Modification of the existing maximum residue levels for penthiopyrad in Florence fennels and celeries

EFSA (European Food Safety Authority),
Maria Anastassiadou, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Alejandro Rojas, Angela Sacchi, Miguel Santos, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Corteva submitted a request to the competent national authority in Italy to modify the existing maximum residue levels (MRLs) for the active substance penthiopyrad in Florence fennels and celeries. The data submitted in support of the request were found to be sufficient to derive MRL proposals for Florence fennels and celeries. Adequate analytical methods for enforcement are available to control the residues of penthiopyrad in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of penthiopyrad residues and of its metabolite PAM, resulting from the use of penthiopyrad according to the reported agricultural practice is unlikely to present a risk to consumer health. The reliable end points, appropriate for use in regulatory risk assessment, are presented.

© 2020 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: penthiopyrad, Florence fennel, celeries, fungicide, MRL, consumer risk assessment

Requestor: European Commission
Question number: EFSA-Q-2019-00609
Correspondence: pesticides.mrl@efsa.europa.eu
Acknowledgements: EFSA wishes to thank the following for the support provided to this scientific output: Laszlo Bura, Viktoria Krivova, Silvia Ruocco and Viktor Toth.

Suggested citation: European Food Safety Authority (EFSA), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Theobald A, Vagenende B and Verani A, 2020. Reasoned Opinion on the modification of the existing maximum residue levels for penthiopyrad in Florence fennels and celeries. EFSA Journal 2020;18(9):6259, 33 pp. https://doi.org/10.2903/j.efsa.2020.6259

ISSN: 1831-4732

© 2020 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Corteva submitted an application to the competent national authority in Italy (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance penthiopyrad in Florence fennel and celeries. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 16 September 2019. To accommodate for the intended SEU use of penthiopyrad, the EMS proposed to raise the existing MRL from 15 to 20 mg/kg in Florence fennel and celeries.

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

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of penthiopyrad following foliar application was investigated in crops belonging to fruits, leafy, cereal/grass and pulses/oilseeds crop groups. The metabolism of penthiopyrad followed a similar pathway in all crops investigated, where the main identified products were penthiopyrad, PCA and PAM. Significant amounts of a mainly conjugated metabolite 753-A-OH were present in grapes and cabbage.

Studies investigating the nature of penthiopyrad residues under standard hydrolysis conditions were assessed during the EU pesticides peer review showing that the active substance is hydrolytically stable; the same conclusion is applicable to metabolite 753-A-OH. The effect of processing on the nature of residues of metabolite PAM has not been investigated and this was noted as a data gap by the EU pesticides peer review. However, since the residues of PAM are below 0.1 mg/kg in the crops under consideration and since the individual contribution of PAM residues in the crops under consideration to the theoretical maximum daily intake (TMDI) is below the trigger value of 10%, such studies are not required under the current assessment.

The nature of penthiopyrad residues in rotational crops was investigated in leafy crops, root crops and cereals during the EU pesticides peer review where it was concluded that the metabolic pathway of penthiopyrad in rotational crops is similar to that in primary crops; no formation of new metabolites was observed.

Based on the metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the residue definition for enforcement was proposed as penthiopyrad, while for risk assessment, two separate residue definitions were proposed: (1) sum of penthiopyrad and metabolite 753-A-OH, expressed as penthiopyrad; and (2) PAM metabolite. The same residue definitions are applicable to rotational crops. In processed products, pending the investigation of the behaviour of PAM residues under hydrolysis conditions, no conclusion on whether the same residue definitions are applicable to processed commodities, could be derived by the EU pesticides peer review. For the uses on the crops under consideration, EFSA concludes that the metabolism of penthiopyrad in primary crops has been sufficiently addressed.

Sufficiently validated analytical methods based on LC-MS/MS are available to quantify residues of penthiopyrad in the crops under consideration.

The available residue trials are sufficient to derive an MRL proposal of 20 mg/kg for penthiopyrad in Florence fennels and celeries in support of the intended SEU use.

The magnitude of penthiopyrad residues in rotational crops was investigated in the framework of the EU pesticides peer review. In rotational crops, planted after the harvest of treated primary crop, quantifiable residues were observed only in radish roots from the second crop rotation. Since the application rate of penthiopyrad in the intended good agricultural practice (GAP) on Florence fennel and celeries is lower (0.3 N), significant residues in rotational crops would not be expected. However, during the EU pesticides peer review, it could not be concluded whether the rotational crop studies are representative for the soil plateau levels of penthiopyrad that will be reached after multiple-year applications; thus, an accumulation of metabolite DM-PCA in rotational crops cannot be excluded. Considering that new studies were not submitted under the current application, EFSA keeps the recommendation of the EU pesticides peer review that Member States granting authorisations for penthiopyrad uses, must consider setting specific risk mitigation measures in order to avoid the possible occurrence of penthiopyrad-related residues in succeeding crops following multi-year applications.
applications. Based on the currently available data, the consumer risk assessment can only be conducted considering a single (annual) application and rotation cycle.

Residues of penthiopyrad in commodities of animal origin were not assessed since the crops under consideration are normally not fed to livestock.

The toxicological profile of penthiopyrad was assessed during the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) value of 0.1 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.75 mg/kg bw. Metabolite 753-A-OH is of a similar toxicity as the parent. For PAM metabolite, an ADI of 0.0024 mg/kg bw per day and an ARfD of 0.024 mg/kg bw were derived in the framework of the assessment of confirmatory data in a Technical Report from EFSA.

The consumer risk assessment was performed according to the two risk assessment residue definitions derived for penthiopyrad under the framework of the EU pesticides peer review: ‘sum of penthiopyrad and metabolite 753-A-OH, expressed as penthiopyrad’ and ‘metabolite PAM’. The consumer exposure was calculated using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The acute exposure was calculated only for the crops under consideration.

The chronic exposure was calculated for the crops under consideration, using the risk assessment values as derived from the submitted residue trials. For remaining commodities for which the existing penthiopyrad MRL is set above the LOQ, the median residue levels according to risk assessment residue definitions were available from the previous EFSA outputs and from the JMPR assessments, as for some commodities, the existing EU MRL was set on the basis of Codex residue limits (CXL). The input values for animal commodities were as reported in the previous EFSA outputs. The remaining commodities of plant origin for which the existing EU MRL for penthiopyrad is set at the LOQ were not considered as no uses of penthiopyrad on these commodities have been reported since the approval of penthiopyrad, implementation of safe CXLs and EFSA assessments.

For the residue definition ‘sum of penthiopyrad and metabolite 753-A-OH, expressed as penthiopyrad’, no long-term consumer intake concerns were identified. The highest chronic intake accounted for up to 9% the ADI (NL, toddler diet). The contribution of residues to the total consumer exposure accounted for 0.19% of the ADI for celery and < 0.1% of the ADI for Florence fennel. Acute consumer risk was not identified for the crops under consideration. The acute consumer exposure accounted for 45% of the ARfD for boiled Florence fennel, 18% of the ARfD for raw Florence fennel, 33% of the ARfD for boiled celeries and 37% of the ARfD for raw celeries. Although specific data on residues of metabolite 753-A-OH were not available for all crops, given the wide safety margin, it can be assumed that the absence of these data will not considerably affect the consumer exposure.

Regarding residues of metabolite PAM, no long-term consumer intake concerns were identified. The highest chronic intake accounted for a maximum of 60% of the ADI (NL, toddler). The contribution of residues to the total consumer exposure accounted individually for less than 0.2% of the ADI for the crops under consideration. An acute consumer risk was not identified for the crops under consideration; the highest acute consumer exposure was calculated for boiled Florence fennel (7% of the ARfD) and accounted for 3% of ARfD for raw Florence fennel and of 6% of the ARfD for celery.

EFSA concluded that the proposed use of penthiopyrad on Florence fennel and celery will not result in a consumer exposure exceeding the toxicological reference values for penthiopyrad and PAM metabolite and therefore is unlikely to pose a risk to consumers’ health. It is, however, noted that some uncertainties related to potential accumulation of residues in rotational crops and the behaviour of PAM metabolite under processing remains not fully addressed, which might be relevant for future authorisations of penthiopyrad. Pending studies assessing residue uptake in rotational crops following multi-year applications of penthiopyrad, the consumer risk assessment was conducted considering residues in crops occurring after a single application of penthiopyrad and a single rotation cycle.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

| Code   | Commodity     | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification   |
|--------|---------------|-------------------------|-------------------------|-------------------------|
| 270030 | Celeries      | 15                      | 20                      | The submitted data are sufficient to derive an MRL proposal for the intended SEU use. Risk for consumers unlikely |
| 270040 | Florence fennels | 15                      | 20                      |                         |
Modification of the existing maximum residue levels for penthiopyrad in Florence fennels and celeries

MRL: maximum residue level; SEU: southern Europe.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
Modification of the existing maximum residue levels for penthiopyrad in Florence fennels and celeries

Table of contents

Abstract .......................................................................................................................................................... 1
Summary ...................................................................................................................................................... 3
Assessment .................................................................................................................................................... 7
1. Residues in plants ................................................................................................................................ 8
   1.1. Nature of residues and methods of analysis in plants ................................................................. 8
       1.1.1. Nature of residues in primary crops ...................................................................................... 8
       1.1.2. Nature of residues in rotational crops ................................................................................... 8
       1.1.3. Nature of residues in processed commodities ........................................................................ 8
       1.1.4. Methods of analysis in plants .................................................................................................. 9
       1.1.5. Storage stability of residues in plants ...................................................................................... 9
       1.1.6. Proposed residue definitions ................................................................................................... 9
       1.2. Magnitude of residues in plants .................................................................................................. 10
           1.2.1. Magnitude of residues in primary crops .............................................................................. 10
           1.2.2. Magnitude of residues in rotational crops ......................................................................... 10
           1.2.3. Magnitude of residues in processed commodities .............................................................. 10
           1.2.4. Proposed MRLs ................................................................................................................... 10
2. Residues in livestock ............................................................................................................................ 10
3. Consumer risk assessment .................................................................................................................... 10
4. Conclusion and Recommendations .................................................................................................... 12
References .................................................................................................................................................. 12

Abbreviations ............................................................................................................................................ 13

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs .................. 15
Appendix B – List of end points ............................................................................................................. 16
Appendix C – Pesticide Residue Intake Model (PRIMo) ........................................................................ 22
Appendix D – Input values for the exposure calculations ...................................................................... 26
Appendix E – Used compound codes .................................................................................................... 32
Assessment

The European Food Safety Authority (EFSA) received an application from Corteva to modify the existing maximum residue level (MRL) for penthiopyrad in Florence fennel and celeries. The detailed description of the intended SEU uses of penthiopyrad on Florence fennel and celeries, which is the basis for the current MRL application, is reported in Appendix A.

Penthiopyrad is the ISO common name for \((RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide\) (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Penthiopyrad was evaluated in the framework of Directive 91/414/EEC\(^1\) with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as foliar application on pome fruit, tomato, aubergines, cucurbits, cucumbers, courgettes and cereals. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2013). Penthiopyrad was approved\(^2\) for the use as fungicide on 4 May 2014. The confirmatory data requested as a specific provision on the implementation of Regulation (EU) No 1187/2013 regarding the toxicological profile and the reference values of the metabolite PAM were provided by the applicant Corteva in September 2014 and were evaluated by the RMS (United Kingdom, 2016) in an addendum to the DAR. The RMS distributed the addendum to the Member States and EFSA for comments, which were addressed in a Technical Report from EFSA (EFSA, 2016a).

The process of renewal of the first approval has not yet been initiated.

The EU MRLs for penthiopyrad are established in Annex IIIA of Regulation (EC) No 396/2005\(^3\). The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed, but proposals of MRL modifications from previous EFSA reasoned opinions (EFSA, 2012, 2016b) have been implemented in the MRL legislation.\(^4\) Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.\(^5,6\)

In accordance with Article 6 of Regulation (EC) No 396/2005, Corteva submitted an application to the competent national authority in Italy (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance penthiopyrad in Florence fennel and celeries. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 16 September 2019. To accommodate for the intended SEU uses of penthiopyrad, the EMS proposed to raise the existing penthiopyrad MRL from 15 to 20 mg/kg both in Florence fennel and celery.

EFSA based its assessment on the evaluation report submitted by the EMS (Italy, 2019), the draft assessment report (DAR) (and its addendum) (United Kingdom, 2012, 2013) prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance penthiopyrad (EFSA, 2013), the technical report of EFSA prepared in light of confirmatory data (EFSA, 2016a), as well as the conclusions from previous EFSA opinions on penthiopyrad (EFSA, 2012, 2016b).

For this application, the data requirements established in Regulation (EU) No 544/2011\(^7\) and the guidance documents applicable at the date of submission of the application to the EMS are applicable.

---

1. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2. Commission Implementing Regulation (EU) No 1187/2013 of 21 November 2013 approving the active substance penthiopyrad, 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 313, 22.11.2013, p. 42–46.
3. Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
4. For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
5. Commission Regulation (EU) No 491/2014 of 5 May 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametocridin, azoxystrobin, cycloxidym, cyfluthrin, dinotefuran, fenbucnazole, fenvalerate, fluodioxon, fluopyram, flufriatol, flupyradix, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products OJ L 146, 16.5.2014, p. 1–91.
6. Commission Regulation (EU) 2015/845 of 27 May 2015 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, chlorantraniliprole, cyantraniliprole, dicamba, diniflubenzon, fenpyroximate, fludioxonil, glufosinate-ammonium, imazapic, imazapyr, indoxacarb, isoaflutole, mandipropamid, penthiopyrad, propiconazole, pyrimethanil, spiroxtran and trifenapac in or on certain products OJ L 138, 4.6.2015, p. 1–69.
7. 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.
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.

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

The evaluation report submitted by the EMS (Italy, 2019) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of penthiopyrad in primary crops was assessed during the EU pesticides peer review following foliar application in fruits, leafy crops, cereals/grass and pulses/oilseeds (EFSA, 2013, 2016b).

After foliar applications, the metabolism of penthiopyrad appeared to follow a similar pathway in all crops investigated, where the main identified products were penthiopyrad, PCA and PAM. Significant amounts of mainly conjugated metabolite 753-A-OH were present in grapes and cabbage. The metabolism showed to be more extensive in rapeseed with PAM being the predominant part of the total residues (EFSA, 2013).

The metabolism study in leafy crops is considered representative for the intended use of penthiopyrad on Florence fennels and celeries. Thus, EFSA concludes that plant metabolism in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Celeries and Florence fennel can be grown in a crop rotation. Degradation of penthiopyrad in soil was investigated in the framework of the EU pesticides peer review (EFSA, 2013). Penthiopyrad exhibits medium to very high persistence in soil. According to field degradation studies, the DT90 value for penthiopyrad is above the trigger value of 100 days (with maximum of 169 days). Metabolites PAM, DM-PCA and PCA were observed at levels above 10% AR. Metabolite DM-PCA exhibits moderate to high persistence in soil. The DT90 field values for metabolites DM-PCA, PCA and PAM were not estimated, but, when recalculated from available DT50 values, these would also account for more than 100 days, with the highest value for metabolite DM-PCA. Enantioselective degradation of penthiopyrad was observed in all soils investigated (EFSA, 2013).

Given the above mentioned, the nature and magnitude of penthiopyrad residues in rotational crops were further investigated.

The metabolism of penthiopyrad in rotational crops spinach, lettuce, radish and wheat was investigated in the EU pesticides peer review following one soil application of penthiopyrad at an application rate of 800 g/ha. The major identified compounds in rotational crops were penthiopyrad, DM-PCA, PCA, and 753-A-OH (EFSA, 2013). In the framework of the EU pesticides peer review, it was concluded that the metabolic pathway of penthiopyrad in rotational crops is similar to that in primary crops; no formation of new metabolites was observed (EFSA, 2013).

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of penthiopyrad residues was assessed during the peer review under standard processing conditions, such as pasteurisation, baking/brewing/boiling and sterilisation, and it was concluded that the parent compound is hydrolytically stable (EFSA, 2013).
For metabolite 753-A-OH, no experimental data were submitted; however, based on the similarity of the structure with the parent compound, it was concluded to have the same behaviour under processing conditions (EFSA, 2013).

The effect of processing on the nature of residues of metabolite PAM has not been investigated and this was noted as a data gap by the peer review (EFSA, 2013). However, since the residues of PAM are below 0.1 mg/kg in the crops under consideration and since the individual contribution of PAM residues in the crops under consideration to the TMDI is below the trigger value of 10% (see Section 3), such studies are not required under the current assessment.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of penthiopyrad residues in plant commodities were assessed during the EU pesticides peer review (EFSA, 2013). The multiresidue method DFG-S19 based on liquid chromatography (LC-MS/MS) was sufficiently validated for the determination of penthiopyrad residues in high acid, high water and high oil content commodities at the limit of quantification (LOQ) of 0.01 mg/kg. For dry matrices, the validated LOQ is 0.05 mg/kg. An independent laboratory validation was identified as missing for commodities of high oil content (EFSA, 2013). A single-residue method based on liquid chromatography (HPLC-MS/MS) is also available for the determination of penthiopyrad and metabolite PAM at the validated LOQ of 0.01 mg/kg in matrices with high water, high acid, high oil content, in dry/high starch and dry/high protein content commodities (EFSA, 2013, 2016b).

EFSA concludes that sufficiently validated enforcement methods are available for the determination of penthiopyrad residues in the crops under consideration.

1.1.5. Storage stability of residues in plants

The stability of penthiopyrad and its metabolites PAM and 753-A-OH in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review where it was demonstrated that the residues are stable for 18 months in all crop matrices when stored at −20°C (EFSA, 2013).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the EU pesticides peer review (EFSA, 2013):

- Residue definition for monitoring: penthiopyrad;
- Residue definition for risk assessment:
  1) sum of penthiopyrad and metabolite 753-A-OH, expressed as penthiopyrad;
  2) metabolite PAM.

The same residue definitions are applicable to rotational crops. In processed products, pending the investigation of the behaviour of PAM residues under hydrolysis conditions, no conclusion whether the same residue definitions are applicable to processed commodities, could be derived (EFSA, 2013). The current residue definition set for enforcement in Regulation (EC) No 396/2005 is identical to the residue definition for monitoring reported above.

For the use on crops under consideration, EFSA concludes that the metabolism of penthiopyrad is sufficiently addressed, and the residue definitions derived under the EU pesticides peer review are applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the intended SEU use of penthiopyrad on Florence fennel and celeries, the applicant performed four residue trials on celeries (in Spain and Italy) and one trial on Florence fennel (in Italy) during the growing seasons of 2016 and 2017. All trials were found good agricultural practice (GAP) compliant.
The crop samples were analysed for the parent compound and the metabolites 753-A-OH and PAM, as relevant for the residue definitions for risk assessment.

The results of the residue trials are presented in the Table B.1.2.1 of the appendix.

The applicant proposes to extrapolate the residue data from celeries to Florence fennels. According to EU guidance document (European Commission, 2017), such an extrapolation is acceptable and is sufficiently supported by residue data. Thus, the residue data of Florence fennel and celery were combined for deriving an MRL proposal in both commodities.

According to the assessment of the EMS (Italy, 2019), the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The submitted data are sufficient to derive an MRL proposal of 20 mg/kg for penthiopyrad in celeries and Florence fennels in support of the intended SEU use.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of penthiopyrad residues to crops that are grown in a crop rotation has been assessed in EU pesticides peer review (EFSA, 2013). The uptake of penthiopyrad in spinach, lettuce, radish and wheat was investigated following two applications of penthiopyrad on primary crops barley or cucumber at an individual application rate of 400 g/ha. 30, 60, 120 and 365 days following the last application, the primary crops were harvested and rotational crops were planted. Quantifiable residues were only measured in radish roots from 60-day plant back interval (PBI) (max 0.017 mg/kg).

Since the maximum annual application rate on Florence fennel and celeries is lower (300 g/ha) than the application rate tested in the rotational crop studies (800 g/ha), it is concluded that residues in rotational crop are expected to be low, provided that the active substance is applied according to the proposed GAP.

However, during the peer review, it could not be concluded whether the rotational crop studies are representative for the soil plateau levels of penthiopyrad that will be reached after multiple-year applications of penthiopyrad; thus, an accumulation of DM-PCA in rotational crops cannot be excluded (EFSA, 2013). New rotational crop studies reflecting the uptake of penthiopyrad residues after multi-year applications were not provided in the framework of the current application; therefore, EFSA maintains the previous recommendation that risk managers should apply appropriate risk mitigation measures to avoid residues of penthiopyrad and its relevant metabolites in rotational crops following multi-year applications. Based on the currently available data, the consumer risk assessment can only be conducted considering a single application and rotation cycle.

1.2.3. Magnitude of residues in processed commodities

In the framework of the current assessment, the applicant did not submit studies investigating the effect of processing on the magnitude of residues of penthiopyrad and PAM metabolite in processed celeries and Florence fennel.

Processing studies are not required for the crops under consideration for the residues of PAM, due to low levels of it in the raw agricultural commodity (RAC). Studies investigating the effect of processing on the magnitude of penthiopyrad and 753-A-OH would be desirable, but are currently not requested, considering low consumer exposure to penthiopyrad residues.

1.2.4. Proposed MRLs

EFSA concludes that the data submitted are sufficient to derive an MRL of 20 mg/kg in support of the intended SEU use of penthiopyrad on celeries and Florence fennels. In Section 3, EFSA assessed whether residues in Florence fennel and celeries resulting from the intended uses of penthiopyrad in the SEU are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as Florence fennel and celeries are not used for feed purposes.

3. Consumer risk assessment

EFSA performed dietary risk assessment using revision 3.1 of the EFSA PRIMo. This exposure assessment model contains food consumption data for different subgroups of the EU population and
allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (EFSA, 2018, 2019).

The toxicological profile of penthiopyrad was assessed during the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) value of 0.1 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.75 mg/kg bw (EFSA, 2013). For 753-A-OH metabolite, peer review experts concluded that it is of a similar toxicity as the parent.

The toxicological profile of PAM was assessed during the assessment of confirmatory data in the Technical Report of EFSA (EFSA, 2016a) and the data were sufficient to derive an ADI value of 0.0024 mg/kg bw per day and an ARfD of 0.024 mg/kg bw.

The most recent consumer risk assessment which was performed for penthiopyrad and PAM in 2016 by EFSA (EFSA, 2016b) was now updated using the risk assessment values as derived for Florence fennel and celeries from the submitted residue trials and taking into account the conclusions of EFSA on the confirmatory data assessment (EFSA, 2016a).

Considering the two risk assessment residue definitions set for penthiopyrad, two separate risk assessments were performed as outlined below.

- **Sum of penthiopyrad and 753-A-OH, expressed as penthiopyrad**
  
  **Long-term (chronic) dietary risk assessment**

  The long-term exposure assessment was performed taking into account the supervised trial median residue (STMR) values derived for celeries and Florence fennel from the submitted residue trials. For a wide range of commodities, the median residue levels were available from the previous EFSA reasoned opinions which were included in the calculation (EFSA, 2012, 2016b). For several plant commodities (coconuts, pine nut kernels, potatoes, spring onions, and pulses, okra, azaroles, kaki, baby leaf lettuce, maize, sweet corn), the existing EU MRL was set on the basis of CXL (FAO, 2012). In order to derive input values for the exposure assessment, the data from the previous EFSA output (EFSA, 2012) and the JMPR evaluation were considered (FAO, 2012) as in most cases the same residue data sets were used to derive MRL or CXL proposals. In cases where residues of metabolite 753-A-OH are not present or occur at very low levels (i.e. conversion factor from enforcement to risk assessment (CF) of 1) in a similar crop group, the LOQ of 0.01 mg/kg for metabolite was added to the input value for penthiopyrad. Where higher levels of metabolite 753-A-OH occur (pome fruit, relevant for azarole and kaki), the CF from enforcement to risk assessment as derived by EFSA in the previous output (EFSA, 2012) was applied to the input value of penthiopyrad.

  For the commodities of animal origin, the LOQ of 0.01 mg/kg was used as an input value, according to previous EFSA assessments (EFSA, 2012).

  The remaining commodities of plant origin were not considered as no uses of penthiopyrad on these commodities have been reported since the approval of penthiopyrad, implementation of safe CXLs and EFSA assessments.

  The complete list of input values is presented in Appendix [Error! Reference source not found.].

  The calculated exposure accounted for a maximum of 9% of the ADI (NL, toddler diet). The contribution of residues in the crops under assessment accounted for up to 0.19% of the ADI for celeries and < 0.1% of the ADI for Florence fennels.
  
  **Short-term (acute) dietary risk assessment**

  The acute consumer risk assessment was performed only for the crops under consideration, using the HR values as derived from residue trials submitted for the current assessment. The highest acute consumer exposure accounted for 45% and 18% of the ARfD for processed and raw Florence fennel, respectively, and for 33% and 37% of the ARfD for processed and raw celery, respectively.

  Although in some commodities full residue data set on metabolite 753-A-OH was not available, considering the large safety margin, the lack of these data is not expected to affect considerably the consumer exposure.

- **PAM metabolite**
  
  **Long-term (chronic) dietary risk assessment**

  The long-term exposure assessment was performed taking into account the STMR values derived for residues of PAM in celeries and Florence fennel from the submitted residue trials.

  For all commodities for which the current MRLs for penthiopyrad are set above the LOQ, the input values for exposure assessment to PAM residues were available from the previously issued EFSA outputs (EFSA, 2012, 2016b).
For pine nuts, coconuts, potatoes, spring onions, pulses, azaroles, kaki, sweet corn, baby leaf lettuce, maize and okra, the existing EU MRL for penthiopyrad was set on the basis of CXL, and therefore, the residue data available by the JMPR were recalculated to obtain the input values for PAM (FAO, 2012). For most of these crops, the same residue data sets were used by EFSA in the previous assessment (EFSA, 2012), but due to different extrapolation rules or assessment approaches, the MRL proposals for these crops were different from the CXLs or were not derived at all.

For ruminant meat, fat, liver and kidney, the LOQ of 0.01 mg/kg was used as an input value according to the previous EFSA assessment (EFSA, 2012).

The highest estimated long-term dietary intake accounted for 60% of the ADI (NL, toddler diet). The contribution of residues for the crops under assessment was low: 0.18% of the ADI for celeries and < 0.1% of the ADI for Florence fennels.

Short-term (acute) dietary risk assessment

The acute consumer risk assessment was performed only for the crops under consideration, using the HR values as derived from residue trials submitted for the current assessment. Acute consumer risk was not identified for the crops under consideration (7% of the ARfD for processed Florence fennel and 6% of the ARfD for celeries).

For further details on the exposure calculations, a screenshot of the report sheet of the EFSA Pesticide Residues Intake Model (PRIMo) is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal of 20 mg/kg for Florence fennel and celeries in support of the intended SEU use.

EFSA concluded that the proposed use of penthiopyrad on Florence fennel and celeries will not result in a consumer exposure exceeding the toxicological reference values for penthiopyrad and PAM metabolite and therefore is unlikely to pose a risk to consumers’ health. It is, however, noted that some uncertainties related to potential accumulation of residues in rotational crops and the behaviour of PAM metabolite under processing remains not fully addressed. Pending studies assessing residue uptake in rotational crops following multi-year applications of penthiopyrad, the consumer risk assessment was conducted considering residues in crops occurring after a single application of penthiopyrad and a single rotation cycle. Risk mitigation measures might be considered by risk managers in order to avoid penthiopyrad-related residues in rotational crops.

The MRL recommendations are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the setting of new MRLs for penthiopyrad in various crops. EFSA Journal 2012;10(10):2948, 96 pp. https://doi.org/10.2903/j.efsa.2012.2948
EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance penthiopyrad. EFSA Journal 2013;11(2):3111, 144 pp. https://doi.org/10.2903/j.efsa.2013.3111
EFSA (European Food Safety Authority), 2016a. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for penthiopyrad in light of confirmatory data. EFSA supporting publication 2016;EN-1072, 21 pp. https://doi.org/10.2903/sp.efsa.2016.en-1072
EFSA (European Food Safety Authority), 2016b. Reasoned opinion on the modification of the MRLs for penthiopyrad in stone fruits and cereals. EFSA Journal 2016;14(12):4648, 19 pp. https://doi.org/10.2903/j.efsa.2016.4648
EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Verani A, 2019. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1. EFSA supporting publication 2019;16(3):EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.en-1605
European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.
European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.
European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.
European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.
European Commission, 1997g. 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, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.
European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.
FAO (Food and Agriculture Organization of the United Nations), 2012. Penthiopyrad In: Pesticide residues in food – 2012. Evaluations, Part I, Residues. FAO Plant Production and Protection Paper 215.
Italy, 2019. Evaluation report on the modification of MRLs for penthiopyrad in Florence fennel and celeries. September, 2019, 48 pp.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org
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.
United Kingdom, 2012. Draft assessment report on the active substance penthiopyrad prepared by the rapporteur Member State the United Kingdom in the framework of Directive 91/414/EEC, January 2012. Available online: www.efsa.europa.eu
United Kingdom, 2013. Final addendum to the draft assessment report on the active substance penthiopyrad, prepared by the rapporteur Member State the United Kingdom in the framework of Directive 91/414/EEC. January 2013. Available online: www.efsa.europa.eu
United Kingdom, 2016. Addendum to the assessment report on penthiopyrad, confirmatory data, March 2016, revised in June 2016. Available online: www.efsa.europa.eu

**Abbreviations**

| a.s. | active substance |
| ADI | acceptable daily intake |
| ARFD | acute reference dose |
| BBCH | growth stages of mono- and dicotyledonous plants |
| bw | body weight |
| CF | conversion factor for enforcement to risk assessment residue definition |
| CXL | Codex maximum residue limit |
| DALA | days after last application |
| DAR | draft assessment report |
| DAT | days after treatment |
| DM | dry matter |
| DT₉₀ | period required for 90% dissipation (define method of estimation) |
| EC | emulsifiable concentrate |
| EMS | evaluating Member State |
| FAO | Food and Agriculture Organization of the United Nations |
| GAP | Good Agricultural Practice |
| GC | gas chromatography |
| GC-FID | gas chromatography with flame ionisation detector |
| GC-MS | gas chromatography with mass spectrometry |
| GC-MS/MS | gas chromatography with tandem mass spectrometry |
| GS | growth stage |
| HPLC | high-performance liquid chromatography |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I\(^{(a)}\) | Pests or group of pests controlled | Preparation | Conc. a.s. | Method kind | Range of growth stages & season\(^{(c)}\) | Number min–max | Interval between application (min) | g a.s./hl min–max | Water L/ha min–max | Rate | Unit | PHI (days)\(^{(d)}\) | Remarks |
|----------------------|------------------------|-----------------|-----------------------------------|-------------|-----------|------------|---------------------------------|-----------------|----------------------|-----------------|-----------------|------|-----|----------------|---------|
| Florence fennels     | SEU                    | F               | Sclerotinia sp.                    | SC          | 200.0     | Foliar treatment – broadcast spraying | 40–49            | 1                       | 200–1,000        | 300 g a.i./ha       | 7    |     |                | Method of application: medium/high volume ground directed overall spray with tractor |
| Celeries             | SEU                    | F               | Sclerotinia sp.                    | SC          | 200.0     | Foliar treatment – broadcast spraying | 40–49            | 1                       | 200–1,000        | 300 g a.i./ha       | 7    |     |                | Method of application: medium/high volume ground directed overall spray with tractor |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI – minimum preharvest interval.
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                             | Grapes      | Foliar  | (1 x 400 g/ha) | 20 and 60 DAT₁ | Radiolabelling: [¹⁴C]-pyrazole and thienyl penthiopyrad ring (EFSA, 2013, 2016b) |
|                                   | Tomatoes    | Foliar  | (1 x 1,500 g/ha)| 14 and 21 DAT₁|                |
| Leafy                            | Cabbage     | Foliar  | (1 x 200 g/ha) | 21 DAT₁      |                |
|                                   |             | Foliar  | (1 x 1,000 g/ha)| 21 DAT₁      |                |
| Cereals/grass                    | Wheat       | Foliar  | (2 x 250 g/ha) | 32 DAT₂      |                |
| Pulses/oilseeds                  | Canola      | Foliar  | (2 x 400 g/ha) | 14 DAT₁      |                |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Radish      | 1 x 800 g a.s/ha (Soil treatment) | 30, 60, 120, 365 | Radiolabelling: [¹⁴C]-pyrazole and thienyl penthiopyrad ring (EFSA, 2013) |
| Leafy crops                         | Lettuce     |         |                |           |                |
| Cereal (small grain)                | Spinach     |         |                |           |                |
|                                    | Wheat       |         |                |           |                |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | Yes     | Radiolabelling: [¹⁴C]-pyrazole and thienyl penthiopyrad (EFSA, 2013) |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | For PAM metabolite, no studies are available |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Yes |                |

DAT: days after treatment; DAT₁: days after first treatment; DAT₂: days after second treatment; PBI: plant back interval.
Can a general residue definition be proposed for primary crops?

Rotational crop and primary crop metabolism similar?

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

Plant residue definition for monitoring (RD-Mo)

Plant residue definition for risk assessment (RD-RA)

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

Plant products (Available studies)

| Category               | Commodity                  | T (°C) | Stability period | Compounds covered                                                                 | Comment/Source |
|------------------------|----------------------------|--------|-----------------|-----------------------------------------------------------------------------------|----------------|
| High water content     | Lettuce, apple, potato     | −20    | 18 Months       | Penthiopyrad, PAM, 753-A-OH, 753-F-DO, PCA, and DM-PCA                             | EFSA (2013)    |
| High oil content       | Oilseed rape               | −20    | 18 Months       | Penthiopyrad                                                                      |                |
| High protein content   | Dried bean                 | −20    | 18 Months       | Penthiopyrad                                                                      |                |
| Dry/high starch        | Wheat grain                | −20    | 18 Months       | Penthiopyrad                                                                      |                |
| High acid content      | Grapes*                    | −20    | 18 Months       | Penthiopyrad                                                                      |                |
| Processed products     | Dry Grape pomace, grape juice | 20    | 18 Months       | Penthiopyrad                                                                      |                |
| Others                 | Cereal straw               | −20    | 18 Months       | Penthiopyrad                                                                      |                |
|                        | Wheat forage               | −20    | 18 Months       | Penthiopyrad                                                                      |                |
|                        | Raisins                    | −20    | 18 Months       | Penthiopyrad                                                                      |                |

*: 753-A-OH not analysed in grape.

HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL<sup>(c)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|--------------------------------------|-----------------|-----------------|
| Celeries, Florence fennel | SEU | Mo: 0.31, 0.61, 0.66, 6.5, 7.4  
RA (1): 0.31, 0.62, 0.67, 6.5, 7.4  
RA (2): < 0.01, 0.011, 0.015, 0.026, 0.038 | Residue trials on celeries and Florence fennel compliant with SEU GAP were combined  
Underlined values refer to residue trials on Florence fennel  
Extrapolation to Florence fennel is possible | 20 | Mo: 7.4  
RA (1): 7.4  
RA (2): 0.038 | Mo: 0.66  
RA (1): 0.67  
RA (2): 0.015 |

**Enforcement residue definition:** Penthiopyrad  
**Risk assessment residue definition (RD RA):**  
(1): Sum of penthiopyrad and metabolite 753-A-OH, expressed as penthiopyrad  
(2): Metabolite PAM

**MRL:** maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.  
<sup>(a)</sup>: 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.  
<sup>(b)</sup>: Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.  
<sup>(c)</sup>: Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Yes | EFSA (2013) |
|-------------------------------------------------------------------------------------------------|-----|-------------|
| Residues in rotational and succeeding crops expected based on field rotational crop study?     | Yes | Primary crops barley and cucumber grown as primary crop were treated with penthiopyrad at two applications of 400 g/ha. 30, 60, 120 and 365 days DALA the primary crops were harvested and following crops planted. Quantifiable residues were measured only in radish roots from 60-day PBI (max 0.017 mg/kg). Studies after multiple-year applications of penthiopyrad are not available and presence of residues cannot be excluded for future applications (EFSA, 2013) |

DALA: days after last application; PBI: plant-back interval.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

| Sum of penthiopyrad and its metabolite 753-A-OH, expressed as penthiopyrad | ARfD | 0.75 mg/kg bw (EFSA, 2013) |
|-------------------------------------------------------------------------|------|---------------------------|
| Highest IESTI, according to EFSA PRIMo                                  |      |                           |
| Celeries: 37% of ARfD                                                   |      |                           |
| Florence fennels: 18% of ARfD (raw; adult exposure)                     |      |                           |
| Florence fennels: 45% of ARfD (processed/boiled; children exposure)     |      |                           |
| Assumptions made for the calculations                                  |      |                           |
| The calculation is based on the highest residue levels estimated in Florence fennel and celeries according to the submitted residue trials. |      |                           |
| Calculations performed with PRIMo revision 3.1.                         |      |                           |

| PAM                                                                    | ARfD | 0.024 mg/kg bw (EFSA, 2016a) |
|-----------------------------------------------------------------------|------|-----------------------------|
| Highest IESTI, according to EFSA PRIMo                                |      |                             |
| Celeries: 6% of ARfD                                                   |      |                             |
| Florence fennels: 3% of ARfD (raw; adult exposure)                    |      |                             |
| Florence fennels: 7% of ARfD (processed/boiled; children exposure)    |      |                             |
| The calculation is based on the highest residue levels estimated in Florence fennel and celeries according to the submitted residue trials. |      |                             |
| Calculations performed with PRIMo revision 3.1.                       |      |                             |
Sum of penthiopyrad and its metabolite 753-A-OH, expressed as penthiopyrad

| ADI                          | 0.1 mg/kg bw per day (EFSA, 2013) |
|------------------------------|-----------------------------------|
| Highest IEDI, according to EFSA PRIMo | 9% ADI (NL, toddler) |
| Contribution of crops assessed: | Celeries: 0.19% of ADI |
|                              | Florence fennels: < 0.1% of ADI |

Assumptions made for the calculations

Calculations are based on the median residue levels as estimated in Florence fennel and celeries from the submitted residue trials. Additionally, the median residue levels for the crops assessed in previous EFSA reasoned opinions were available and were included in the calculation.

For several plant commodities, the existing EU MRL was set on the basis of CXL (FAO 2012), but due to different risk assessment residue definitions, the residue data on metabolite 753-A-OH were not available. The input values for these crops were derived as follows:

- a) coconuts, pine nuts, potatoes, spring onions, pulses: STMR for penthiopyrad as derived by the JMPR (FAO, 2012) + LOQ of 0.01 mg/kg for 753-A-OH, as in these crops/crop groups according to EFSA assessment (EFSA 2012) no residues of 753-A-OH were present and the same residue data sets were used both by the EFSA and the JMPR.

- b) azaroles and kaki: the STMR for penthiopyrad as derived by the JMPR (FAO, 2012) x conversion factor (CF) of 1.3 (from enforcement to risk assessment RD) for pome fruits as derived in the previous EFSA reasoned opinion (EFSA, 2012); the same residue data sets were used by the EFSA and the JMPR.

- c) baby leaf crops (including brassica species): the STMR for penthiopyrad in turnip greens as derived by the JMPR (FAO, 2012) + LOQ of 0.01 mg/kg for 753-A-OH, since in lettuces/mustard greens low levels of metabolite 753-A-OH occur (CF of 1) according to the previous EFSA assessment (EFSA, 2012).

- d) okra, maize: the STMR value for peppers and maize, respectively, as derived in the EFSA assessment (EFSA, 2012) since the same residue data sets were used by the JMPR to derive CXL proposal.

For the commodities of animal origin, the existing EU MRL set at the LOQ of 0.01 mg/kg was used as an input value.

The remaining commodities of plant origin were not considered as no uses of penthiopyrad on these commodities have been reported since the approval of penthiopyrad, implementation of safe CXLs and EFSA assessments.

Calculations performed with PRIMo revision 3.1.
PAM

ADI
0.0024 mg/kg bw per day (EFSA, 2016a)

Highest IEDI, according to EFSA PRIMo
60% ADI (NL, toddler)

Contribution of crops assessed: Celeries: 0.18% of ADI
Florence fennels: <0.1% of ADI

Assumptions made for the calculations

Calculations are based on the median residue levels as estimated for Florence fennel and celeries from the submitted residue trials. For a wide range of commodities, the STMR values for metabolite PAM were available from the previously issued EFSA outputs (EFSA, 2012, 2016b). For pine nuts, coconuts, potatoes, spring onions, pulses, azaroles, kaki, sweet corn, baby leaf lettuce, maize, okra, the existing EU MRL for penthiopyrad was set on the basis of CXL and therefore the residue data available by the JMPR were recalculated to obtain the input values for PAM (FAO, 2012). For most of these crops the same residue data sets were used by EFSA in the previous assessment (EFSA, 2012), but due to different extrapolation rules or assessment approaches the MRL proposals for these crops were different from the CXLs or were not derived at all. For ruminant meat, fat, liver and kidney, the LOQ of 0.01 mg/kg was used as an input value according to the previous EFSA assessment.

For the remaining commodities of plant and animal origin, the existing EU MRLs for penthiopyrad are set at the LOQ and these commodities were excluded from the exposure calculation, assuming no use of penthiopyrad on respective crops and no transfer of PAM residues to animal commodities.

Calculations performed with PRIMo revision 3.1.

B.4. Recommended MRLs

| Code(a) | Commodity        | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                      |
|---------|------------------|-------------------------|-------------------------|------------------------------------------------------------|
| 270030  | Celeries         | 15                      | 20                      | The submitted data are sufficient to derive an MRL proposal for the intended SEU use. Risk for consumers unlikely |
| 270040  | Florence fennels | 15                      | 20                      |                                                            |

MRL: maximum residue level; SEU: southern Europe.

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

(F): Fat soluble

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; CXL: Codex maximum residue limit; MRL: maximum residue level; STMR: supervised trials median residue; LOQ: limit of quantification.
### Penthiopyrad

**Toxicological reference values**

| Chemical | LOQ (mg/kg) | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI |
|----------|-------------|------------------------|----------------|--------------|
| Penthiopyrad | 0.05 - 0.07 | 0.75 | | Assessment/children |

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

#### Normal mode

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

**As of data reviewed by the ADI**

| Commodity/group of commodities | Exposure resulting from MRLs set at LOQ (µg/kg bw per day) | 3rd contributor to MS diet (in % of ADI) |
|-------------------------------|----------------------------------------------------------|--------------------------------------|
| **Cauliflowers**              |                                                          |                                      |
| 9%                            | 9.30                                                     | 2%                                   |
| 2%                            | 2%                                                       | 0.7%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.8%                          |                                                          | 0.0%                                 |
| **Cress and other sprouts and shoots** | | |
| 0.2%                          |                                                          | 0.0%                                 |
| **Head cabbages**             |                                                          |                                      |
| 0.8%                          |                                                          | 0.0%                                 |
| **Lettuces**                  |                                                          |                                      |
| 4%                            | 4.19                                                     | 0.9%                                 |
| 1%                            | 0.35                                                     | 0.2%                                 |
| **Lamb's lettuce/corn salads**|                                                          |                                      |
| 0.2%                          |                                                          | 0.0%                                 |
| **Peas, (pods)**              |                                                          |                                      |
| 0.2%                          |                                                          | 0.1%                                 |
| **Tomatoes**                  |                                                          |                                      |
| 4%                            | 3.94                                                     | 0.7%                                 |
| 0.7%                          | 0.2%                                                     | 0.1%                                 |
| **Spinaches**                 |                                                          |                                      |
| 3%                            | 3.34                                                     | 0.5%                                 |
| 0.5%                          | 0.1%                                                     | 0.0%                                 |
| **Sugar beet roots**          |                                                          |                                      |
| 4%                            | 3.72                                                     | 0.3%                                 |
| 0.3%                          | 0.0%                                                     | 0.0%                                 |
| **Other lettuce and other salad plants** | | |
| 0.2%                          |                                                          | 0.0%                                 |
| **Tomatoes**                  |                                                          |                                      |
| 2%                            | 1.71                                                     | 0.1%                                 |
| 0.1%                          | 0.0%                                                     | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.1%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Other lettuce and other salad plants** | | |
| 0.1%                          |                                                          | 0.0%                                 |
| **Tomatoes**                  |                                                          |                                      |
| 0.1%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.1%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.1%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Other lettuce and other salad plants** | | |
| 0.0%                          |                                                          | 0.0%                                 |
| **Tomatoes**                  |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cauliflowers**              |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Cherries (sweet)**          |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |
| **Spinaches**                 |                                                          |                                      |
| 0.0%                          |                                                          | 0.0%                                 |

**Conclusion:**

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

| Unprocessed commodities | Results for children | Results for adults |
|-------------------------|----------------------|--------------------|
|                         | No. of commodities for which ARfD/ADI is exceeded (IESTI): | No. of commodities for which ARfD/ADI is exceeded (IESTI): |
| IESTI                   |                      |                    |
| Highest % of ARfD/ADI   | Commodities         | MRL/input for RA   | Exposure |
|                         |                     | (mg/kg)            | (µg/kg bw) |
| 37% Celeries            | 20/7.4              | 277                |
| 16% Florence fennels    | 20/7.4              | 120                |
|                         |                      |                    |
| Highest % of ARfD/ADI   | Commodities         | MRL/input for RA   | Exposure |
|                         |                     | (mg/kg)            | (µg/kg bw) |
| 18% Florence fennels    | 20/7.4              | 138                |
| 16% Celeries            | 20/7.4              | 118                |

Expand/collapse list

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

| Processed commodities | Results for children | Results for adults |
|-----------------------|----------------------|--------------------|
|                       | No. of commodities for which ARfD/ADI is exceeded (IESTI): | No. of commodities for which ARfD/ADI is exceeded (IESTI): |
| IESTI                 |                      |                    |
| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA   | Exposure |
|                       |                     | (mg/kg)            | (µg/kg bw) |
| 45% Florence fennels/boiled | 20/7.4              | 335                |
| 33% Celery/boiled     | 20/7.4              | 250                |
| 19% Florence fennels/boiled | 20/7.4              | 143                |

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of Penthiopyrad is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.
### PAM metabolite

**Toxicological reference values**

- **LOQs (mg/kg)** range from: 0.01 to: 0.05
- **ADI (mg/kg bw per day):** 0.0024
- **ARfD (mg/kg bw):** 0.024

**Source of ADI:** EFSA
**Source of ARfD:** EFSA

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

**Year of evaluation:** 2016

---

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|-------------------------------|----------------------------------|-----------------------------------------------|
| Spinaches                     | 33%                              | 15%                                           |
| Apples                        | 25%                              | 14%                                           |
| Apples                        | 28%                              | 19%                                           |
| Wheat                         | 26%                              | 25%                                           |
| Apples                        | 24%                              | 24%                                           |
| Sugar beet roots              | 23%                              | 23%                                           |
| Soyabeans                     | 19%                              | 19%                                           |
| Potatoes                      | 18%                              | 18%                                           |
| Wheat                         | 18%                              | 18%                                           |
| Spinaches                     | 16%                              | 16%                                           |
| Wheat                         | 16%                              | 16%                                           |
| Lettuces                      | 15%                              | 15%                                           |
| Milk: Cattle                  | 14%                              | 14%                                           |
| Soyabeans                     | 14%                              | 14%                                           |
| Spinaches                     | 13%                              | 13%                                           |
| Spinaches                     | 12%                              | 12%                                           |
| Potatoes                      | 11%                              | 11%                                           |
| Spinaches                     | 10%                              | 10%                                           |
| Spinaches                     | 9%                               | 9%                                            |
| Potatoes                      | 8%                               | 8%                                            |
| Spinaches                     | 7%                               | 7%                                            |
| Spinaches                     | 6%                               | 6%                                            |
| Spinaches                     | 5%                               | 5%                                            |
| Spinaches                     | 4%                               | 4%                                            |
| Spinaches                     | 3%                               | 3%                                            |
| Spinaches                     | 2%                               | 2%                                            |
| Spinaches                     | 1%                               | 1%                                            |

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

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

**Normal mode**

**Conclusion:**

- DK adult
- LT adult
- FI 6 yr
- FR toddler 2-3 yr
- FR child 3-15 yr
- UK infant
- DE child
- UK vegetarian
- FI 3 yr
- DE women 14-50 yr
- NL toddler
- PL general
- DE general
- ES adult
- FR adult
- IT toddler
- IT adult
- UK adult
- FR adult
- NL child
- SE general
- ES child
- PT general
- DE women 14-50 yr
- GEMS/Food G11
- GEMS/Food G10
- GEMS/Food G09
- GEMS/Food G08
- GEMS/Food G07
- GEMS/Food G06
- GEMS/Food G15
- RO general
- GEMS/Food G16

**Input values**

- Details – chronic risk assessment
- Supplementary results – chronic risk assessment
- Details – acute risk assessment
- Details – acute risk assessment/children
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Results for children

| Commodity                        | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Commodity                        | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|----------------------------------|---------------------------|---------------------|----------------------------------|---------------------------|---------------------|
| Kaki/Japanese persimmons         | 0.4/0.4                   | 19                  | Chards/beet leaves               | 30/0.58                   | 15                  |
| Leeks                            | 3/0.26                    | 15                  | Japanese persimmons             | 0.4/0.4                   | 8.8                 |
| Spinaches                        | 30/0.58                   | 13                  | Spinaches                        | 30/0.58                   | 19                  |
| Lettuces                         | 15/2.0                    | 9.7                 | Lettuces                         | 15/2.6                    | 3.1                 |
| Collard leaf                      | 30/0.58                   | 9.1                 | Collard leaf                     | 46/0.7                    | 2.7                 |
| Rhubarbs                         | 15/0.16                   | 6.7                 | Rhubarbs                         | 30/0.58                   | 2.3                 |
| Spring onions/green onions and Welch onions | 45/2.6 | 4.1               | Spring onions/green onions and Welch onions | 45/2.6 | 2.3               |
| Malons                           | 0.6/0.03                  | 4.0                 | Malons                           | 15/0.26                   | 1.7                 |
| Watermelons                      | 0.6/0.03                  | 3.2                 | Watermelons                      | 15/0.26                   | 1.4                 |
| Heat cabbages                    | 4.05/0.7                  | 2.9                 | Heat cabbages                    | 4.05/0.7                  | 1.2                 |
| Pears                            | 0.5/0.02                  | 2.8                 | Pears                            | 30/0.58                   | 1.1                 |
| Sweet peppers/red peppers        | 2/0.02                    | 2.2                 | Sweet peppers/red peppers        | 0.6/0.03                  | 1.1                 |
| Potatoes                         | 0.05/0.05                 | 1.5                 | Potatoes                         | 0.05/0.05                 | 0.71                |
| Calorics                         | 200/0.4                   | 1.4                 | Calorics                         | 0.5/0.02                  | 0.61                |

### Results for adults

| Commodity                        | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Commodity                        | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|----------------------------------|---------------------------|---------------------|----------------------------------|---------------------------|---------------------|
| Chards/beet leaves/boiled        | 30/0.58                   | 16                  | Chards/beet leaves/boiled        | 30/0.58                   | 7.3                 |
| Spinaches/frozen, boiled         | 30/0.58                   | 8.1                 | Spinaches/frozen, boiled         | 30/0.58                   | 4.8                 |
| Leeks/boiled                     | 30/0.58                   | 8.1                 | Leeks/boiled                     | 30/0.58                   | 4.8                 |
| Rhubarbs/sauce/puree             | 15/0.16                   | 6.7                 | Rhubarbs/sauce/puree             | 15/0.16                   | 2.6                 |
| Pumpkins/boiled                  | 0.6/0.03                  | 2.4                 | Pumpkins/boiled                  | 0.6/0.03                  | 2.4                 |
| Broccoli/boiled                  | 40/0.2                    | 1.9                 | Broccoli/boiled                  | 40/0.2                    | 1.9                 |
| Florence fennels/boiled          | 200/0.4                   | 1.7                 | Florence fennels/boiled          | 200/0.4                   | 1.7                 |
| Cauliflowers/boiled              | 4/0.02                    | 1.7                 | Cauliflowers/boiled              | 200/0.4                   | 1.3                 |
| Sugar beets (root/sugar)         | 0.5/0.12                  | 1.1                 | Sugar beets (root/sugar)         | 0.5/0.12                  | 1.1                 |
| Potatoes/fried                   | 0.05/0.01                 | 0.93                | Potatoes/fried                   | 0.05/0.01                 | 0.93                |
| Courgettes/boiled                | 0.7/0.02                  | 0.64                | Courgettes/boiled                | 0.7/0.02                  | 0.64                |
| Potatoes/fried (flakes)          | 0.05/0.05                 | 0.59                | Potatoes/fried (flakes)          | 0.05/0.05                 | 0.59                |
| Apples/juice                     | 0.5/0.01                  | 0.54                | Apples/juice                     | 0.5/0.01                  | 0.54                |
| Tumms/boiled                     | 0.6/0.01                  | 0.51                | Tumms/boiled                     | 0.6/0.01                  | 0.51                |
| Pears/boiled                     | 0.5/0.01                  | 0.51                | Pears/boiled                     | 0.5/0.01                  | 0.51                |

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of PAM metabolite is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.

www.efsa.europa.eu/efsajournal 25 EFSA Journal 2020;18(9):6259
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Not relevant.

D.2. Consumer risk assessment

- **Penthiopyrad**

| Commodity               | Chronic risk assessment | Acute risk assessment<sup>(a)</sup> |
|-------------------------|-------------------------|-------------------------------------|
|                         | Input value (mg/kg)     | Comment                            |
| Celeriess               | 0.67                    | STMR                               | 7.4 | HR |
| Florence fennels        | 0.67                    | STMR                               | 7.4 | HR |
| Almonds                 | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Brazil nuts             | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Cashew nuts             | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Chestnuts               | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Coconuts                | 0.02                    | STMR penthiopyrad (FAO, 2012)      |     |    |
| Pine nut kernels        | 0.02                    | STMR penthiopyrad (FAO, 2012)      |     |    |
| Hazelnuts/cobnuts       | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Macadamia               | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Pecans                  | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Pistachios              | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Walnuts                 | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Other tree nuts         | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Apples                  | 0.15                    | STMR (EFSA, 2012)                  |     |    |
| Pears                   | 0.15                    | STMR (EFSA, 2012)                  |     |    |
| Quinces                 | 0.15                    | STMR (EFSA, 2012)                  |     |    |
| Medlar                  | 0.15                    | STMR (EFSA, 2012)                  |     |    |
| Loquats/Japanese medlars| 0.15                    | STMR (EFSA, 2012)                  |     |    |
| Other pome fruit (Kaki/Japanese persimmon, azaroles) | 0.18 | STMR penthiopyrad (FAO, 2012) × CF (1.3) |
| Apricots                | 0.76                    | STMR (EFSA, 2016b)                 |     |    |
| Cherries (sweet)        | 1.14                    | STMR (EFSA, 2012)                  |     |    |
| Peaches                 | 0.76                    | STMR (EFSA, 2016b)                 |     |    |
| Plums                   | 0.11                    | STMR (EFSA, 2012)                  |     |    |
| Strawberries            | 0.79                    | STMR (EFSA, 2012)                  |     |    |
| Potatoes                | 0.02                    | STMR penthiopyrad (FAO, 2012)      |     |    |
| Cassava roots/ manioc   | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Sweet potatoes          | 0.02                    | STMR (EFSA, 2012)                  |     |    |
| Yams                    | 0.02                    | STMR (EFSA, 2012)                  |     |    |

Risk assessment residue definition (1): Sum of penthiopyrad and its metabolite 753-A-OH, expressed as penthiopyrad.
| Commodity                        | Chronic risk assessment | Acute risk assessment<sup>(a)</sup> |
|---------------------------------|------------------------|-------------------------------------|
|                                 | Input value (mg/kg)    | Comment (mg/kg)                      |
| Arrowroots                      | 0.02                   | STMR (EFSA, 2012)                   |
| Other tropical root and tuber vegetables | 0.02                   | STMR (EFSA, 2012)                   |
| Beetroots                       | 0.08                   | STMR (EFSA, 2012)                   |
| Carrots                         | 0.08                   | STMR (EFSA, 2012)                   |
| Celeriacs/turnip-rooted celeries | 0.08                   | STMR (EFSA, 2012)                   |
| Horseradishes                   | 0.08                   | STMR (EFSA, 2012)                   |
| Jerusalem artichokes            | 0.08                   | STMR (EFSA, 2012)                   |
| Parsnips                        | 0.08                   | STMR (EFSA, 2012)                   |
| Parsley roots/Hamburg roots parsley | 0.08                   | STMR (EFSA, 2012)                   |
| Radishes                        | 0.29                   | STMR (EFSA, 2012)                   |
| Salsifies                       | 0.08                   | STMR (EFSA, 2012)                   |
| Swedes/rutabagas                | 0.08                   | STMR (EFSA, 2012)                   |
| Turnips                         | 0.08                   | STMR (EFSA, 2012)                   |
| Other root and tuber vegetables | 0.08                   | STMR (EFSA, 2012)                   |
| Garlic                          | 0.07                   | STMR (EFSA, 2012)                   |
| Onions                          | 0.07                   | STMR (EFSA, 2012)                   |
| Shallots                        | 0.07                   | STMR (EFSA, 2012)                   |
| Spring onions/green onions and Welsh onions | 0.75                   | STMR penthiopyrad (FAO, 2012) + LOQ (0.01 mg/kg) 753-A-OH (EFSA, 2012) |
| Other bulb vegetables           | 0.07                   | STMR (EFSA, 2012)                   |
| Tomatoes                        | 0.32                   | STMR (EFSA, 2012)                   |
| Sweet peppers/bell peppers      | 0.23                   | STMR (EFSA, 2012)                   |
| Okra/Lady’s fingers             | 0.23                   | STMR peppers (EFSA, 2012)          |
| Aubergines/egg plants           | 0.32                   | STMR (EFSA, 2012)                   |
| Cucumbers                       | 0.19                   | STMR (EFSA, 2012)                   |
| Gherkins                        | 0.19                   | STMR (EFSA, 2012)                   |
| Courgettes                      | 0.19                   | STMR (EFSA, 2012)                   |
| Other cucurbits – edible peel   | 0.19                   | STMR (EFSA, 2012)                   |
| Melons                          | 0.21                   | STMR (EFSA, 2012)                   |
| Pumpkins                        | 0.21                   | STMR (EFSA, 2012)                   |
| Watermelons                     | 0.21                   | STMR (EFSA, 2012)                   |
| Other cucurbits – inedible peel | 0.21                   | STMR (EFSA, 2012)                   |
| Sweet corn                      | 0.02                   | STMR (EFSA, 2012)                   |
| Broccoli                        | 1.12                   | STMR (EFSA, 2012)                   |
| Cauliflowers                    | 1.12                   | STMR (EFSA, 2012)                   |
| Commodity                                      | Chronic risk assessment | Acute risk assessment<sup>(a)</sup> |
|-----------------------------------------------|-------------------------|-----------------------------------|
|                                               | Input value             | Comment                           | Input value   | Comment |
|                                               | (mg/kg)                 |                                   | (mg/kg)       |         |
| Other flowering brassica                      | 1.12 STMR (EFSA, 2012)  |                                   |               |         |
| Head cabbages                                 | 0.39 STMR (EFSA, 2012)  |                                   |               |         |
| Lamb's lettuce/corn salads                    | 2.75 STMR (EFSA, 2012)  |                                   |               |         |
| Lettuces                                      | 2.75 STMR (EFSA, 2012)  |                                   |               |         |
| Cress and other sprouts and shoots            | 2.75 STMR (EFSA, 2012)  |                                   |               |         |
| Land cress                                    | 2.75 STMR (EFSA, 2012)  |                                   |               |         |
| Roman rocket/rucola                           | 2.75 STMR (EFSA, 2012)  |                                   |               |         |
| Red mustards                                  | 2.75 STMR (EFSA, 2012)  |                                   |               |         |
| Baby leaf crops (including brassica species)  | 9.55 STMR (FAO, 2012)   |                                   |               |         |
| Other lettuce and other salad plants          | 2.75 STMR (EFSA, 2012)  |                                   |               |         |
| Spinaches                                     | 2.79 STMR (EFSA, 2012)  |                                   |               |         |
| Purslanes                                     | 2.79 STMR (EFSA, 2012)  |                                   |               |         |
| Chards/beet leaves                            | 2.79 STMR (EFSA, 2012)  |                                   |               |         |
| Other spinach and similar                     | 2.79 STMR (EFSA, 2012)  |                                   |               |         |
| Chervil                                       | 2.75 STMR (EFSA, 2012)  |                                   |               |         |
| Parsley                                       | 2.75 STMR (EFSA, 2012)  |                                   |               |         |
| Beans (with pods)                             | 0.63 STMR (EFSA, 2012)  |                                   |               |         |
| Beans (without pods)                          | 0.06 STMR (EFSA, 2012)  |                                   |               |         |
| Peas (with pods)                              | 1.15 STMR (EFSA, 2012)  |                                   |               |         |
| Peas (without pods)                           | 0.08 STMR (EFSA, 2012)  |                                   |               |         |
| Cardoons                                      | 3.02 STMR (EFSA, 2012)  |                                   |               |         |
| Leeks                                         | 0.71 STMR (EFSA, 2012)  |                                   |               |         |
| Rhubarbs                                      | 3.02 STMR (EFSA, 2012)  |                                   |               |         |
| Pulses                                        | 0.02 STMR penthiopyrad (FAO, 2012) + LOQ (0.01 mg/kg) 753-A-OH (EFSA, 2012) | |               |         |
| Peanuts/groundnuts                            | 0.02 STMR penthiopyrad (FAO, 2012) + LOQ (0.01 mg/kg) 753-A-OH (EFSA, 2012) | |               |         |
| Sunflower seeds                               | 0.11 STMR (EFSA, 2012)  |                                   |               |         |
| Rapeseeds/canola seeds                        | 0.038 STMR (EFSA, 2012) |                                   |               |         |
| Soyabean                                      | 0.02 STMR (EFSA, 2012)  |                                   |               |         |
| Cotton seeds                                  | 0.12 STMR (EFSA, 2012)  |                                   |               |         |
| Barley                                        | 0.08 STMR (EFSA, 2012)  |                                   |               |         |
| Maize/corn                                    | 0.02 STMR (EFSA, 2012)  |                                   |               |         |
| Common millet/proso millet                    | 0.19 STMR (EFSA, 2012)  |                                   |               |         |
| Oat                                           | 0.08 STMR (EFSA, 2012)  |                                   |               |         |
| Rye                                           | 0.02 STMR (EFSA, 2012)  |                                   |               |         |
| Sorghum                                       | 0.19 STMR (EFSA, 2012)  |                                   |               |         |
### Commodity

| Commodity | Chronic risk assessment | Acute risk assessment(a) |
|-----------|-------------------------|--------------------------|
|           | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Wheat     | 0.02 | STMR (EFSA, 2012) | | |
| Sugar beet roots | 0.097 | STMR (EFSA, 2012) | | |

**Animal commodities:** MRL | Regulation (EU) No 2017/1016

STMR: supervised trials median residue; HR: highest residue; CF: conversion factor; LOQ: limit of quantification.

(a): Acute risk assessment undertaken only with regard to the crops under consideration.

### PAM metabolite

| Commodity | Chronic risk assessment | Acute risk assessment(a) |
|-----------|-------------------------|--------------------------|
|           | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Celeries  | 0.015 | STMR | 0.038 | HR |
| Florence fennels | 0.015 | STMR | 0.038 | HR |
| Almonds   | 0.01 | STMR (EFSA, 2012) | | |
| Brazil nuts | 0.01 | STMR (EFSA, 2012) | | |
| Cashew nuts | 0.01 | STMR (EFSA, 2012) | | |
| Chestnuts | 0.01 | STMR (EFSA, 2012) | | |
| Coconuts  | 0.01 | STMR (EFSA, 2012; FAO, 2012) | | |
| Hazelnuts/cobnuts | 0.01 | STMR (EFSA, 2012) | | |
| Macadamia | 0.01 | STMR (EFSA, 2012) | | |
| Pecans    | 0.01 | STMR (EFSA, 2012) | | |
| Pine nut kernels | 0.01 | STMR (EFSA, 2012; FAO, 2012) | | |
| Pistachios | 0.01 | STMR (EFSA, 2012) | | |
| Walnuts   | 0.01 | STMR (EFSA, 2012) | | |
| Apples    | 0.01 | STMR (EFSA, 2012) | | |
| Pears     | 0.01 | STMR (EFSA, 2012) | | |
| Quinces   | 0.01 | STMR (EFSA, 2012) | | |
| Medlar    | 0.01 | STMR (EFSA, 2012) | | |
| Loquats/Japanese medlars | 0.01 | STMR (EFSA, 2012) | | |
| Apricots  | 0.01 | STMR (EFSA, 2016b) | | |
| Cherries (sweet) | 0.01 | STMR (EFSA, 2012) | | |
| Peaches   | 0.01 | STMR (EFSA, 2016b) | | |
| Plums     | 0.01 | STMR (EFSA, 2012) | | |
| Kaki/Japanese persimmon, azaroles | 0.0108 | STMR pome fruit (FAO, 2012) | | |
| Strawberries | 0.019 | STMR (EFSA, 2012) | | |
| Potatoes  | 0.01 | STMR (FAO, 2012) | | |
| Cassava roots/manioc | 0.01 | STMR (EFSA, 2012) | | |
| Sweet potatoes | 0.01 | STMR (EFSA, 2012) | | |
| Yams      | 0.01 | STMR (EFSA, 2012) | | |
| Arrowroots | 0.01 | STMR (EFSA, 2012) | | |
| Beetroots | 0.01 | STMR (EFSA, 2012) | | |
| Carrots   | 0.01 | STMR (EFSA, 2012) | | |
| Celeriacs/turnip rooted celeries | 0.01 | STMR (EFSA, 2012) | | |
| Horseradishes | 0.01 | STMR (EFSA, 2012) | | |
| Commodity                          | Chronic risk assessment | Acute risk assessment<sup>(a)</sup> |
|-----------------------------------|-------------------------|-------------------------------------|
|                                   | Input value (mg/kg)     | Comment                             | Input value (mg/kg) | Comment |
| Jerusalem artichokes              | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Parsnips                          | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Parsley roots/Hamburg roots parsley | 0.01                | STMR (EFSA, 2012)                   |                    |         |
| Radishes                          | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Salsifies                         | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Swedes/rutabagas                  | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Turnips                           | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Garlic                            | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Onions                            | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Shallots                          | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Spring onions/green onions        | 0.084                   | STMR (EFSA, 2012, FAO, 2012)        |                    |         |
| and Welsh onions                 |                         |                                     |                    |         |
| Tomatoes                          | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Sweet peppers/bell peppers        | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Aubergines/egg plants             | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Cucumbers                         | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Gherkins                          | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Courgettes                        | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Okra                              | 0.005                   | STMR peppers (FAO, 2012)            |                    |         |
| Melons                            | 0.013                   | STMR (EFSA, 2012)                   |                    |         |
| Pumpkins                          | 0.013                   | STMR (EFSA, 2012)                   |                    |         |
| Watermelons                       | 0.013                   | STMR (EFSA, 2012)                   |                    |         |
| Sweet corn                        | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Broccoli                          | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Cauliflowers                      | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Head cabbages                     | 0.011                   | STMR (EFSA, 2012)                   |                    |         |
| Lamb’s lettuce/corn salads        | 0.063                   | STMR (EFSA, 2012)                   |                    |         |
| Lettuces                          | 0.063                   | STMR (EFSA, 2012)                   |                    |         |
| Cress and other sprouts and shoots| 0.063                   | STMR (EFSA, 2012)                   |                    |         |
| Land cress                        | 0.063                   | STMR (EFSA, 2012)                   |                    |         |
| Roman rocket/ruccola              | 0.063                   | STMR (EFSA, 2012)                   |                    |         |
| Red mustards                      | 0.063                   | STMR (EFSA, 2012)                   |                    |         |
| Baby leaf crops (including brassica species) | 0.032 | STMR turnip greens (FAO, 2012) | | |
| Spinaches                         | 0.218                   | STMR (EFSA, 2012)                   |                    |         |
| Purslanes                         | 0.218                   | STMR (EFSA, 2012)                   |                    |         |
| Chards/beet leaves                | 0.218                   | STMR (EFSA, 2012)                   |                    |         |
| Spinach and similar               | 0.218                   | STMR (EFSA, 2012)                   |                    |         |
| Chervil                           | 0.063                   | STMR (EFSA, 2012)                   |                    |         |
| Parsley                           | 0.063                   | STMR (EFSA, 2012)                   |                    |         |
| Beans (with pods)                 | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Beans (without pods)              | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Peas (with pods)                  | 0.016                   | STMR (EFSA, 2012)                   |                    |         |
| Peas (without pods)               | 0.01                    | STMR (EFSA, 2012)                   |                    |         |
| Cardoons                          | 0.06                    | STMR (EFSA 2012)                    |                    |         |
| Leeks                             | 0.084                   | STMR (EFSA, 2012)                   |                    |         |
| Commodity                   | Chronic risk assessment | Acute risk assessment<sup>(a)</sup> |
|-----------------------------|-------------------------|-------------------------------------|
|                             | Input value (mg/kg)     | Comment                             |
| Rhubarbs                    | 0.06                    | STMR (EFSA, 2012)                   |
| Pulses                      | 0.01                    | STMR (EFSA, 2012)                   |
| Peanuts/groundnuts          | 0.01                    | STMR (EFSA, 2012)                   |
| Sunflower seeds             | 0.01                    | STMR (EFSA, 2012)                   |
| Rapeseeds/canola seeds      | 0.012                   | STMR (EFSA, 2012)                   |
| Soyabeans                   | 0.01                    | STMR (EFSA, 2012)                   |
| Cotton seeds                | 0.023                   | STMR (EFSA, 2012)                   |
| Barley                      | 0.01                    | STMR (EFSA, 2012)                   |
| Maize/corn                  | 0.01                    | STMR (EFSA, 2012)                   |
| Oat                         | 0.01                    | STMR (EFSA, 2012)                   |
| Rye                         | 0.01                    | STMR (EFSA, 2012)                   |
| Sorghum                     | 0.023                   | STMR (EFSA, 2012)                   |
| Wheat                       | 0.01                    | STMR (EFSA, 2012)                   |
| Sugar beet roots            | 0.01                    | STMR (EFSA, 2012)                   |
| Ruminant meat, fat, kidney, | 0.01                    | LOQ (EFSA, 2012)                    |
| liver                       |                         |                                     |

STMR: supervised trials median residue; HR: highest residue; LOQ: limit of quantification.

<sup>(a)</sup>: Acute risk assessment undertaken only with regard to the crops under consideration.
### Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|---------------------|----------------------------------------|-----------------------|
| Penthiopyrad        | (RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide O=C(Nc1ccsc1C(C)CC(C)C)c1cn(C)nc1C(F)(F)F PFFIDZXUXFLSSR-UHFFFAOYSA-N | ![Structural formula](attachment://penthiopyrad_smilie.png) |
| 753-A-OH            | N-[2-(4-hydroxy-4-methylpentan-2-yl)thiophen-3-yl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide O=C(Nc1ccsc1C(C)CC(C)(O)c1cn(C)nc1C(F)(F)F PTOONGKKGPZDRB-UHFFFAOYSA-N | ![Structural formula](attachment://753-A-OH_smile.png) |
| 753-F-DO            | N-[5-hydroxy-5-(1,3-dimethylbutyl)-2-oxo-2,5-dihydrothiophen-4-yl]-1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide OC1(SC(=O)C=CN(C)(=O)c1cn(C)nc1C(F)(F)F)C(C)CC(C)C XHRDZJHMDZCQRN-UHFFFAOYSA-N | ![Structural formula](attachment://753-F-DO_smile.png) |
| PAM                 | 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide FC(F)(F)c1nn(C)cc1C(N)=O UTBJLKDQNCKAS-UHFFFAOYSA-N | ![Structural formula](attachment://PAM_smile.png) |
| PCA                 | 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxylic acid FC(F)(F)c1nn(C)cc1C(=O)O FZNKQnejGXCJH-UHFFFAOYSA-N | ![Structural formula](attachment://PCA_smile.png) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-----------------------------------------------|---------------------------------|
| DM-PCA                        | 3-(trifluoromethyl)-1H-pyrazole-4-carboxylic acid OC(=O)c1c[NH]nc1C(F)(F)F VHKTORCXXPIFI-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.

(a): The metabolite name in bold is the name used in the conclusion.

(b): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).

(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).