s./ha on cabbages, the major component identified was pyridalyl, representing 74–82% (0.864–3.84 mg eq/kg) of the TRR (Netherlands, 2012; EFSA, 2013). No other metabolite was present at significant levels in these crops.

After two applications of 561 g a.s./ha on cotton, the metabolism was more extensive than in fruits and leafy vegetables and parent pyridalyl represented only 6–13% of the TRR (0.011–0.024 mg eq/kg) in seeds and 43–65% of the TRR in gin trash (6.21–7.09 mg eq/kg), 21 days after the last application. Several metabolites resulting from the cleavage of the ether bound accounting for 2–11% of the TRR were identified (S-1812-PYP, TPPA, HTFP and HPDO), but no single metabolite was present at levels higher than 0.01 mg/kg (Netherlands, 2012; EFSA, 2013). The metabolic pathway of pyridalyl was similar in fruits, leafy vegetables and pulses and oilseeds.

1.1.2. Nature of residues in rotational crops

Pyridalyl is authorised on crops that may be grown in rotation. The field DT90 reported in the soil degradation studies evaluated in the framework of the peer review was 176–350 days (EFSA, 2013). Two confined rotational crop studies, a first one with pyridalyl radiolabelled either on the pyridyl or propenyl moiety and a second one with pyridalyl radiolabelled on the phenyl moiety, were available for this review (Netherlands, 2012). Pyridalyl was applied at a rate of 1.120 kg a.s./ha onto bare soil. Carrots, lettuce and wheat were planted at nominal plant-back intervals (PBI) of 30, 120 and circa 390 days after treatment (DAT).

The uptake of residues was dependent of the 14C label position (EFSA, 2009). In the studies with the propenyl and phenyl labels, limited uptake was observed. In particular, TRRs in the propenyl study

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8 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, 11.06.2011, p. 127–175.
(at all PBIs) and in the phenyl study (at PBI of 120 and 390 DAT) were too low for further characterisation (max 0.05 mg eq/kg). In the study with the phenyl label, at 30 DAT, the only identified compound was pyridalyl accounting for 27% TRR (0.011 mg eq/kg) in wheat hay and for 53.8% and 59.4% in carrot tops and roots, respectively. However, with the pyridyl label, the TRRs were significantly higher, ranging from 0.076 to 3.32 mg eq./kg in the crops planted at 30 and 120 days after treatment, decreasing to 0.024–0.512 mg eq./kg at 390 DAT (Netherlands, 2018). Metabolite HTFP (free and conjugated form) was the main component in all sampling intervals, accounting for 9.2–87% TRR, up to a maximum absolute level of 1.909 mg eq./kg in the carrot tops (120 DAT). In addition, metabolite HPDO was detected in lower amounts in wheat straw at 3–23% TRR (0.493 mg eq./kg) and carrot tops (0.211 mg eq./kg, DAT 30 but only 0.047 mg eq./kg, DAT 390). Minor identified metabolites were N-methyl-HTFP in wheat forage only (< 5.2% TRR) and N-methyl-HPDO (up to 11% TRR in wheat straw).

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed (Netherlands, 2012). Studies were conducted with radiolabelled pyridalyl simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). Pyridalyl was stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/baking and sterilisation (EFSA, 2009, 2013).

1.1.4. Methods of analysis in plants

A hyphenated analytical method DFG-S19 (modified) with a limit of quantification (LOQ) of 0.01 mg/kg in high water content commodities and an LOQ of 0.02 mg/kg for high oil content commodities was evaluated during the peer review (EFSA, 2013). This primary method is supported by an independent laboratory validation (ILV). During the completeness check, the EURLs reported that pyridalyl could be enforced with a LOQ of 0.01 mg/kg in all four main plant matrices (EURL, 2018).

1.1.5. Stability of residues in plants

The storage stability of pyridalyl was investigated (Netherlands, 2012). The available studies assessed in the framework of the peer review (EFSA, 2013) demonstrated the storage stability of pyridalyl for a period of 10 months when stored at –20°C in high water content matrices (tomato, pepper), for a period of 20 months when stored at –20°C in high oil content matrices (cotton seed) and for 19 months when stored at –20°C in dry matrices (cotton gin trash). In addition, metabolites HPDO and HTFP were found to be stable for a period of 28 months in dry content matrices (wheat straw) and high water content matrices (carrot roots and tops) at –20°C, whereas metabolite S-1812-DP was stable for at least 10 months in dry content matrices (cotton gin trash) at –20°C (EFSA, 2013). All crops under review belong to high water content matrices.

1.1.6. Proposed residue definitions

The metabolism of pyridalyl was similar in all crops assessed and the processing of pyridalyl is not expected to modify the nature of residues. As the parent compound was found to be a sufficient marker, the residue definition for enforcement is proposed as ‘pyridalyl’ only. The metabolism profile in the rotational crops study showed additional metabolites not identified in the primary and rat studies, but at very low levels.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in high water content commodities and a LOQ of 0.02 mg/kg for high oil matrices is available (EFSA, 2013). According to the EURLs the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses (EURL, 2018).

As concluded in the framework of the peer review, the metabolic profile in the rotational crop study is different from the metabolism observed in the primary crops (EFSA, 2013).

In the framework of the peer review, it was considered that, since metabolites TPPA and S-1812-PYP were recovered in low levels in the cotton metabolism study and HTFP and HPDO (free and conjugated) were not detected in the field rotational crop trials above the LOQ (see Section 1.2.2), the residue definition for risk assessment should be set as ‘pyridalyl’ only (EFSA, 2013). The same residue definition for risk assessment is proposed in the current MRL review.
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of pyridalyl residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Netherlands, 2018) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2013) or in the framework of a previous MRL application (EFSA, 2009). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017). For all crops, available residue trials are sufficient to derive MRL and risk assessment values.

1.2.2. Magnitude of residues in rotational crops

Three rotational crop field studies were available for this review (Netherlands, 2012; EFSA, 2013). Pyridalyl was applied four times on cotton, tomato or pepper at a total rate of ca. 600 g a.s./ha.

Within 1, 3, 6 or 11–12 months after the last application, rotational crops (carrots, tomatoes, broccoli, barley, lettuce and wheat) were sown. Samples were collected at harvest and analysed for the parent pyridalyl and metabolites HTFP and HPDO (free and conjugated) achieving an LOQ of 0.01 or 0.02 mg/kg for each individual compound. No residues of pyridalyl, HTFP and HPDO above the LOQ were detected in any of the rotational crop investigated at all PBI investigated.

Considering these field studies, it is concluded that no significant residue levels (> 0.02 or > 0.01 mg/kg) of pyridalyl, HTFP or HPDO will occur in rotational crops provided that the active substance is applied according to the GAPs under review (total maximum application rate of 600 g a.s./ha per year).

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on tomato, pepper and cotton (EFSA, 2009, 2013; Netherlands, 2012). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for tomato (puree) while limited processing factors (not fully supported by data, since less than three independent studies were available) were derived for processed tomato (washed, peeled and canned, juice, ketchup and paste), chilli/sweet pepper (canned) and cotton (hull, oil and meal).

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

1.2.4. Proposed MRLs

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

2. Residues in livestock

Pyridalyl is not authorised for uses on crops that might be fed to livestock. Further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary (European Commission, 1997e).

Although not needed for the current review, since MRLs for livestock are not necessary, it is noted that a metabolism study and feeding study with laying hen were submitted in the framework of the peer review (Netherlands, 2012; EFSA, 2013). These studies can be considered in case uses on crops that are fed to livestock will be requested in the future.

3. Consumer risk assessment

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 3 of the EFSA PRIMo (EFSA, 2018). Input values for the exposure calculations were
derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix D. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance (EFSA, 2013; European Commission, 2013).

The chronic exposure values calculated were compared with the toxicological reference value for pyridalyl derived by EFSA (2013). The highest chronic exposure was calculated for GEMS Food G06, representing 5% of the acceptable daily intake (ADI). This calculation indicates that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health.

Conclusions

The metabolism of pyridalyl in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as pyridalyl. This residue definition is also applicable to processed commodities. Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water content matrices at the LOQ of 0.01 mg/kg and in high oil content commodities with an LOQ of 0.02 mg/kg. According to the EURs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses in all plant matrices.

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

Pyridalyl is not authorised for uses on crops that might be fed to livestock. Further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3 of the EFSA PRIMo. The exposure values calculated were compared with the toxicological reference value for pyridalyl derived by EFSA. The highest chronic exposure was calculated for GEMS Food G06, representing 5% of the ADI. This calculation indicates that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Recommendations

MRL recommendations (see Table 2) were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion. All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation.

Table 2: Summary table

| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | MRL (mg/kg) | Comment |
|-------------|-----------|-------------------------|-----------------------|-------------|---------|
|             | Enforcement residue definition: pyridalyl |                |                       |             |         |
| 231010      | Tomatoes  | 1                       |                      | 1.5         | Recommended(a) |
| 231020      | Sweet peppers/bell peppers | 2                   |                      | 0.9         | Recommended(a) |
| 231030      | Aubergines/eggplants | 1                        |                      | 1.5         | Recommended(a) |
|             | Other commodities of plant and/or animal origin | See Reg. (EC) No 1050/2009 |                  |             | Further consideration needed(b) |

MRL: maximum residue level; CXL: Codex maximum residue limit; GAP: Good Agricultural Practice; LOQ: Limit of quantification.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).
(b): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
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**Abbreviations**

| Abbreviation | Description |
|--------------|-------------|
| a.s.         | active substance |
| ADI          | acceptable daily intake |
| ARFD         | acute reference dose |
| BBCH         | growth stages of mono- and dicotyledonous plants |
| bw           | body weight |
| CXL          | codex maximum residue limit |
| DAR          | draft assessment report |
| DAT          | days after treatment |
| DB           | dietary burden |
| DM           | dry matter |
| DT₉₀         | period required for 90% dissipation (define method of estimation) |
| eq           | residue expressed as a.s. equivalent |
| EW           | Emulsion in water |
| EURLS        | European Union Reference Laboratories for Pesticide Residues (former CRLs) |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | Good Agricultural Practice |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| ILV          | independent laboratory validation |
| InChIKey     | International Chemical Identifier Key |
| ISO          | International Organisation for Standardization |
| IUPAC        | International Union of Pure and Applied Chemistry |
| LOQ          | limit of quantification |
| Mo           | monitoring |
| MRL          | maximum residue level |
| MS           | Member States |
| NEDI         | national estimated daily intake |
| NEU          | northern European Union |
| NTMDI        | national theoretical maximum daily intake. |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant-back interval |
| PF           | processing factor |
| PHI          | preharvest interval |
| PRIMo (EFSA)| Pesticide Residues Intake Model |
| PROFile (EFSA)| Pesticide Residues Overview File |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SEU          | southern European Union |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TMDI         | theoretical maximum daily intake |
| TRR          | total radioactive residue |
### Appendix A – Summary of authorised uses considered for the review of MRLs

#### A.1. Authorised indoor uses in the EU

| Crop and/or situation | MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|------------|--------------------------------|---------------|---------|
|                       |               |             |                                   | Type(b) Conc. a.s. Method kind | Range of growth stages & season(c) | Number min–max | Interval between application (min) | a.s./hL min–max | Water L/ha min–max | Rate and unit |               |                     |
| Tomatoes NL I | Spodoptera exigua, Chrysodeixis chalcites | EW 100 g/L | Foliar treatment – broadcast spraying |  | – | 4 | 7 | – | – | 150 g a.s./ha | 3 | Max. 4 applications in 2 blocks of 2 applications each. Min interval of 7 days within a block and minimum interval of 28 days between blocks |
| Sweet peppers/ bell peppers NL I | Spodoptera exigua, Chrysodeixis chalcites | EW 100 g/L | Foliar treatment – broadcast spraying |  | – | 4 | 7 | – | – | 150 g a.s./ha | 3 | Max. 4 applications in 2 blocks of 2 applications each. Min interval of 7 days within a block and minimum interval of 28 days between blocks |
| Aubergines NL I | Spodoptera exigua, Chrysodeixis chalcites | EW 100 g/L | Foliar treatment – broadcast spraying |  | – | 4 | 7 | – | – | 150 g a.s./ha | 3 | Max. 4 applications in 2 blocks of 2 applications each. Min interval of 7 days within a block and minimum interval of 28 days between blocks |

MRL: maximum residue level; MS: Member State; a.s: active substance; EW: Emulsion in water.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s)       | Application(s)          | Sampling (DAT)       | Comment/source       |
|----------------------------------|-------------|---------------|-------------------------|----------------------|----------------------|
| Fruit crops                      | Tomato      | Foliar, 4 × 225 g a.s./ha | At PHI 1–7 days         | Netherlands (2012), EFSA (2013) |
| Leafy crops                      | Chinese cabbage | Foliar, 4 × 225 g a.s./ha | At PHI 3 days            |                       |
| Pulses/oilseeds                  | Cotton      | Foliar, 2 × 561 g a.s./ha | At PHI 21 days           |                       |

| Rotational crops (available studies) | Crop groups   | Crop(s)     | Application(s) | PBI (DAT) | Comment/source       |
|--------------------------------------|---------------|-------------|----------------|-----------|----------------------|
| Root/tuber crops                     | Carrots       | Bare soil, 1,120 g a.s./ha | 30, 120 and ca 390 | Netherlands (2012), EFSA (2013) |
| Leafy crops                          | Lettuce       |             |                |           |                      |
| Cereal (small grain)                 | Wheat         |             |                |           |                      |

| Processed commodities (hydrolysis study) | Conditions                                                                 | Stable? | Comment/source       |
|------------------------------------------|---------------------------------------------------------------------------|---------|----------------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4)                                       | Yes     | Netherlands (2012), EFSA (2013) |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5)                          | Yes     |                       |
|                                          | Sterilisation (20 min, 120°C, pH 6)                                       | Yes     |                       |

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; LOQ: limit of quantification; ILV: independent laboratory validation.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity                  | T (°C) | Stability period | Compounds covered | Comment/source |
|----------------------------------|----------|----------------------------|--------|-----------------|-------------------|----------------|
| High water content               | Tomato, Pepper | –20 | 10 Months | Pyridalyl | EFSA (2013) |
| High oil content                 | Cotton   | –20 | 20 Months | Pyridalyl | EFSA (2013) |
| Dry                              | Wheat straw | –20 | 28 Months | HPDO, HTFP | EFSA (2013) |
| Dry                              | Carrot (roots and tops) | –20 | 28 Months | HPDO, HTFP | EFSA (2013) |
| Dry                              | Cotton gin trash | –20 | 19 Months | Pyridalyl | EFSA (2013) |
| Dry                              | Cotton gin trash | –20 | 10 Months | S-1812-DP | EFSA (2013) |

**Comment/Source**

- Residues in rotational crops are mostly the result of the uptake of the main soil metabolite HTFP (further metabolised to HPDO). Pyridalyl not expected to be present in significant levels (EFSA, 2013).

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

- Matrices with high water content, DFG-S19 (modified): LOQ 0.01 mg/kg
- Matrices with high oil content, DFG-S19 (modified): LOQ 0.02 mg/kg
- Confirmatory method available
- ILV available (EFSA, 2013)
- EUR-L reported that pyridalyl could be enforced with a LOQ of 0.01 mg/kg in all four main plant matrices (EUR-L, 2018)

**a.s.: active substance; DAT: days after treatment; PHI: preharvest interval; PBI: plant-back interval; LOQ: limit of quantification; ILV: independent laboratory validation.**
B.1.2. Magnitude of residues in plants

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

| Commodity                  | Region/indoor(s) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|----------------------------|------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|-----------------|
| **Residue definition for enforcement – pyridalyl** |                  |                                                                 |                                                                    |                        |              |                 |
| Tomatoes/Aubergines        | EU, indoor       | 0.11; 0.20; 0.23; 0.25; 0.33; 0.36; 0.37; 0.47; 0.81; 0.88    | Trials on tomatoes compliant with GAP (EFSA, 2013). Extrapolation to aubergines is applicable. MRL\textsubscript{OECD} = 1.42 | 1.5                    | 0.88         | 0.35            |
| Sweet peppers/bell peppers| EU, indoor       | 0.20; 0.23; 0.23; 0.24; 0.27; 0.33; 0.36; 0.41               | Trials on sweet peppers compliant with GAP (EFSA, 2013). MRL\textsubscript{OECD} = 0.84 | 0.9                    | 0.41         | 0.26            |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

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

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

B.1.2.2. Residues in rotational crops

Overall summary

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

Yes  
Following bare soil application of 1,120 g a.s./ha (2N), metabolite HTFP (free and conjugated form) was the main component in all sampling intervals, found at up to 1.909 mg eq/kg in carrot tops 120 DAT, while metabolite HPDO was detected in wheat straw at 0.493 mg eq/kg and at 0.211 mg eq./kg in carrot tops, 30 DAT. Parent detected only at very low levels

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

No  
Pyridalyl, HTFP and HPDO were all below the LOQs (<0.01 or < 0.02 mg/kg) in carrots, broccoli, lettuce, barley, wheat and tomato grown after treatment of ca 600 g a.s./ha on the primary crops cotton, pepper and tomato (EFSA, 2013)

a.s.: active substance; DAT: days after treatment; LOQ: limit of quantification.
B.1.2.3. Processing factors

| Processed commodity       | Number of valid studies\(^{(a)}\) | Processing Factor (PF) | Comment/source |
|---------------------------|-----------------------------------|------------------------|----------------|
|                           |                                   | Individual values      | Median PF      |                |
| Tomato, washed fruits     | 2                                 | 0.58; 1.1              | 0.84           | Tentative\(^{(b)}\) (EFSA, 2009) |
| Tomato, peel              | 1                                 | 3.5                    | 3.5            | Tentative\(^{(b)}\) (EFSA, 2009) |
| Tomato, peeled fruits     | 1                                 | 0.11                   | 0.11           | Tentative\(^{(b)}\) (EFSA, 2009) |
| Tomato, canned            | 2                                 | < 0.03; < 0.5          | < 0.3          | Tentative\(^{(b)}\) (EFSA, 2009) |
| Tomato, paste             | 1                                 | 1.3                    | 1.3            | Tentative\(^{(b)}\) (EFSA, 2009) |
| Tomato, ketchup           | 2                                 | 0.37; 0.5              | 0.4            | Tentative\(^{(b)}\) (EFSA, 2009) |
| Tomato, juice             | 2                                 | < 0.3; n.d.            | < 0.3          | Tentative\(^{(b)}\) (EFSA, 2009) |
| Tomato, puree             | 3                                 | 0.32; 0.4; 0.8         | 0.4            | (EFSA, 2009)   |
| Chilli pepper, canned     | 1                                 | 2.4                    | 2.4            | Tentative\(^{(b)}\) (EFSA, 2009) |
| Chilli pepper, canned     | 1                                 | 0.6                    | 0.6            | Tentative\(^{(b)}\) (EFSA, 2009) |
| liquid                    |                                   |                        |                |                |
| Sweet pepper, canned      | 1                                 | 0.4                    | 0.4            | Tentative\(^{(b)}\) (EFSA, 2009) |
| Cotton, hull              | 1                                 | 0.8                    | 0.8            | Tentative\(^{(b)}\) (EFSA, 2009) |
| Cotton seed, oil          | 1                                 | 0.2                    | 0.2            | Tentative\(^{(b)}\) (EFSA, 2009) |
| Cotton, meal              | 1                                 | < 0.1                  | < 0.1          | Tentative\(^{(b)}\) (EFSA, 2009) |
| Chilli pepper, canned solid |                               |                        |                |                |

PF: processing factor (= residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo).

\(^{(a)}\): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

\(^{(b)}\): A tentative PF is derived based on a limited data set (less than three independent studies).

B.2. Residues in livestock

Not relevant as crops under review are not fed to livestock.

B.3. Consumer risk assessment

| ARID                      | Not relevant since no ARID has been considered necessary (EFSA, 2013) |
|---------------------------|---------------------------------------------------------------------|
| ADI                       | 0.03 mg/kg bw per day (EFSA, 2013)                                   |
| TMDI according to EFSA PRIMo | Not assessed in this review                                           |
| NTMDI, according to (to be specified) | Not assessed in this review                                           |
| Highest IEDI, according to EFSA PRIMo (rev.3.0) | 5% ADI (GEMS Food G06)                                               |
| NEDI (% ADI)              | Not assessed in this review                                           |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation |

ADi: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; IEDI: international estimated daily intake; WHO: World Health Organization; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; GAP: Good Agricultural Practice; MRL: maximum residue level.
Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

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

### Table B.1: Proposed MRLs

| Code number | Commodity                  | Existing EU MRL (mg/kg) | MRL (mg/kg) | Comment                  |
|-------------|----------------------------|-------------------------|-------------|--------------------------|
| 231010      | Tomatoes                   | 1                       | 1.5         | Recommended<sup>(a)</sup> |
| 231020      | Sweet peppers/bell peppers| 2                       | 0.9         | Recommended<sup>(a)</sup> |
| 231030      | Aubergines/eggplants       | 1                       | 1.5         | Recommended<sup>(a)</sup> |
| –           | Other commodities of plant and/or animal origin | See Reg. (EC) No 1050/2009 | –          | Further consideration needed<sup>(b)</sup> |

MRL: maximum residue level; CXL: codex maximum residue limit; GAP: Good Agricultural Practice; LOQ: limit of quantification.

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

(b): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### PRIMo(EU)

#### Pyridalyl

| Commodity/ group of commodities | MS Diet | Calculated exposure (µg/kg bw per day) | Exposures contributing to the dietary intake (µg/kg bw per day) | Highest contributor to dietary intake (µg/kg bw per day) | Commodity/ group of commodities | Calculated exposure (µg/kg bw per day) | Exposures contributing to the dietary intake (µg/kg bw per day) | Highest contributor to dietary intake (µg/kg bw per day) |
|---------------------------------|---------|--------------------------------------|---------------------------------------------------------------|-------------------------------------------------------|---------------------------------|--------------------------------------|---------------------------------------------------------------|-------------------------------------------------------|
| Tomatoes                        | 0.86    | 0.86 Tomatoes                          |                                                               |                                                       | Sweet peppers/bell peppers     | 0.86 Tomatoes                          |                                                               |                                                       |
| Sweet peppers/bell peppers     | 0.50    | 0.50 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.50 Tomatoes                          |                                                               |                                                       |
| Aubergines/egg plants          | 0.48    | 0.48 Tomatoes                          |                                                               |                                                       | Sweet peppers/bell peppers     | 0.48 Tomatoes                          |                                                               |                                                       |
| F adult                         | 0.46    | 0.46 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.46 Tomatoes                          |                                                               |                                                       |
| DE child                        | 0.42    | 0.42 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.42 Tomatoes                          |                                                               |                                                       |
| DE general                      | 0.41    | 0.41 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.41 Tomatoes                          |                                                               |                                                       |
| ES adult                        | 0.39    | 0.39 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.39 Tomatoes                          |                                                               |                                                       |
| ES child                        | 0.37    | 0.37 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.37 Tomatoes                          |                                                               |                                                       |
| IT toddler                      | 0.36    | 0.36 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.36 Tomatoes                          |                                                               |                                                       |
| IT adult                        | 0.35    | 0.35 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.35 Tomatoes                          |                                                               |                                                       |
| NL toddler                      | 0.34    | 0.34 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.34 Tomatoes                          |                                                               |                                                       |
| NL child                        | 0.33    | 0.33 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.33 Tomatoes                          |                                                               |                                                       |
| UK child                        | 0.32    | 0.32 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.32 Tomatoes                          |                                                               |                                                       |
| US child                        | 0.31    | 0.31 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.31 Tomatoes                          |                                                               |                                                       |
| US adult                        | 0.30    | 0.30 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.30 Tomatoes                          |                                                               |                                                       |
| US toddler                      | 0.29    | 0.29 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.29 Tomatoes                          |                                                               |                                                       |
| UK infant                       | 0.28    | 0.28 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.28 Tomatoes                          |                                                               |                                                       |
| DE women 14-50 yr               | 0.27    | 0.27 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.27 Tomatoes                          |                                                               |                                                       |
| FR child 3 15 yr                | 0.26    | 0.26 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.26 Tomatoes                          |                                                               |                                                       |
| FR toddler 2 3 yr               | 0.26    | 0.26 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.26 Tomatoes                          |                                                               |                                                       |
| NL infants                      | 0.25    | 0.25 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.25 Tomatoes                          |                                                               |                                                       |
| ES infant                       | 0.24    | 0.24 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.24 Tomatoes                          |                                                               |                                                       |
| DK child                        | 0.23    | 0.23 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.23 Tomatoes                          |                                                               |                                                       |
| DK adult                        | 0.22    | 0.22 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.22 Tomatoes                          |                                                               |                                                       |
| DE adult                        | 0.21    | 0.21 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.21 Tomatoes                          |                                                               |                                                       |
| FR adult                        | 0.20    | 0.20 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.20 Tomatoes                          |                                                               |                                                       |
| DE general                      | 0.19    | 0.19 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.19 Tomatoes                          |                                                               |                                                       |
| US adult                        | 0.18    | 0.18 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.18 Tomatoes                          |                                                               |                                                       |
| US toddler                      | 0.17    | 0.17 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.17 Tomatoes                          |                                                               |                                                       |
| FR child 3 15 yr                | 0.16    | 0.16 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.16 Tomatoes                          |                                                               |                                                       |
| FR toddler 2 3 yr               | 0.16    | 0.16 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.16 Tomatoes                          |                                                               |                                                       |
| US infant                       | 0.15    | 0.15 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.15 Tomatoes                          |                                                               |                                                       |
| NL child                        | 0.14    | 0.14 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.14 Tomatoes                          |                                                               |                                                       |
| NL adult                        | 0.13    | 0.13 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.13 Tomatoes                          |                                                               |                                                       |
| SI child                        | 0.12    | 0.12 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.12 Tomatoes                          |                                                               |                                                       |
| SI adult                        | 0.11    | 0.11 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.11 Tomatoes                          |                                                               |                                                       |
| SI general                      | 0.10    | 0.10 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.10 Tomatoes                          |                                                               |                                                       |
| SI toddler                      | 0.09    | 0.09 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.09 Tomatoes                          |                                                               |                                                       |
| SI child 3 15 yr                | 0.08    | 0.08 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.08 Tomatoes                          |                                                               |                                                       |
| SI toddler 2 3 yr               | 0.08    | 0.08 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.08 Tomatoes                          |                                                               |                                                       |
| SI child 3 15 yr                | 0.07    | 0.07 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.07 Tomatoes                          |                                                               |                                                       |
| SI toddler 2 3 yr               | 0.07    | 0.07 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.07 Tomatoes                          |                                                               |                                                       |
| SI child 3 15 yr                | 0.06    | 0.06 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.06 Tomatoes                          |                                                               |                                                       |
| SI toddler 2 3 yr               | 0.06    | 0.06 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.06 Tomatoes                          |                                                               |                                                       |
| SI child 3 15 yr                | 0.05    | 0.05 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.05 Tomatoes                          |                                                               |                                                       |
| SI toddler 2 3 yr               | 0.05    | 0.05 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.05 Tomatoes                          |                                                               |                                                       |
| SI child 3 15 yr                | 0.04    | 0.04 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.04 Tomatoes                          |                                                               |                                                       |
| SI toddler 2 3 yr               | 0.04    | 0.04 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.04 Tomatoes                          |                                                               |                                                       |
| SI child 3 15 yr                | 0.03    | 0.03 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.03 Tomatoes                          |                                                               |                                                       |
| SI toddler 2 3 yr               | 0.03    | 0.03 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.03 Tomatoes                          |                                                               |                                                       |
| SI child 3 15 yr                | 0.02    | 0.02 Tomatoes                          |                                                               |                                                       | Aubergines/egg plants          | 0.02 Tomatoes                          |                                                               |                                                       |

**Conclusion:**

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

Show results for all crops

| Unprocessed commodities | Results for children (IESTI) | Results for adults (IESTI) |
|-------------------------|------------------------------|----------------------------|
| Highest % of ARfD/ADI   | No. of commodities for which ARfD/ADI is exceeded | No. of commodities for which ARfD/ADI is exceeded |
| Commodities            | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
| Tomatoes/juice         | 22% | 0.35 | 6.7 | 4% | Tomatoes/sauce/puree | 0.35 | 1.2 |

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

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

D.1. Livestock dietary burden calculations

Not applicable as crops under review are not fed to livestock and therefore dietary burden is not triggered.

D.2. Consumer risk assessment

| Commodity                     | Chronic risk assessment | Input value (mg/kg) | Comment |
|-------------------------------|-------------------------|---------------------|---------|
| Residue definition for risk assessment | pyridalyl               |                     |         |
| Tomatoes                      |                         | 0.35                | STMR    |
| Sweet peppers/bell peppers   |                         | 0.26                | STMR    |
| Aubergines/eggplants         |                         | 0.35                | STMR    |

STMR: supervised trials median residue.
Appendix E – Decision tree for deriving MRL recommendations

**Evaluation of the GAPs and available residues data at EU level**

- GAP or DB > 0.1 mg/kg DM in EU?
  - Yes
  - MRL And RA derived in Section 3?
    - Yes
    - MRL fully supported by data?
      - Yes
      - (F) Establish tentative EU MRL?
      - No
      - (G) Specific LOQ or default MRL?
    - No
    - Not considered for the RA.
  - No
  - Is RD-RA derived for this commodity?
    - Yes
    - MRL And RA derived in Section 3?
      - Yes
      - MRL fully supported by data?
        - Yes
        - (F) Establish tentative EU MRL?
        - No
        - (G) Specific LOQ or default MRL?
      - No
      - Not considered for the RA.
    - No
    - Not considered for the RA.

**Consumer risk assessment for GAPs evaluated at EU level – EU scenarios**

- Not considered for the RA.
- Current EU MRL is included in the RA.
- Tentative median/highest values are included in the RA.
- Median/highest values are included in the RA.
- Risk identified?
  - Yes
  - Fall-back MRL available?
    - Yes
    - Recommendations resulting from EU authorisations and import tolerances
    - No
    - Recommendations resulting from EU authorisations and import tolerances
  - No
  - Recommendations resulting from EU authorisations and import tolerances

- Risk identified?
  - Yes
  - Fall-back MRL available?
    - Yes
    - Recommendations resulting from EU authorisations and import tolerances
    - No
    - Recommendations resulting from EU authorisations and import tolerances
  - No
  - Recommendations resulting from EU authorisations and import tolerances

**Recommendations resulting from EU authorisations and import tolerances**

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

- CXL available?
  - Yes
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes
        - CXL lower?
          - No
    - No
  - No

Consumer risk assessment with consideration of the existing CXL

- CXL is included in the RA?
  - Yes
    - Risk identified?
      - Yes
    - No
  - No

- CXL supported by data?
  - Yes
    - Risk identified?
      - Yes
    - No
  - No

Recommendations with consideration of the existing CXL

- (I) Maintain EU recommendation indicating that no CXL is available.
- (II) Maintain EU recommendation indicating CXL is not compatible.
- (III) Maintain EU recommendation indicating that CXL is covered.
- (IV) Maintain EU recommendation; higher CXL is not safe for consumer.
- (V) Maintain current CXL or EU recommendation?
  - Yes
    - CXL is included in the RA.
    - Risk identified?
      - Yes
    - No
  - No
    - CXL supported by data?
      - Yes
        - Risk identified?
          - Yes
        - No
      - No
        - Risk identified?
          - Yes
    - No

- (VI) Maintain EU recommendation; higher CXL is not safe for consumer.
- (VII) CXL is recommended; EU recommendation is covered as well.
## Appendix F – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|---------------------|---------------------------------------|-----------------------|
| pyridal             | 2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl 3-[5-(trifluoromethyl)-2-pyridyloxy]propyl ether | ![Structural formula of pyridal](image) |
|                     | Cl\(\text{C(Cl)=C\text{O}c1cc(Cl)c(OCCOC2ccc(cn2)C(F)(F)c(Cl)c1)}\) | ![InChiKey of pyridal](image) |
| S-1812-DP           | 3,5-dichloro-4-(3-[5-(trifluoromethyl)-2-pyridyloxy]propxy)phenol | ![Structural formula of S-1812-DP](image) |
|                     | FC(F)(F)c1cnc(OCCOC2c(Cl)cc(O)cc2Cl)c1cc1 | ![InChiKey of S-1812-DP](image) |
| S-1812-PYP          | 3-[(5-(trifluoromethyl)-2-pyridinyl)oxy]-1-propanol | ![Structural formula of S-1812-PYP](image) |
|                     | FC(F)(F)c1cnc(OCCCO)c1c1 | ![InChiKey of S-1812-PYP](image) |
| TPPA                | 3-[(5-(trifluoromethyl)-2-pyridinyl)oxy]propanoic acid | ![Structural formula of TPPA](image) |
|                     | FC(F)(F)c1cnc(OCCC(=O)O)c1c1 | ![InChiKey of TPPA](image) |
| HTFP                | 5-(trifluoromethyl)pyridin-2-ol | ![Structural formula of HTFP](image) |
|                     | FC(F)(F)c1cnc(O)c1c1 | ![InChiKey of HTFP](image) |
| N-methyl-HTFP       | 1-methyl-5-(trifluoromethyl)-2(1H)-pyridinone | ![Structural formula of N-methyl-HTFP](image) |
|                     | O=\text{C1C}(-\text{CN}1\text{C})(\text{F})(\text{F})F | ![InChiKey of N-methyl-HTFP](image) |
| HPDO                | 3-hydroxy-5-(trifluoromethyl)-2(1H)-pyridinone | ![Structural formula of HPDO](image) |
|                     | OC1(-\text{CN}1\text{C})(\text{O})(\text{F})(\text{F})F | ![InChiKey of HPDO](image) |
| N-methyl-HPDO       | 3-hydroxy-1-methyl-5-(trifluoromethyl)-2(1H)-pyridinone | ![Structural formula of N-methyl-HPDO](image) |
|                     | OC1(-\text{CN}(\text{C}1=\text{O})(\text{F})(\text{F})F | ![InChiKey of N-methyl-HPDO](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 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 July 2018).
(c): ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 7 December 2018).