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

European Food Safety Authority (EFSA)
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Abstract

The applicant BASF Agro BV submitted a request to the competent national authority in the Netherlands to evaluate the confirmatory data that were identified in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps, residue trials on strawberries, onions, garlic, tomatoes, peppers, cucumbers, artichokes, leeks and rape seeds were submitted. The data gaps are considered satisfactorily addressed, except the use on strawberries (southern Europe). The indoor use on melon is no longer supported according to the applicant and the rapporteur Member State. EFSA updated the previously performed dietary risk assessment for pendimethalin and concluded that the short-term and long-term intake of residues resulting from the use of this active substance on crops treated according to the agricultural practices that were sufficiently supported by data is unlikely to present a risk to consumer health.

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Summary

In 2012, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for pendimethalin according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) four additional residue trials supporting the northern Good Agricultural Practice (GAP) and eight residue trials supporting the southern GAP on strawberries;
2) eight residue trials on carrots supporting the northern GAPs on horseradish, parsnips, parsley root and salsify;
3) four additional residue trials supporting the northern GAP and six additional residue trials supporting the southern GAP on onions, garlic and shallots;
4) two additional residue trials on tomatoes and eight residue trials on cucumbers supporting the northern GAP on tomatoes, peppers and cucurbits with edible and inedible peel;
5) four additional residue trials on tomatoes and eight residue trials on cucumbers supporting the southern GAP on solanacea and cucurbits with inedible peel;
6) two residue trials supporting the indoor GAP on melons;
7) four residue trials supporting the southern GAP on witloof;
8) two additional residue trials supporting the northern GAP and four residue trials supporting the southern GAP on globe artichoke;
9) six additional residue trials supporting the northern GAP on onion, garlic and shallots;
10) eight residue trials supporting the northern GAP on rape seed;
11) four residue trials on representative crops supporting the northern GAP on herbal infusions (flowers), spices (seeds) and spices (fruits and berries);
12) an independent laboratory validation (ILV) of the analytical method for enforcement of residues in liver and kidneys.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 1127/2014, including footnotes related to data gaps number 1, 2, 3, 4, 5, 6, 8, 9 and 12, indicating the type of information that should be provided by a party having an interest in maintaining the proposed tentative MRLs by 24 October 2016. Data gaps number 7, 10 and 11 were not implemented in the MRL regulation; the MRLs for these crops were all set at the limit of quantification (LOQ). Furthermore, data gaps number 2 and 12 were addressed in a subsequent EFSA reasoned opinion and in the course of the renewal process for pendimethalin, respectively (EFSA, 2014, 2016); thus, the respective footnotes have been deleted in the MRL legislation.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, BASF Agro BV submitted an application to the competent national authority in the Netherlands (rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 31 October 2017. When assessing the evaluation report, EFSA identified data gaps or points which needed further clarification. On 25 June 2018 the RMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|------------|----------------|--------------|---------------------------|
| 0152000 | Strawberries | 0.05* (ft) | 0.05* | EFSA concludes that the data gap for the NEU use on strawberries is sufficiently addressed, while for the SEU use the submitted data is insufficient to address the data gap (4 additional trials are required). For the NEU use, the existing MRL is confirmed. Member States to reconsider the national authorisations for SEU, since the uses are not sufficiently supported by residue trials |

Enforcement residue definition: Pendimethalin(†)
| Code<sup>(a)</sup> | Commodity | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation |
|------------------|-----------|-----------------|--------------|---------------------------|
| 0220010, 0220020, 0220030 | Garlic, Onions and Shallots | 0.05* (ft) | 0.05* | The submitted data addressed the data gap identified by EFSA. The existing MRL is confirmed |
| 0231010, 0231020, 0231030 | Tomatoes, peppers, aubergines | 0.05* (ft) | 0.05* | The submitted data addressed the data gap identified by EFSA. The existing MRL is confirmed |
| 0232010, 0232020, 0232030 | Cucumbers, gherkins, courgettes | 0.05* (ft) | 0.05* or 0.01* | The submitted data addressed the data gap identified by EFSA. The lowering of the MRL set at the LOQ of 0.05 mg/kg to a lower LOQ of 0.01 mg/kg which is achievable with routing analytical methods could be considered |
| 0233010, 0233020, 0233030 | Melons, pumpkins, watermelons | 0.05* (ft) | 0.05* or 0.01* | The submitted data sufficiently addressed the data gap identified for the NEU and SEU outdoor use. The lowering of the MRL set at the LOQ of 0.05 mg/kg to a lower LOQ of 0.01 mg/kg which is achievable with routing analytical methods could be considered. The indoor use is no longer supported by the applicant and therefore Member States should reconsider national authorisations for indoor uses on melons |
| 0270050 | Globe artichoke | 0.05* (ft) | 0.05* | The data gaps for the NEU and SEU use on globe artichoke were sufficiently addressed, suggesting a no-residue situation |
| 0270060 | Leek | 0.05* (ft) | 0.05* or 0.02* | The submitted data addressed the data gap identified by EFSA. The lowering of the MRL set at the LOQ of 0.05 mg/kg to a lower LOQ of 0.02 mg/kg which is achievable with routing analytical methods could be considered |
| 0401060 | Rape seed | 0.05* | 0.05* or 0.01* | Although not required, the applicant submitted GAP compliant residue trials; based on these trials the lowering of the MRL set at the LOQ of 0.05 mg/kg to a lower LOQ of 0.01 mg/kg which is achievable with routing analytical methods could be considered |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; LOQ: limit of quantification.

<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.
<sup>(b)</sup>: Existing EU MRL and corresponding footnote on confirmatory data.
(FT): The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 24.10.2016, or, if that information is not submitted by that date, the lack of it. The numbers indicate the number of the data gap as seen above in the summary section.

(F): Fat-soluble.
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Assessment

The review of existing maximum residue levels (MRLs) of pendimethalin according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed in 2012 (EFSA, 2012). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The list of Good Agricultural Practices (GAPs) assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data were requested are listed in Appendix A.

Following the MRL review, MRLs have been modified by Commission Regulation (EU) No 1127/2014, including footnotes for the tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 24 October 2016.

In accordance with the agreed procedure set out in the working document of the European Commission (European Commission, 2016), BASF Agro BV, submitted an application to the competent national authority in the Netherlands (designated rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided additional residue trials supporting the uses on strawberries, onions, garlic, tomatoes, cucumbers, peppers, globe artichokes, leeks and rape seed.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 31 October 2017 (Netherlands, 2017). EFSA assessed the application as requested by the European Commission in accordance with Article 9 of Regulation (EC) No 396/2005. During the detailed assessment, EFSA identified data gaps or points which needed further clarification, which were requested from the RMS. On 25 June 2018, the RMS submitted a revised evaluation report (Netherlands, 2017), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the RMS (Netherlands, 2017), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 and additional assessments of pendimethalin performed after the MRL review (EFSA, 2012, 2014, 2016, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 1127/2014 are applicable. The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

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

The evaluation report submitted by the RMS (Netherlands, 2017) is considered as a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

Not relevant for the current assessment.

1.1.2. Nature of residues in rotational crops

Not relevant for the current assessment.

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1 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
2 Commission Regulation (EU) No 1127/2014 of 20 October 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 amitrole, dinocap, fipronil, flufenacet, pendimethalin, propyzamide, and pyridate in or on certain products. OJ L 305, 24.10.2014, p. 47–99.
3 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 305, 24.10.2014, p. 47–99.
4 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 1–66.
1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Methods of analysis in plants

According to the RMS, the analytical methods used in the residues field trials were sufficiently validated.

1.1.5. Stability of residues in plants

The samples of the residue trials considered under the current assessment were stored under conditions for which integrity of the samples has been demonstrated. No new information was requested/submitted with the confirmatory data.

1.2. Magnitude of residues in plants

Appendix A contains the GAPs for the crops that were not fully supported by data and for which confirmatory data have not yet been assessed in previous assessments. It should be highlighted that according to the applicant, the maximum application rate for some of the crops under consideration has been slightly reduced; furthermore, some other parameters on the timing of the application or the preharvest interval (PHI) has been slightly revised, leading to less critical GAPs (cGAPs) compared to the GAPs assessed originally in the MRL review. Although some of the older trials assessed by the evaluating Member State (EMS) were performed with the previous application rate of 2 kg a.s./ha, they were still considered valid, given the low residues found and that they are within the 25% acceptable deviation.

1.2.1. Strawberries

Four additional residue trials supporting the northern GAP (NEU) and eight residue trials supporting the southern GAP (SEU) on strawberries were required (EFSA, 2012).

NEU: The applicant submitted additional four NEU field trials conducted with a lower application rate (1 kg a.s./ha instead of 1.59 kg a.s./ha) compared with the NEU GAP. These trials cannot be scaled up to the nominal application rate, because the residues were below the LOQ (OECD, 2016) and are therefore not considered acceptable.

Furthermore, the applicant submitted four field trials conducted in the USA in New York, Wisconsin and Washington. These trials were conducted with an application rate within the acceptable deviation of ±25% compared to the revised cGAP. The RMS proposed to consider these trials as representative for NEU as the climatic conditions correspond mostly to the climate in NEU. EFSA agrees with this argumentation and therefore concludes that the NEU use is sufficiently supported by data. A modification of the existing MRL is not required.

SEU: Four trials conducted in SEU within the ±25% deviation of the application rate were submitted; the residues ranged from < 0.01 mg/kg up to 0.016 mg/kg. Additional two residue trials conducted in SEU with a lower application rate (1 kg a.s./ha) were submitted; these trials, however, are not acceptable.

Considering that quantifiable residues were found in one of the valid trials, a no-residue situation cannot be assumed for strawberries, and therefore, the full number of trials as defined in the EU legislation needs to be provided. Thus, EFSA concludes that for the SEU use four additional residue trials are required to address the confirmatory data requirement.

Overall, the data gap for NEU use on strawberries is sufficiently addressed, while the data gap for the SEU use is still partially open. Based on the trials representative for the NEU use, a modification of the existing MRL is not required. However, Member States have to reconsider the national authorisations granted in SEU, since this use is not sufficiently supported by residue trials.

1.2.2. Bulb vegetables (onions, garlic, shallots)

Four additional residue trials supporting the northern GAP and six residue trials supporting the southern GAP on onions, garlic and shallots were required (EFSA, 2012).

NEU: The applicant submitted one valid field trial on garlic conducted in NEU with an application rate within the acceptable deviation of ±25% and two valid trials on onions. In addition, three US
trials in onions performed in regions with climatic conditions comparable with the NEU (i.e. Michigan, New York and Washington) were provided. In none of the trials, residues above the LOQ were found.

SEU: Six trials were submitted supporting the SEU use conducted within the ± 25% range of the cGAP which are considered valid. Furthermore, the applicant submitted additional three trials conducted in the USA in California and Texas which were considered representative for SEU.

EFSA concludes that the data gap on bulb vegetables is considered addressed. A modification of the existing MRL is not required.

1.2.3. Fruit ing vegetables (tomatoes, peppers, aubergines, cucumbers, courgettes, gherkins)

Two additional residue trials on tomatoes and eight residue trials on cucumbers supporting the northern GAP on tomatoes, peppers and cucurbits with edible and inedible peel were requested\(^5\); furthermore, four residue trials on tomatoes and eight residue trials on cucumbers supporting the southern GAP on solanacea and cucurbits with inedible peel were required\(^6\) (EFSA, 2012).

- Tomatoes, aubergines (SEU):
  
  The applicant submitted two acceptable residue trials in tomatoes conducted in SEU. Furthermore, five trials conducted in the USA, which were found to be representative for the SEU conditions, were submitted to support the use on tomatoes. The submitted two SEU and five USA trials in combination with the four SEU trials assessed during the MRL review are considered sufficient to support the SEU use on tomatoes and by extrapolation for aubergines.

- Peppers (SEU):
  
  The applicant submitted two residue trials conducted in SEU. The trials are not independent therefore only one trial is considered acceptable. The residues were below the LOQ of 0.05 mg/kg, confirming the overall picture that no quantifiable residues are expected in the solanacea group. Formally, the available data are not sufficient to derive an MRL proposal neither on the basis of trials on the specific crop (one additional trial would be required to confirm a no-residue situation) nor by extrapolation (four additional trials in cucumbers would be required). However, the residue trials in melons can be used to replace the missing cucumber trials. Thus, EFSA concludes that since in none of the residue trials in fruiting vegetables (SEU and NEU uses) quantifiable residues were observed, also for peppers a no-residue situation can be reasonable assumed.

- Cucumbers (SEU):
  
  The applicant submitted four residue trials conducted in SEU reflecting the GAP for fruiting vegetables. All residue trials resulted in residues below the LOQ of 0.01 mg/kg.

- Melons (SEU):
  
  Four SEU residue trials with residues below the LOQ of 0.01 mg/kg are available, which is sufficient to demonstrate that no residues are expected.

- Tomatoes (NEU):
  
  The applicant submitted four residue trials conducted on tomatoes supporting the NEU use. The trials were conducted in accordance with the GAP. The submitted four NEU residue trials combined with the six NEU trials assessed during the MRL review are considered sufficient to support the NEU use on tomatoes.

\(^5\) Considering that the NEU GAPs for fruiting vegetables (tomatoes, peppers, cucumbers, gherkins, courgettes, melons, pumpkin, watermelons) defines the application of pendimethalin at an early growth stage before the edible part of the crop is formed, eight residue trials in tomatoes and eight trials in cucumbers are required to derive a MRL for the whole group of fruiting vegetables (European Commission, 2017). Since six valid residue trials in tomatoes were available in the framework of the MRL review, two additional tomato trials and eight cucumber trials were requested. Alternatively, residue trials on the individual crops would be appropriate to address the data gaps identified.

\(^6\) Considering that the SEU GAPs for fruiting vegetables (tomatoes, peppers, aubergines, melons) defines the application of pendimethalin at an early growth stage before the edible part of the crop is formed, eight residue trials in tomatoes and eight trials in cucumbers are required to derive a MRL for the whole group of fruiting vegetables. In the framework of the MRL review, four valid residue trials in tomatoes and four trials in melons were available; thus, in compliance with the EU guidance document on extrapolation (European Commission, 2017), EFSA asked for four additional tomato trials and eight cucumber trials. Alternatively, the residue trials on the individual crops would be appropriate to address the data gap identified.
• Peppers (NEU):

No residue trials are available representative for the NEU use in peppers. According to the EU guidance document on extrapolation, eight trials on tomatoes and eight trials on cucumbers would allow to derive a group MRL for fruiting vegetables (except cucumbers). In the given case, 10 residue trials in tomatoes, 4 trials in cucumbers are available.

Formally, the available data are not sufficient to derive an MRL proposal neither on the basis of trials on the specific crop (at least two trials would be required to confirm a no-residue situation) nor by extrapolation (four additional trials in cucumbers would be required). However, considering the overall database for fruiting vegetables, EFSA concludes that also for the NEU use in peppers a no-residue situation can be reasonable assumed.

• Cucumbers (NEU):

The applicant submitted four residue trials conducted in NEU. The trials were conducted in compliance with the GAP. In all trials, residues were below the LOQ of 0.01 mg/kg; therefore, the number of trials is considered sufficient to support the use on cucumbers (no-residue situation). The results can be extrapolated to other cucurbits with edible peel for which GAPs were reported (i.e. gherkins and courgettes).

• Melons, pumpkins, watermelons (NEU):

For the NEU use, no trials were available. However, considering the overall database for fruiting vegetables, EFSA concludes that also for the NEU use in melons, pumpkins and watermelons a no-residue situation can be reasonable assumed.

Conclusion for fruiting vegetables (NEU and SEU uses): EFSA concluded that the submitted data are sufficient to address the data gaps identified during the MRL review for the crops belonging to the crop group of fruiting vegetables, including solanacea and cucurbits with edible and inedible peel. The new data confirm the existing MRLs set at the LOQ. For crops belonging to the subgroups of cucurbits (edible and inedible peel), the lowering of the existing MRL set at the LOQ of 0.05 mg/kg to a LOQ of 0.01 mg/kg could be considered by risk managers.

• Melons (indoor use):

No residue trials were submitted to address the data requirements for the indoor use on melon. The RMS notified EFSA that the applicant no longer supports the aforementioned use.

1.2.4. Globe artichokes

Two additional residue trials supporting the northern GAP and four residue trials supporting the southern GAP on globe artichoke were required (EFSA, 2012).

NEU: The applicant submitted three NEU residue trials conducted according to the GAP. In these trials, no quantifiable residues were found (residues below the LOQ of 0.01 mg/kg). Since the trials were performed in the same location within a few days, they are not independent. Thus, only one trial is considered acceptable.

SEU: Two valid, GAP-compliant residue trials conducted in SEU were submitted. Furthermore, the applicant submitted three trials conducted in the USA which were performed with an exaggerated application rate (4.73–6.42 kg/ha, PHI 200–226 days). The PHI for the USA trials is not within the acceptable range of 90 days according to the European GAP; and therefore, these trials are not suitable to support the use in globe artichokes.

EFSA concludes that the number of valid residue trials in globe artichokes is sufficient to address the data gap identified in the framework of the MRL review, suggesting a no-residue situation. A modification of the existing MRL is not required.

1.2.5. Leek

Six additional residue trials supporting the northern GAP on leek were required (EFSA, 2012).

NEU: The applicant submitted 11 residue trials conducted in Germany according to the NEU gap on leek. Two of the studies are considered as replicates. Therefore, in total, 10 residue trials are considered as valid. In none of the trials, residues above the LOQ of 0.02 mg/kg were found.

SEU: Although no SEU GAP was assessed in the framework of the MRL review, the applicant provided five SEU residue trials in leek, reflecting a GAP which is comparable with or more critical than
the NEU GAP. In none of the trials, residues above the LOQ were identified. This information is considered not relevant in the framework of this evaluation.

EFSA concludes that the submitted data are considered sufficient to address the data gap on the NEU use on leeks. The lowering of the existing MRL set at the LOQ of 0.05 mg/kg to a LOQ of 0.02 mg/kg could be considered by risk managers.

1.2.6. Rape seed

In the EFSA MRL review, eight residue trials supporting the northern GAP on rape seed were required (EFSA, 2012). However, the data requirement was not taken over in a footnote when implementing the MRL proposals derived by EFSA.

Although not explicitly requested, the applicant submitted four residue trials conducted on rape seed according to the GAP. All trials resulted in residues below the LOQ of 0.01 mg/kg. The number of trials is considered sufficient to confirm the MRL proposal derived during the MRL review. A modification of the existing MRL is not required.

2. Residues in livestock

The submitted data does not have an impact on the input values used in the livestock dietary burden calculation; therefore there is no need to reassess the MRLs for livestock.

3. Consumer risk assessment

Although the confirmatory data submitted under the current application did not lead to a revision of the MRLs, EFSA recalculated the dietary risk assessment, taking into account that in the framework of the renewal of the approval EFSA suggested the setting of an acute reference dose (ARfD) of 0.3 mg/kg body weight (EFSA, 2014) which was not in place when the MRL review was performed. Thus, EFSA updated the dietary risk assessment performed for pendimethalin including the relevant highest residue (HR)/supervised trials median residue (STMR) values for the commodities assessed in this reasoned opinion and information from previous assessments (EFSA, 2012, 2015).

The estimated long-term dietary intake of pendimethalin was in the range of 0.3–1.6% of the acceptable daily intake (ADI).

The calculated maximum exposure in percentage of the ARfD accounted for 1.0% of the ARfD for peppers, 1.0% of the ARfD for tomatoes, 0.7% for onions, 0.5% for melons and less than 0.5% for the remaining commodities.

Thus, EFSA concluded that the short-term and long-term intake of residues resulting from the use of this active substance on crops treated according to the agricultural practices reported in the framework of the MRL review (EFSA, 2012) that were sufficiently supported by data is unlikely to present a risk to consumer health.

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

To address the data gaps identified in the framework of the MRL review (EFSA, 2012), residue trials on strawberries, onions, garlic and shallots, tomatoes, peppers, cucumbers, globe artichokes, leeks and rape seeds were submitted. EFSA concluded that the data were sufficient to address the data gaps, except for strawberries (SEU use).

The RMS stated that the applicant no longer supports the indoor use on melon; therefore, no data was submitted to address the data gap on the indoor use on melon.

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

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
cGAP critical GAP
CS capsule suspension
DAR draft assessment report
DAT days after treatment
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
InChIKey International Chemical Identifier Key
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LOQ limit of quantification
MRL maximum residue level
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PHI pre-harvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SEU southern Europe
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
### Appendix A – Summary of GAPs on crops relevant for confirmatory data

Compared to the GAPs assessed in the MRL review, the applicant submitted slightly revised GAPs, suggesting a lower application rate or a different growth stage of the application.

| Crop | Region | Outdoor/ Indoor | Member state or Country | Pest controlled | Formulation | Application rate | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|--------|-----------------|--------------------------|----------------|-------------|-----------------|-----------------------------|-------------------------------|
| Strawberries | NEU | Outdoor | DE | Weeds | CS 455.0 g/L | Full treatment - spraying | 93 | 1 | 1.32 | 1.59 | kg a.i./ha | n.a. | Revised application rate (before: 2 kg/ha); revised application time: late autumn-winter (dormant period) (before: BBCH 57, from post-planting until flower initiation but before flower truss emergence) |
| Garlic | NEU | Outdoor | LT | Weeds | CS 455.0 g/L | Full treatment - spraying | 11 | 13 | 1 | 0.99 | 1.64 | kg a.i./ha | n.a. | Revised PHI (before PHI = 56 days, only in Denmark) |
| Onion | NEU | Outdoor | DE | Weeds | CS 455.0 g/L | Full treatment - spraying | 13 | 1 | 1 | 0.80 | 2.02 | kg a.i./ha | n.a. | Revised PHI (before PHI = 56 days, only in Denmark) |
| Shells | NEU | Outdoor | BE, LU | Weeds | CS 455.0 g/L | Full treatment - spraying | 13 | 1 | 1 | 0.80 | 1.14 | kg a.i./ha | n.a. | Revised PHI (before PHI = 56 days, only in Denmark) |
| Tomatoes | NEU | Outdoor | CZ | Weeds | CS 455.0 g/L | Soil treatment - spraying | 8 | 1 | 1 | 1.32 | 1.64 | kg a.i./ha | n.a. | Application time: pre-emergence |
| Peppers | NEU | Outdoor | SK | Weeds | CS 455.0 g/L | Soil treatment - spraying | 8 | 1 | 1 | 1.32 | 1.64 | kg a.i./ha | n.a. | Application time: pre-emergence |
| Cucumbers | NEU | Outdoor | DE | Weeds | CS 455.0 g/L | Soil treatment - general (see also comment field) | 0 | 1 | 1 | 0.40 | 1.60 | kg a.i./ha | n.a. | Revised information on application (BBCH before pre-emergence, after planting) |
| Celeriac | NEU | Outdoor | LT | Weeds | CS 455.0 g/L | Soil treatment - general (see also comment field) | 18 | 1 | 1 | 0.40 | 1.60 | kg a.i./ha | n.a. | Application time: pre-emergence, after planting |
| Zucchini | NEU | Outdoor | DE | Weeds | CS 455.0 g/L | Soil treatment - general (see also comment field) | 18 | 1 | 1 | 0.40 | 1.60 | kg a.i./ha | n.a. | Application time: pre-emergence, after planting |
| Melons | NEU | Outdoor | DE | Weeds | CS 455.0 g/L | Soil treatment - general (see also comment field) | 1 | 1 | 1 | 1.59 | 2.13 | kg a.i./ha | n.a. | Revised PHI (before PHI = 70 days, only in Germany) |
| Watermelons | NEU | Outdoor | DE | Weeds | CS 455.0 g/L | Soil treatment - general (see also comment field) | 1 | 1 | 1 | 1.59 | 2.13 | kg a.i./ha | n.a. | Application time: pre-emergence, after planting |
| Blueberries | NEU | Outdoor | SI | Weeds | CS 455.0 g/L | Soil treatment - general (see also comment field) | 1 | 1 | 1 | 0.40 | 1.60 | kg a.i./ha | n.a. | Application time: pre-emergence, after planting |
| Globe artichokes | NEU | Outdoor | DE | Weeds | CS 455.0 g/L | Full treatment - spraying | 18 | 1 | 1 | 1.60 | 2.13 | kg a.i./ha | n.a. | Revised PHI (before PHI = 70 days, only in Germany) |
| Leek | NEU | Outdoor | DE | Weeds | CS 455.0 g/L | Full treatment - spraying | 0 | 13 | 1 | 1.00 | 1.64 | kg a.i./ha | n.a. | Revised application rate (before: 0.3–2 kg/ha); revised PHI (before: PHI = 56 days, only in Denmark) |
| Rape seed | NEU | Outdoor | DE | Weeds | CS 455.0 g/L | Full treatment - spraying | 10 | 1 | 1 | 0.91 | 2.13 | kg a.i./ha | n.a. | Revised PHI (before PHI = 56 days, only in Denmark) |
### Critical Outdoor GAPs for Southern Europe

| Crop | Region | Variety | Member state or Country | Pests controlled | Formulation | Application | Application rate | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|--------|---------|--------------------------|------------------|-------------|-------------|----------------|-----------------------------|--------------------------------|
|      |        |         |                          |                  | Conc. Unit  | Method       | Min. Max. | Min. Max. | Min. Max. | Rate Unit |
|      |        |         |                          |                  | g/L         | Soil treatment - spraying | 1.32 | 2.00 | kg a.i./ha | n.a. |

- **Strawberries**: Application time: pre-planting or post-planting at the end of winter stop GAPs for Southern Europe
- **Garlic**: Revised application rate (before 1–2 kg/ha), revised PHI (before PHI = 75 days, only in Italy)
- **Onion**: Revised application rate (before 1–2 kg/ha), revised PHI (before PHI = 75 days, only in Italy)
- **Tomatoes**: Revised application rate (before 0.4–2 kg/ha), revised PHI (before PHI = 75 days, only in Italy)
- **Peppers**: Revised application rate (before 0.4–2 kg/ha), revised PHI (before PHI = 75 days, only in Italy)
- **Aubergines (eggplants)**: Revised application rate (before 0.4–2 kg/ha), revised PHI (before PHI = 75 days, only in Italy)
- **Melons**: Revised application rate (before post-planting pre-emergence)
- **Globe artichokes**: Revised application rate (before 1–2 kg/ha), revised PHI (before PHI = 75 days, only in Italy)

**GAP**: Good Agricultural Practice; MRL: maximum residue level; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; NEU: northern Europe; SEU: southern Europe; CS: capsule suspension; a.i.: active ingredient; n.a.: not applicable.

### Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)

| Crop | Region | Variety | Member state or Country | Pests controlled | Formulation | Application | Application rate | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|--------|---------|--------------------------|------------------|-------------|-------------|----------------|-----------------------------|--------------------------------|
|      |        |         |                          |                  | Conc. Unit  | Method       | Min. Max. | Min. Max. | Min. Max. | Rate Unit |
|      |        |         |                          |                  | g/L         | Soil treatment - spraying | 1.00 | 1.65 | kg a.i./ha | 60 |

- **Melons**: Application time: post-planting pre-emergence

**GAP**: Good Agricultural Practice; MRL: maximum residue level; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; NEU: northern Europe; SEU: southern Europe; CS: capsule suspension; a.i.: active ingredient; n.a.: not applicable.
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

No new information has been submitted under the current assessment. The residue definitions derived in the framework of the MRL review (EFSA, 2012) have been confirmed in the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (EFSA, 2016).

B.1.1.2. Stability of residues in plants

No new information has been submitted under the current assessment.
### B.1.2. Magnitude of residues in plants

| Commodity                  | Region/ indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|----------------------------|-------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------|---------------|
| Strawberries               | NEU               | EFSA (2012): 4 × < 0.05 (Netherlands, 2017): 4 × < 0.05 (US trials) | Residue trials (Netherlands, 2017) were conducted in the EU and in USA are considered representative for NEU | 0.05*                  | 0.05         | 0.05          |
|                            | SEU               | EFSA (2012): – (Netherlands, 2017): 2 × < 0.01, 0.011, 0.016 (scaled) | Residue trials on strawberries conducted in SEU compliant with GAP. Number of trials not sufficient to address confirmatory data requirements for SEU use | –                      | –            | –             |
| Onions                     | NEU               | EFSA (2012): 4 × < 0.05 (Netherlands, 2017): 2 × < 0.01, 3 × < 0.05 (US trials) | Residue trials on onions and garlic compliant with GAP. US onion trials were conducted under climatic conditions considered comparable with NEU Combined data on onions and garlic with extrapolation to onions, garlic and shallots | 0.05*                  | 0.05         | 0.05          |
|                            | SEU               | EFSA (2012): 2 × < 0.05 (Netherlands, 2017): 6 × < 0.01, 3 × < 0.05 (US trials) | Residue trials on onions compliant with GAP. Trials with LOQ of 0.05 mg/kg were conducted in the USA, under conditions considered comparable with SEU. Extrapolation to onions, garlic and shallots acceptable | 0.05*                  | 0.05         | 0.05          |
| Tomatoes, cucumbers        | NEU               | Tomatoes: EFSA (2012): 6 × < 0.05 (Netherlands, 2017): 4 × < 0.01 Cucumbers: (Netherlands, 2017): 4 × < 0.01 | Overall evidence suggests a no-residue situation for all NEU uses in fruiting vegetables for which GAPs were assessed (further considerations in the assessment) For the crops belonging to the subgroup of cucurbits (edible peel), the setting of the MRL at the LOQ of 0.01 mg/kg could be considered | 0.05*                  | 0.05         | 0.05          |
|                            | SEU               | Tomatoes: EFSA (2012): 4 × < 0.05 (Netherlands, 2017): 2 × < 0.01, 5 × < 0.05 (US trials) Peppers: (Netherlands, 2017): < 0.05 Melons: EFSA (2012): 4 × < 0.01 Cucumbers: (Netherlands, 2017): 4 × < 0.01 | Overall evidence suggests a no-residue situation for all SEU uses in fruiting vegetables for which GAPs were assessed (further considerations in the assessment) For the crops belonging to the subgroup of cucurbits (edible and inedible peel), the setting of the MRL at the LOQ of 0.01 mg/kg could be considered | 0.05*                  | 0.05         | 0.05          |
| Commodity      | Region/ indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) |
|---------------|--------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|----------------------|------------------------|
| Melons        | Indoor                   | --                                                            | Indoor use in melons no longer supported by applicant                           |                        |                      |                        |
|               | Globe artichokes NEU     | EFSA (2012): 2 × < 0.05 (Netherlands, 2017): < 0.01          | Residue trials on artichokes compliant with GAP. Number of trials sufficient to demonstrate no-residue situation | 0.05\(^*\)            | 0.05                 | 0.01                   |
|               | SEU                      | (Netherlands, 2017): 2 × < 0.01                                |                                                                                   |                        |                      |                        |
| Leek          | NEU                      | EFSA (2012): 2 × < 0.05 (Netherlands, 2017): 10 × < 0.02      | Residue trials on leeks compliant with GAP                                         | 0.02\(^*\)            | 0.02                 | 0.02                   |
|               |                          | (Netherlands, 2017): 4 × < 0.01                                |                                                                                   |                        |                      |                        |
| Oilseed rape  | NEU                      | (Netherlands, 2017): 4 × < 0.01                                | Residue trials compliant with GAP. Number of trials sufficient, considering the absence of residues | 0.01\(^*\)            | 0.01                 | 0.01                   |

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

\(^*\): Indicates that the MRL is proposed at the limit of quantification.
\(^{(a)}\): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
\(^{(b)}\): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
\(^{(c)}\): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
B.2. Residues in livestock

The submitted information does not trigger the re-assessment of the livestock dietary burden.

B.3. Consumer risk assessment

| ARfD | 0.3 mg/kg bw (EFSA, 2016) |
|------|--------------------------|
| Highest IESTI, according to EFSA PRIMo |
| Peppers: 1% of ARfD |
| Tomatoes: 1% of ARfD |
| Onions: 0.7% of ARfD |
| Melons: 0.5% of ARfD |
| Other commodities: < 0.5% of ARfD |
| Assumptions made for the calculations |
| The acute risk assessment was performed only for the commodities assessed for confirmatory data; the calculations are based on highest residues (HR)/median residues (STMR) found in the crop commodities. |

| ADI | 0.125 mg/kg bw per day (EFSA, 2016) |
|------|----------------------------------|
| Highest IEDI, according to EFSA PRIMo |
| 1.6% ADI |
| Contribution of crops assessed: < 1% of ADI |
| Assumptions made for the calculations |
| The risk assessment performed in the framework of previous assessments was updated, including the STMR values derived for the crops assessed for confirmatory data. |

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.

B.4. Recommended MRLs

| Code | Commodity | Existing MRL | Proposed MRL | Conclusion/recommendation |
|------|-----------|--------------|--------------|----------------------------|
| 0152000 | Strawberries | 0.05* (ft) | 0.05* | EFSA concludes that the data gap for the NEU use on strawberries is sufficiently addressed, while for the SEU use the submitted data is insufficient to address the data gap (4 additional trials are required). For the NEU use, the existing MRL is confirmed. Member States to reconsider the national authorisations for SEU, since the uses are not sufficiently supported by residue trials |
| 0220010, 0220020, 0220030 | Garlic, Onions and Shallots | 0.05* (ft) | 0.05* | The submitted data addressed the data gap identified by EFSA. The existing MRL is confirmed |
| 0231010, 0231020, 0231030 | Tomatoes, peppers, aubergines | 0.05* (ft) | 0.05* | The submitted data addressed the data gap identified by EFSA. The existing MRL is confirmed |
| 0232010, 0232020, 0232030 | Cucumbers, gherkins, courgettes | 0.05* (ft) or 0.01* | 0.05* | The submitted data addressed the data gap identified by EFSA. The lowering of the MRL set at the LOQ of 0.05 mg/kg to a lower LOQ of 0.01 mg/kg which is achievable with routing analytical methods could be considered |
| Code<sup>(a)</sup> | Commodity | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation |
|-----------------|-----------|-------------------------|--------------|---------------------------|
| 0233010, 0233020, 0233030 | Melons, pumpkins, watermelons | 0.05* (ft) | 0.05* or 0.01* | The submitted data sufficiently addressed the data gap identified for the NEU and SEU outdoor use. The lowering of the MRL set at the LOQ of 0.05 mg/kg to a lower LOQ of 0.01 mg/kg which is achievable with routing analytical methods could be considered. The indoor use is no longer supported by the applicant and therefore Member States should reconsider national authorisations for indoor uses on melons. |
| 0270050 | Globe artichoke | 0.05* (ft) | 0.05* | The data gaps for the NEU and SEU use on globe artichoke were sufficiently addressed, suggesting a no-residue situation. |
| 0270060 | Leek | 0.05* (ft) | 0.05* or 0.02* | The submitted data addressed the data gap identified by EFSA. The lowering of the MRL set at the LOQ of 0.05 mg/kg to a lower LOQ of 0.02 mg/kg which is achievable with routing analytical methods could be considered. |
| 0401060 | Rape seed | 0.05* | 0.05* or 0.01* | Although not required, the applicant submitted GAP compliant residue trials; based on these trials the lowering of the MRL set at the LOQ of 0.05 mg/kg to a lower LOQ of 0.01 mg/kg which is achievable with routing analytical methods could be considered. |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; LOQ: limit of quantification.

<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.
<sup>(b)</sup>: Existing EU MRL and corresponding footnote on confirmatory data.
<sup>(F)</sup>: Fat-soluble.
## Appendix C – Pesticide Residue Intake Model (PRiMo)

### Pendimethalin

**Status of the active substance:** Code no.

**LOQ (mg/kg bw):** Proposed LOQ:

| Toxicological end points | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD | Year of evaluation | Year of evaluation |
|--------------------------|------------------------|-----------------|---------------|----------------|-------------------|-------------------|
|                          | 0.125                  | 0.3             |               |                |                   |                   |

| No of diets exceeding ADI: | 0 | --- | 2 |

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | 1st contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) | pTMRLs at LOQ (in % of ADI) |
|-------------------------------|----------------------------------------|----------------------------------------|----------------------------------------|-----------------------------|
| 0.3 NL child                  | 0.2 Potatoes                           | 0.2 Milk and milk products: Cattle     | 0.2 Milk and milk products: Cattle     |                             |
| 0.5 DE child                  | 0.2 Carrots                            | 0.2 Carrots                            | 0.2 Carrots                            |                             |
| 0.3 WHO Cluster diet B        | 0.1 Tomatoes                           | 0.1 Potatoes                           | 0.1 Potatoes                           |                             |
| 0.4 FR toddler                | 0.2 Potatoes                           | 0.2 Potatoes                           | 0.2 Beans (with pods)                  |                             |
| 0.2 FR infant                 | 0.1 Maize                              | 0.1 Maize                              | 0.1 Maize                              |                             |
| 0.3 WHO Cluster diet E        | 0.2 Potatoes                           | 0.1 Carrots                            | 0.1 Carrots                            |                             |
| 0.3 PT General population     | 0.2 Wheat                              | 0.2 Carrots                            | 0.2 Carrots                            |                             |
| 0.2 DK child                  | 0.1 Potatoes                           | 0.1 Wheat                              | 0.1 Wheat                              |                             |
| 0.2 UK Infant                 | 0.2 Carrots                            | 0.1 Wheat                              | 0.1 Wheat                              |                             |
| 0.3 WHO Cluster diet D        | 0.2 Potatoes                           | 0.1 Carrots                            | 0.1 Carrots                            |                             |
| 0.3 SE general population 90th percentile | 0.2 Potatoes                           | 0.1 Wheat                              | 0.1 Wheat                              |                             |
| 0.3 UK Toddler                | 0.2 Potatoes                           | 0.2 Wheat                              | 0.2 Wheat                              |                             |
| 0.3 WHO regional European diet| 0.1 Wheat                              | 0.1 Wheat                              | 0.1 Wheat                              |                             |
| 0.1 ES child                  | 0.1 Milk and milk products: Cattle     | 0.1 Milk and milk products: Cattle     | 0.1 Milk and milk products: Cattle     |                             |
| 0.2 WHO Cluster diet F        | 0.1 Potatoes                           | 0.1 Potatoes                           | 0.1 Potatoes                           |                             |
| 0.1 NL general                | 0.1 Wheat                              | 0.1 Wheat                              | 0.1 Wheat                              |                             |
| 0.2 FR all population         | 0.2 Wine grapes                        | 0.1 Tomatoes                           | 0.1 Tomatoes                           |                             |
| 0.2 IT kids/toddler           | 0.1 Wheat                              | 0.2 Tomatoes                           | 0.2 Tomatoes                           |                             |
| 0.3 ES adult                  | 0.1 Wheat                              | 0.1 Potatoes                           | 0.1 Potatoes                           |                             |
| 0.1 UK vegetarian             | 0.1 Beans                              | 0.1 Beans                              | 0.1 Beans                              |                             |
| 0.1 LT adult                  | 0.1 Potatoes                           | 0.1 Tomatoes                           | 0.1 Tomatoes                           |                             |
| 0.1 IT adult                  | 0.1 Apples                             | 0.1 Tomatoes                           | 0.1 Tomatoes                           |                             |
| 0.2 DK adult                  | 0.1 Carrots                            | 0.1 Potatoes                           | 0.1 Potatoes                           |                             |
| 0.2 PL general population     | 0.1 Apples                             | 0.1 Apples                             | 0.1 Apples                             |                             |
| 0.1 UK Adult                  | 0.1 Potatoes                           | 0.1 Potatoes                           | 0.1 Potatoes                           |                             |
| 0.1 FI adult                  | 0.1 Wheat                              | 0.1 Wheat                              | 0.1 Wheat                              |                             |

### Conclusion:

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

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The acute risk assessment is based on the ARfD.

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

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

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

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

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## Appendix D – Input values for the exposure calculations

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Strawberries               | 0.05                    | STMR                  | 0.05                | HR                    |
| Garlic                     | 0.05                    | STMR                  | 0.05                | HR                    |
| Onions                     | 0.05                    | STMR                  | 0.05                | HR                    |
| Shallots                   | 0.05                    | STMR                  | 0.05                | HR                    |
| Tomatoes                   | 0.05                    | STMR                  | 0.05                | HR                    |
| Peppers                    | 0.05                    | STMR                  | 0.05                | HR                    |
| Aubergines (eggplants)     | 0.05                    | STMR                  | 0.05                | HR                    |
| Cucumbers                  | 0.01                    | STMR                  | 0.05                | HR                    |
| Gherkins                   | 0.01                    | STMR                  | 0.01                | HR                    |
| Courgettes                 | 0.01                    | STMR                  | 0.01                | HR                    |
| Melons                     | 0.01                    | STMR                  | 0.01                | HR                    |
| Watermelons                | 0.01                    | STMR                  | 0.01                | HR                    |
| Pumpkins                   | 0.05                    | STMR                  | 0.05                | HR                    |
| Globe artichokes           | 0.01                    | STMR                  | 0.05                | HR                    |
| Leek                       | 0.02                    | STMR                  | 0.02                | HR                    |
| Rape seed                  | 0.01                    | STMR                  | 0.01                | STMR                  |
| Other plant commodities    | See EFSA (2015)          | –                     | –                   | –                     |

### Risk assessment residue definition for commodities of plant origin: pendimethalin

- **STMR**: supervised trials median residue; **HR**: highest residue; **MRL**: maximum residue level.

### Risk assessment residue definition for commodities of animal origin: pendimethalin

- **Other animal commodities**: See EFSA (2012)
- **Acute risk assessment** is performed only for the crops under consideration
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|--------------------------------|--------------------------------------------------|---------------------------------|
| pendimethalin                | \(N\)-(1-ethylpropyl)-2,6-dinitro-3,4-xylidine | ![Structural formula](image) |

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

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup> ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).

<sup>(c)</sup> ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).