Modification of the existing maximum residue level for phenmedipham in strawberries

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Landwirtschaftliches Technologiezentrum Augustenberg submitted a request to the competent national authority in Germany to modify the existing maximum residue level (MRL) for the active substance phenmedipham in strawberries. Noting that at least one additional trial is missing, an MRL of 0.7 mg/kg was derived for the intended NEU use of phenmedipham on strawberries. Adequate analytical methods for enforcement are available to control the residues of phenmedipham in strawberries at the validated limit of quantification (LOQ) of 0.01 mg/kg. Since the current MRL application was submitted before the finalisation of the EU pesticides peer review of the renewal of the approval of phenmedipham, the consumer exposure assessment was performed according to the conclusions on the toxicity of phenmedipham from the first approval under Directive 91/414/EEC. Accordingly, the long-term intake of residues of phenmedipham resulting from the existing and the intended uses is unlikely to present a risk to consumer health. EFSA notes that the present assessment does not take into account the data gaps identified in the context of the renewal of the approval of phenmedipham under Regulation (EC) No 1107/2009, which prevented experts to derive toxicological reference values (TRVs) for phenmedipham, to derive the risk assessment residue definition for fruit crops and to conclude on the toxicity of relevant metabolites.

Keywords: phenmedipham, strawberries, herbicide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Landwirtschaftliches Technologiezentrum Augustenberg submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance phenmedipham in strawberries. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 1 June 2017. To accommodate for the intended NEU use of phenmedipham, the EMS proposed to raise the existing MRL from 0.3 to 0.9 mg/kg in strawberries.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, and which were requested from the EMS. On 3 March 2020 the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report. On 5 October 2020, the EMS proposed EFSA to resume the assessment on phenmedipham despite the pending open point identified during EU pesticides peer review on the renewal of the approval of phenmedipham concerning the genotoxic potential of the active substance, as this was not yet applicable at time of submission of the MRL application. EFSA resumed the assessment, based on the available information.

Since the current MRL application was submitted before the finalisation of the EU pesticides peer review on the renewal of the approval of phenmedipham, the current assessment is based on the conclusions derived in the first approval of phenmedipham according to Directive 91/414/EEC and in the framework of the review of existing phenmedipham MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review).

The metabolism of phenmedipham in primary crops has been investigated in the framework of the MRL review following foliar application on root crops (sugar beet) and fruits (strawberries). It is noted that the same metabolism study with strawberries and more studies on sugar beet have also been assessed under the process for renewal of the approval. The MRL review concluded that in strawberries parent phenmedipham is degraded but remains the main compound of the residue. EFSA concludes that for the assessment of this application, the metabolism of phenmedipham is considered addressed, according to the MRL setting procedure and related data requirements applicable at the time of the submission of this MRL application. However, it is further noted that a data gap for metabolism study with [amino-phenyl-UL-14C] phenmedipham in fruit crops and for the assessment of the toxicity of 3-acetamidophenol was set by the EU pesticides peer review in the context of the renewal of the approval, and thus, it is applicable to future MRL applications of phenmedipham on fruit crops.

In the MRL review, a hydrolysis study to address the effect of processing on the nature of phenmedipham residues was not required, considering low chronic exposure to phenmedipham residues. However, such studies were assessed for the renewal of the approval and the studies demonstrated that the active substance degraded partially into 3-methylaniline (m-toluidine) and methyl (3-hydroxyphenyl)carbamate (MHPC) at baking/brewing and boiling and completely into 3-methylaniline (m-toluidine) under sterilisation conditions. Under pasteurisation conditions, phenmedipham is considered stable. The EU peer review of the renewal of approval set a data gap for the toxicity of 3-methylaniline and proposed that for MHPC the toxicological reference values of phenmedipham, or the lack of them, are applicable.

As the proposed use of phenmedipham is on a semi-permanent crop, investigations of residues in rotational crops are not required.

The MRL review on the basis of metabolism studies in primary and rotational crops, the toxicological significance of metabolites and the capabilities of analytical enforcement methods, proposed to define the risk assessment and enforcement residue definitions in primary crops and processed commodities as parent phenmedipham. The residue definitions were tentative, except the risk assessment residue definition in fruit crops, pending additional metabolism studies on leafy and root primary crops and rotational crops.

The EU peer review of the renewal of approval proposed the enforcement residue definition as ‘phenmedipham’ only for root and fruit crops; the risk assessment residue definition in fruit crops could not be derived. Separate residue definitions for risk assessment and enforcement were proposed for rotational crops and processed commodities.
For the present assessment, EFSA concludes that residue definitions as derived by the MRL review are applicable. In future MRL applications, the conclusions of the EU pesticide peer review of the renewal of approval should be applicable.

Sufficiently validated analytical enforcement methods are available to quantify residues in strawberries at the validated LOQ of 0.01 mg/kg.

Based on seven GAP compliant residue trials, an MRL proposal of 0.7 mg/kg is derived for the intended use of phenmedipham on strawberries. A risk management decision needs to be taken whether an MRL can be proposed on basis of reduced residue data set and considering the data gaps identified in the peer review for renewal of approval.

Specific studies investigating the magnitude of phenmedipham residues in processed strawberries are not required in the context of the current assessment given the low contribution of residues in strawberries to the total theoretical maximum daily intake (TMDI).

Residues of phenmedipham in commodities of animal origin were not assessed since strawberries are normally not fed to livestock.

The toxicological profile of phenmedipham was assessed in the framework of the first approval under Directive 91/414/EEC and the data were considered sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg body weight (bw) day, while the setting of an acute reference dose (ARFD) was not considered necessary. Since the current MRL application was submitted before the finalisation of the EU peer review on the renewal of the approval of phenmedipham, the consumer exposure assessment was undertaken in line with conclusions of the MRL review and the first approval of phenmedipham under Directive 91/414/EEC. It is, however, noted that during the renewal of the approval process, the toxicological reference values for phenmedipham could not be derived since a genotoxic potential for phenmedipham could not be excluded; furthermore, the toxicity of degradation product 3-methylaniline also remains a data gap.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). A short-term dietary risk assessment was not required. In the framework of the MRL review, a comprehensive long-term exposure assessment was performed taking into account the existing uses at EU level. EFSA updated the calculation with the supervised trial median residue (STMR) value derived from the residue trials on strawberry submitted in support of this MRL application. Crops on which no uses were reported in the MRL review or for which the MRL proposals were not implemented in the MRL regulation (sugar beet) were excluded from the calculation.

The estimated long-term dietary intake of phenmedipham residues accounted for 11% of the ADI (NL toddler diet), considering the proposed use on strawberries and the reported uses (except sugar beet) of phenmedipham in the MRL review. The highest contribution of residues in strawberries to the overall long-term exposure is 0.18% of the ADI for DE child diet. EFSA concluded that, according to the conclusions on the toxicity of phenmedipham from the first approval of phenmedipham under Directive 91/414/EEC, the long-term intake of residues of phenmedipham resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

However, EFSA notes that new scientific data have become available for the renewal process of phenmedipham under Regulation (EC) No 1107/2009, and various data gaps with regard to the toxicological profile of phenmedipham and its metabolites were identified, which prevented the experts to derive toxicological reference values (TRV) for phenmedipham, to derive the risk assessment residue definition for fruit crops and to conclude on the toxicity of some relevant metabolites. Thus, the conclusions of this assessment are provisional pending the finalisation of the renewal of the approval process of phenmedipham.

Considering the above-mentioned outstanding issues, the proposal for amendment of the existing MRL as reported in the summary table below requires further risk management considerations.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B-D.
| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------------|-----------|-------------------------|-------------------------|------------------------|
| 0152000          | Strawberries | 0.3<sup>(+)</sup> | (0.7) | Further risk management considerations required |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.

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

<sup>(+)</sup>: The European Food Safety Authority identified some information on storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or, if that information is not submitted by that date, the lack of it.

**Enforcement residue definition:** Phenmedipham

MRL is derived on the basis of 7 GAP compliant residue trials supporting the NEU use; one more trial would be required to complete the residue data set. Risk to consumers unlikely, according to the conclusions on the toxicity of phenmedipham from the first approval of the active substance under Directive 91/414/EEC. The present assessment does not consider the data gaps identified in the context of the renewal of the approval of phenmedipham under Regulation (EC) No 1107/2009, which prevented experts to derive toxicological reference values (TRVs) for phenmedipham, to derive the risk assessment residue definition for fruit crops and to conclude on the toxicity of relevant metabolites. The confirmatory data gap of the MRL review on the storage stability has been addressed.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for phenmedipham in strawberries. The detailed description of the intended NEU use of phenmedipham, which is the basis for the current MRL application, is reported in Appendix A.

Phenmedipham is the ISO common name for 3-[(methoxycarbonyl)amino]phenyl(3-methylphenyl) carbamate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Phenmedipham was evaluated in the framework of Directive 91/414/EEC1 with Finland being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was the outdoor foliar application on sugar beet, fodder beet and beetroot in both northern and southern Europe. According to Regulation (EU) No 540/20112, phenmedipham is deemed to have been approved under Regulation (EC) No 1107/20093. This approval is restricted to uses as herbicide. EFSA was not involved in the first peer review of phenmedipham.

The EU peer review in the context of the renewal of the approval of phenmedipham according to Regulation (EC) No 1107/2009 has been completed (EFSA, 2018b), but the renewal decision has not been taken yet, pending the assessment of endocrine-disrupting (ED) properties of phenmedipham. Finland was designated as rapporteur Member State (RMS) and Denmark as co-RMS, evaluating the representative uses of phenmedipham as a post-emergence treatment on sugar beet/fodder beet. The renewal assessment report (RAR) has been peer reviewed by EFSA (EFSA, 2018b). The approval of phenmedipham was extended until 31 July 2021 by Regulation (EU) 2020/8694, pending the assessment of endocrine-disrupting (ED) properties.

The EU MRLs for phenmedipham are established in Annex II of Regulation (EC) No 396/20055. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been completed (EFSA, 2014) and the proposed modifications have been implemented in the MRL legislation.6 There are no Codex Maximum Limits (CXLs) established for phenmedipham.

In accordance with Article 6 of Regulation (EC) No 396/2005, Landwirtschaftliches Technologiezentrum Augustenberg submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to raise the existing maximum residue level (MRL) for the active substance phenmedipham in strawberries from 0.3 to 0.5 mg/kg. 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 EFSA on 1 June 2017. To accommodate for the intended NEU outdoor use of phenmedipham, the EMS proposed to raise the existing MRL from 0.3 to 0.9 mg/kg in strawberries.

During the assessment, EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 3 March 2020, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report. On 5 October 2020, the EMS proposed EFSA to resume the assessment on phenmedipham despite the pending open point identified during EU pesticides peer review on the renewal of the approval of phenmedipham concerning the genotoxic potential of the active substance, as this was not yet applicable at time of submission of the MRL application. EFSA agreed to resume the assessment, based on the available information.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2020), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Finland, 1999), the Commission review report on phenmedipham (European Commission, 2004), as well as the conclusions

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
4 Commission Implementing Regulation (EU) 2020/869 of 24 June 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutiamid, benalaxyl, bethiavallincarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and S-metolachlor. OJ L 201, 25.6.2020, p. 7–9.
5 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.
6 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
from EFSA opinion on the review of existing MRLs for phenmedipham according to Article 12 of Regulation (EC) 396/2005 (EFSA, 2014).

For this application, the data requirements established in Regulation (EU) No 544/20117 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2004, 2010a,b, 2017; OECD, 2011). 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 546/20118.

A selected list of end points, based on the conclusions derived in the first approval of phenmedipham and in the framework of the MRL review of phenmedipham, is presented in Appendix B. Data from the renewal of approval process of phenmedipham are also presented.

The evaluation report submitted by the EMS (Germany, 2020) 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.

EFSA notes that new scientific data have become available for the renewal process of phenmedipham under Regulation (EC) No 1107/2009, as provided in the renewal assessment report (RAR) (Finland, 2016) and assessed in the conclusion on the peer review of the pesticide risk assessment of the active substance phenmedipham (EFSA, 2018b). However, since the current MRL application was submitted before the finalisation of the EU pesticides peer review on the renewal of the approval, the current assessment is based on the conclusions derived in the first approval of phenmedipham according to Directive 91/414/EEC and in the framework of the review of existing phenmedipham MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review). The conclusions of this assessment are thus provisional pending the finalisation of the renewal of the approval process of phenmedipham.

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 phenmedipham in primary crops has been investigated in the framework of the renewal of approval process (EFSA, 2018b) following foliar application in root crops (sugar beet) with both [amino-phenyl-UL-14C] and [phenyl-methyl-UL-14C] phenmedipham and in fruits (strawberries) only with [amino-phenyl-UL-14C] radiolabelled phenmedipham. The metabolism study with strawberries and some of the sugar beet studies were also assessed by the MRL review (EFSA, 2014).

Phenmedipham and its conjugates were the predominant compounds of the total residues in sugar beet in immature and mature leaves (95% total radioactive residue (TRR) and 51% TRR, respectively). In sugar beet root, phenmedipham and its conjugates were detected at a low-level (6.6% TRR) while a major unknown fraction accounted for ca. 26% TRR in roots and 14% TRR in maturity leaves. This fraction was generated only from the amino phenol moiety and constituted of several polar minor metabolite fractions.

In strawberries, phenmedipham was the main compound recovered in fruits (58% TRR) while 3-acetamidophenol accounted for 13% TRR. 3-Aacetamidophenol is a rat metabolite and was not recovered in the sugar beet metabolism study. However, since only one label was investigated in strawberry metabolism studies, the EU pesticide peer review could not conclude on the relevant residues for the risk assessment in fruit crops and, in addition, set a data gap for the toxicity of 3-acetamidophenol (EFSA, 2018b).

Since the MRL application on strawberries was submitted to the EMS (June 2017) before the EU pesticides peer review was completed, EFSA assessed this application according to the MRL setting procedure at the time of the submission of the MRL application. The MRL review in 2014 concluded that in strawberries parent phenmedipham is degraded but still remains a major compound of the recovered residues in crop parts. Cleavage of the carbonate link between the two phenyl rings leads to

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.
8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
the formation of metabolite methyl (3-hydroxyphenyl) carbamate (MHPC). Further cleavage of the carbamate moiety results in the metabolite 3-aminophenol, which is subsequently acetylated to form 3-acetamidophenol. Based on the available metabolism study in strawberries, low residues of metabolites are expected in fruits at harvest with parent phenmedipham being the main compound of the residue (EFSA, 2014).

EFSA concludes that for the assessment of this application, the metabolism of phenmedipham is considered addressed according to the conclusions of the MRL review. It is noted that a data gap for metabolism study with [amino-phenyl-UL-14C] phenmedipham in fruit crops and for the assessment of the toxicity of 3-acetamidophenol was set by the EU pesticides peer review of the renewal of the approval of the active substance and is applicable to future MRL applications of phenmedipham on fruit crops.

1.1.2. Nature of residues in rotational crops

As the proposed use of phenmedipham is on a semi-permanent crop, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

In the MRL review, no studies were assessed or required to address the effect of processing on the nature of phenmedipham residues, considering low chronic exposure to phenmedipham residues (EFSA, 2014).

The nature of phenmedipham residues during processing (standard hydrolysis study) was investigated in the framework of the renewal of approval process (EFSA, 2018b). Under standard hydrolysis conditions when investigated with phenyl-methyl labelling, phenmedipham degraded partially into 3-methylaniline (m-toluidine) under conditions representative of baking/brewing and boiling (86% applied radioactivity (AR)) and completely into 3-methylaniline (m-toluidine) under sterilisation conditions. Under these conditions, it can reasonably be assumed that the formation of aniline can be excluded. For the amino phenol labelling form, a complete degradation of phenmedipham to MHPC was observed under conditions representative of baking/brewing and boiling and also under conditions representative of sugar production. Under pasteurisation conditions, phenmedipham is considered stable for both labelled forms (82–87% of AR). The EU pesticides peer review on the renewal of the approval concluded that the nature of phenmedipham residues in raw and processed commodities is different (EFSA, 2018b).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of phenmedipham residues in plant matrices were assessed during the renewal of approval process (EFSA, 2018b). Phenmedipham residues can be monitored in food and feed of plant origin by the multiresidue method DFG S19 (extended revision) using liquid chromatography with tandem mass spectrometry (LC-MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in all commodity groups. In addition, there is QuEChERS method using gas chromatography-mass spectrometry (GC-MS) and/or LC-MS/MS for all plant commodities with LOQs in the range 0.01–0.05 mg/kg.

In the framework of the EU pesticides peer review on the renewal of approval, a specific residue definition for monitoring was proposed in processed commodities of plant origin. In case a specific maximum residue level (MRL) for these commodities is set, monitoring methods for the components included in the residue definition might be required (EFSA, 2018b).

1.1.5. Storage stability of residues in plants

Under the MRL review, a confirmatory data gap was set for the storage stability in matrices with high acid content (EFSA, 2014).

The storage stability of phenmedipham and metabolite MHPC in plant matrices stored under frozen conditions was assessed in the framework of the renewal of approval process (EFSA, 2018b). Storage stability data demonstrated that phenmedipham and MHPC residues are stable up to 24 months in high water, high oil, high protein, high starch and high acid content commodities, when stored at ≤ –18°C.

Thus, in high acid content commodities (relevant for strawberries) residues of phenmedipham and of its metabolite MHPC were stable for at least 24 months when stored at ≤ –18°C.
EFSA notes that the confirmatory data requirement which was set by the MRL review for the storage stability studies in high acid content matrices is sufficiently addressed and the footnote in the MRL legislation can be removed.

1.1.6. Proposed residue definitions

The MRL review, based on metabolism studies in primary and rotational crops, the toxicological significance of metabolites and the capabilities of analytical enforcement methods proposed the following residue definitions in primary crops and processed commodities (EFSA, 2014):

- residue for risk assessment: ‘phenmedipham’ (fruits and fruiting crops; tentative for other crops, pending additional metabolism studies on leafy and root primary crops and rotational crops)
- residue definition for enforcement: ‘phenmedipham’ (tentative, pending additional metabolism studies on leafy and root primary crops and rotational crops)

The EU pesticides peer review in the framework of the renewal of approval of the active substance, based on the metabolic pattern identified in primary and rotational crop metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products, the capabilities of enforcement analytical methods, proposed the following residue definitions (EFSA, 2018b):

- residue for risk assessment:
  - ‘phenmedipham (free and glucoside conjugates)’ (RAC: restricted to sugar beet);
  - ‘sum of phenmedipham and MHPC, and their conjugates, expressed as phenmedipham’ (RAC: rotational crops);
  - ‘sum of phenmedipham and MHPC, expressed as phenmedipham’ and ‘m-toluidine’ (provisional, processed commodities).

- residue definition for enforcement:
  - ‘phenmedipham’ (RAC: root and fruit crops);
  - ‘sum of phenmedipham and MHPC, expressed as phenmedipham’ (processed commodities).

For strawberries, since only one radiolabel was investigated in the plant metabolism studies, no residue definition for risk assessment was proposed by the EU pesticides peer review (EFSA, 2018b).

Since the present MRL application was submitted to the EMS (June 2017) before the EU pesticides peer review on the renewal of approval was completed, EFSA assessed this application according to the MRL setting procedure and related data requirements applicable at the time of the submission of the MRL application. Thus, for the MRL application on strawberries, the residue definitions as proposed by the MRL review are considered applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the intended NEU use of phenmedipham on strawberries, the applicant submitted 10 residue trials on strawberry, which were performed in Germany in 2012 and 2014. One trial had significant residues in the control sample and one trial was performed according to a different use pattern, and therefore, these trials were disregarded.

Two trials from 2014 (LR-O-14-ER-H-01) seem to EFSA not fully independent as the only differing trial parameter was application rate. The EMS proposed to scale the underdosed residue trial value to the intended application rate. EFSA disagreed with this proposal and instead selected the residue value which represents the trial performed at the intended application rate. The data from the replicate plot with lower application rate were disregarded.

Thus, finally, seven valid residue trials on strawberries are available. Strawberries are a major crop in the NEU according to EU guidance document (European Commission, 2017) and therefore, to have a complete residue data set, one more trial would be required.

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9 Pending confirmation of the toxicity of m-toluidine (EFSA, 2018b)
On the basis of the limited available residue data set of seven trials, an MRL of 0.7 mg/kg is calculated for phenmedipham in strawberries.

According to the assessment of the EMS, the analytical methods used to analyse residue trial samples were sufficiently validated and were fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (Germany, 2020).

1.2.2. Magnitude of residues in rotational crops

As the proposed use of phenmedipham is on a semi-permanent crop, investigation of residues in rotational crops is not required.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for strawberries are not available and are not required in the context of the current assessment, considering calculated low consumer exposure (see Section 3).

1.2.4. Proposed MRLs

Based on a limited data set of seven residue trials compliant with the intended NEU GAP of phenmedipham on strawberries, an MRL of 0.7 mg/kg is derived. One additional trial would be required to complete the residue data set.

In Section 3, EFSA assessed whether residues in strawberries resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as strawberries are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a 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, 2018a, 2019).

Since the current MRL application was submitted prior to the finalisation of the EU peer review of the renewal of the approval of phenmedipham, the consumer exposure assessment was undertaken in line with the first approval of phenmedipham and the conclusions of the MRL review (European Commission, 2004; EFSA, 2014). Thus, the toxicological reference values for phenmedipham used in the risk assessment (i.e. ADI value of 0.03 mg/kg bw per day) were those as derived in the first peer review in the framework of the approval of the active substance under Directive 91/414/EEC; the setting of an ARfD was not considered necessary (European Commission, 2004).

It is noted that in the framework of the EU pesticides peer review on the renewal of the approval of phenmedipham, the toxicological reference values for parent compound could not be derived since a genotoxic potential for phenmedipham could not be excluded (EFSA, 2018b). Therefore, the consumer risk assessment could not be conducted. Furthermore, data gaps for the assessment of toxicity were set for the processing degradation product 3-methylaniline (m-toluidine) and the plant metabolite 3-acetamidophenol. The risk assessment residue definition in fruit crops could not be derived (EFSA, 2018b).

Short-term (acute) dietary risk assessment

Considering the toxicological profile of the active substance as concluded in the framework of the approval of the active substance phenmedipham under Directive 91/414/EEC, a short-term dietary risk assessment was not required (European Commission, 2004).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level (EFSA, 2014). EFSA updated the calculation with the STMR value derived from the residue trials in strawberry submitted in support of this MRL application. Crops for which no uses were reported in the MRL review or for which the MRL proposals were not implemented in the MRL legislation (sugar beet) were excluded from the
calculated. A provisional conversion factor of 1.4 as derived by the EU pesticides peer review for sugar beet root was applied to the input value for beetroot to account for potential phenmedipham conjugates.

The input values used in the exposure calculations are summarised in Appendix D.1.

The estimated long-term dietary intake of phenmedipham residues accounted for up to 11% of the ADI (NL toddler diet), considering the proposed use on strawberries and the reported uses of phenmedipham in the MRL review (except sugar beet). The highest contribution of residues in strawberries to the overall long-term exposure is 0.18% of the ADI for DE child diet.

EFSA concluded that, according to the conclusions on the toxicity of phenmedipham from the first approval of phenmedipham under Directive 91/414/EEC, the long-term intake of residues of phenmedipham resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

EFSA notes that on the basis of new scientific data available for the renewal of the approval process of phenmedipham under Regulation (EC) No 1107/2009, various data gaps with regard to the toxicological profile of phenmedipham and its metabolites were identified, which prevented experts to derive toxicological reference values (TRVs) for phenmedipham, to derive the risk assessment residue definition for fruit crops and to conclude on the toxicity of relevant metabolites.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

Based on a limited data set of seven residue trials compliant with the intended NEU GAP of phenmedipham on strawberries, an MRL of 0.7 mg/kg is derived. One additional trial would be required to complete the residue data set.

Since the current MRL application was submitted prior to the finalisation of the EU pesticides peer review of the renewal of the approval of phenmedipham, the consumer exposure assessment was performed in line with the conclusions on the toxicity of phenmedipham from the first approval of phenmedipham under Directive 91/414/EEC and indicated that the long-term intake of phenmedipham residues resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

EFSA notes that on the basis of new scientific data available for the renewal of the approval process of phenmedipham under Regulation (EC) No 1107/2009, various data gaps with regard to the toxicological profile of phenmedipham and its metabolites were identified, which prevented experts to derive toxicological reference values (TRVs) for phenmedipham, to derive the risk assessment residue definition for fruit crops and to conclude on the toxicity of relevant metabolites.

The conclusions of this assessment are thus provisional pending the finalisation of the renewal of the approval process of phenmedipham.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

| Abbreviation | Description                          |
|--------------|--------------------------------------|
| a.s.         | active substance                     |
| ADI          | acceptable daily intake              |
| AR           | applied radioactivity                |
| ARfd         | acute reference dose                 |
| BBCH         | growth stages of mono- and dicotyledonous plants |
| bw           | body weight                          |
| CAC          | Codex Alimentarius Commission        |
| CAS          | Chemical Abstract Service            |
| CF           | conversion factor for enforcement to risk assessment residue definition |
| CIRCA        | (EU) Communication & Information Resource Centre Administrator |
| CS           | capsule suspension                   |
| CV           | coefficient of variation (relative standard deviation) |
| CXL          | Codex maximum residue limit          |
| DAR          | draft assessment report              |
| DAT          | days after treatment                 |
| DM           | dry matter                           |
| DP           | dustable powder                      |
| DS           | powder for dry seed treatment        |
| EC           | emulsifiable concentrate             |
| EDI          | estimated daily intake               |
| EMS          | evaluating Member State              |
| eq           | residue expressed as a.s. equivalent |
| FID          | flame ionisation detector            |
| GAP          | Good Agricultural Practice           |
| GC           | gas chromatography                   |
| GC-FID       | gas chromatography with flame ionisation detector |
Modification of the existing maximum residue level for phenmedipham in strawberries

GC-MS gas chromatography with mass spectrometry
GC-MS/MS gas chromatography with tandem mass spectrometry
GS growth stage
HPLC high-performance liquid chromatography
HPLC-MS high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
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
MS Member States
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
MW molecular weight
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern Europe
SL soluble concentrate
SP water-soluble powder
STMR supervised trials median residue
TAR total applied radioactivity
TMDI theoretical maximum daily intake
TRR total radioactive residue
UV ultraviolet (detector)
WHO World Health Organization
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | Crop and/or situation | Pests or group of pests controlled | Type(b) | Conc. a.s.(c) | Method kind | Range of growth stages & season(c) | Number min–max application per crop/season | Interval between application (min) | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-----------------------|------------------------------------|---------|--------------|------------|-----------------------------------|------------------------------------------|----------------------------------|--------------------------------|-------------|---------|
| Strawberries DE F     | Annual dicotyledonous weeds | SC 160 g/L | Spraying up to BBCH 69 | a) 1     | b) 1       | 5–7 days | 0.32 g a.s./ha | 300 L/ha | Rate kg/ha 14 | 14 | Critical GAP |
| Strawberries DE F     | Annual dicotyledonous weeds | SC 160 g/L | Spraying up to BBCH 69 | a) 2     | b) 2       | 5–7 days | 0.32 g a.s./ha | 300 L/ha | Rate kg/ha 14 | 14 | The GAP is deemed within the envelope of GAP #1 (i.e. no higher residues are anticipated) |
| Strawberries DE F     | Annual dicotyledonous weeds | SC 160 g/L | Spraying up to BBCH 69 | a) 3     | b) 3       | 5–7 days | 0.32 g a.s./ha | 300 L/ha | Rate kg/ha 14 | 14 | The GAP is deemed within the envelope of GAP #1 and # 2 (i.e. no higher residues are anticipated) |

**MRL:** maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; xx: formulation type.

(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 crops**                      |                 | Strawberries| Foliar BBCH 42; 1 x 0.96 kg/ha (1 x 2.88 kg/ha) | 49                | Radiolabelled active substance: [14C-amino-phenyl]-phenmedipham (EFSA, 2014, 2018b; Finland, 2016) |
| **Root crops**                       |                 | Sugar beet  | 1 x 1 kg/ha and 1 x 5 kg/ha (old study) | 5, 10, 20, 30 and 40 | Radiolabelled active substance: [14C-amino-phenyl]-phenmedipham or [14C-phenyl-methyl]-phenmedipham (Finland, 1999, 2016; EFSA, 2014, 2018b) |
|                                      |                 |             | 1 x 2.2 kg/ha (old study)                   | 0, 3, 7, 14, 21 and 28 |
|                                      |                 |             | Foliar: 1 x 1.066 kg/ha (BBCH 14)           | 19 and 137          |
|                                      |                 |             | Foliar: 1 x 1.044 kg/ha (BBCH 14)           |                     |

| **Leafy crops**                      |                 | –           | –                 | –                 | –                  |
| **Cereals/grass**                    |                 | –           | –                 | –                 | –                  |
| **Pulses/oilseeds**                  |                 | –           | –                 | –                 | –                  |
| **Miscellaneous**                    |                 | –           | –                 | –                 | –                  |

| **Rotational crops** (available studies) | **Crop groups** | **Crop(s)** | **Application(s)** | **PBI (DAT)** | **Comment/Source** |
|------------------------------------------|-----------------|-------------|-------------------|---------------|--------------------|
| **Root/tuber crops**                    | Sugar beet      | Soil        | 30, 120, 365      | 30, 164, 305  | From 1.1 to 1.3 kg/ha on bare soil. Both radiolabelled [14C-amino-phenyl]-phenmedipham or [14C-phenyl-methyl]-phenmedipham (Finland, 2016; EFSA, 2018b) |
| **Leafy crops**                         | Lettuce         | Soil        | 30, 120, 365      | 30, 164, 305  |                     |
| **Cereal (small grain)**                | Wheat           | Soil        | 30, 120, 365      | 30, 164, 305  |                     |
|                                          |                 | Soil        |                   |                |                     |
| **Other**                               |                 | –           | –                 | –              | –                  |

| **Processed commodities** (hydrolysis study) | **Conditions** | **Stable?** | **Comment/Source** |
|-----------------------------------------------|----------------|-------------|--------------------|
| **Pasteurisation (20 min, 90°C, pH 4)**       | Yes            | Under standard condition simulating pasteurisation phenmedipham degrades into m-toluidine for 13% AR and MHPC 18% AR, while for other processing conditions phenmedipham degrades completely into m-toluidine and/or MHPC (EFSA, 2018b) |
| **Baking, brewing and boiling (60 min, 100°C, pH 5)** | No             |                         |
| **Sterilisation (20 min, 120°C, pH 6)**       | No             |                         |

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| Question                                                                 | Answer                                                                                           |
|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Can a general residue definition be proposed for primary crops?         | No Root and fruit crops only (EFSA, 2018b)                                                      |
| Rotational crop and primary crop metabolism similar?                    | No In rotational crops, besides phenmedipham, MHPC (soil metabolite) occurs in significant level (25% TRRs in straw) (EFSA, 2018b). |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | No Under standard condition simulating pasteurisation phenmedipham is considered stable, while for other processing conditions phenmedipham degrades completely into m-toluidine and/or MHPC (EFSA, 2018b). |
| Plant residue definition for monitoring (RD-Mo)                         | MRL review (EFSA, 2014), Regulation (EC) No 396/2005: phenmedipham (tentative)                  |
|                                                                        | EU pesticides peer review (EFSA, 2018b):                                                        |
|                                                                        | Root and fruit crops: phenmedipham                                                              |
|                                                                        | Processed commodities: sum of phenmedipham and MHPC, expressed as phenmedipham                  |
| Plant residue definition for risk assessment (RD-RA)                    | MRL review (EFSA, 2014): phenmedipham (fruits and fruiting crops; tentative for other crops)     |
|                                                                        | EU pesticides peer review (EFSA, 2018b):                                                        |
|                                                                        | **Primary crops**: phenmedipham (free and glucoside conjugates) restricted to sugar beet.       |
|                                                                        | **Rotational crops**: sum of phenmedipham and MHPC, and their conjugates, expressed as phenmedipham. |
|                                                                        | **Processed commodities** (provisional):                                                        |
|                                                                        | 1) sum of phenmedipham and MHPC expressed as phenmedipham                                       |
|                                                                        | 2) m-toluidine, pending upon confirmation of the toxicity of m-toluidine.                         |
| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | Matrices with high water content, high oil content, high acid content and dry matrices:         |
|                                                                        | DFG S19 (extended revision) LC–MS/MS: 0.01 mg/kg (phenmedipham)                                  |
|                                                                        | QuEChERS GC–MS and/or LC–MS/MS: 0.01-0.05 mg/kg (phenmedipham)                                   |
|                                                                        | ILV available.                                     (EFSA, 2018b)                                  |

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; LOQ: limit of quantification; GC-MS: gas chromatography with mass spectrometry; LC-MS/MS: liquid chromatography with tandem mass spectrometry; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category                   | Commodity              | T (°C) | Stability period | Compounds covered | Comment/Source                      |
|------------------------------------|-----------------------------|------------------------|--------|------------------|-------------------|-------------------------------------|
|                                    | High water content          | Sugar beet leaves*     | ≤ –20°C | 24 Months        | Parent, MHPC      | EFSA (2018b)                        |
|                                    |                             | Lettuce                | ≤ –18°C | 24 Months        | Parent, MHPC      | EFSA (2018b)                        |
|                                    |                             | Sunflower seed         | ≤ –18°C | 24 Months        | Parent, MHPC      | EFSA (2018b) MHPC: 25% decline after 24 months |
|                                    | High protein content        | Dry pea (seed)         | ≤ –18°C | 24 Months        | Parent, MHPC      | EFSA (2018b)                        |
|                                    |                             | Wheat (grain)          | ≤ –18°C | 24 Months        | Parent, MHPC      | EFSA (2018b)                        |
|                                    |                             | Sugar beet root        | ≤ –20°C | 24 Months        | Parent, MHPC      | EFSA (2018b)                        |
|                                    |                             | Orange                 | ≤ –18°C | 24 Months        | Parent, MHPC      | EFSA (2018b)                        |
|                                    | Others                      |                        |        |                  |                   |                                     |

*Analysed by common moiety method (EFSA, 2018b)
### Magnitude of residues in plants

#### 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 (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|------------------------|------------------------|------------------------|----------------|
| Strawberries | NEU                        | 0.02; 0.04; 0.07; 0.11; 0.18; 0.33; 0.35                      | Residue trials on strawberries compliant with the GAP. One more trial would be required to complete the residue data set (European Commission, 2017). | 0.7                     | 0.35                   | 0.11                   | n/a            |

Residue definition for enforcement and risk assessment (EFSA, 2014): phenmedipham

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; n/a: not applicable.

<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.

<sup>(d)</sup>: Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops

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

| No | Confined rotational crops conducted with radiolabelled $^{14}$C-amino-phenyl or $^{14}$C-phenyl-methyl]-phenmedipham in sugar beet, turnips, lettuce, swiss chard, wheat (from 1.1kg a.s./ha to 1.3 kg a.s./ha, on bare soil). No residues are expected in edible commodities above 0.01 mg/kg (EFSA, 2018b). |

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

| No | In the field rotational crop studies (0.96 kg phenmedipham/soil) no residues of phenmedipham > 0.01 mg/kg were found in the edible crops at any plant-back intervals (PBI) (EFSA, 2018b). |

a.s.: active substance.

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

Acute exposure assessment: Not relevant since no ARfD has been considered necessary (European Commission, 2004).

| ADI | 0.03 mg/kg bw per day (European Commission, 2004) |

Highest IEDI, according to EFSA PRIMo

| 11% ADI (NL toddler diet) |

Contribution of crops assessed:

Strawberry: 0.18% of ADI (DE child)

Assumptions made for the calculations

The calculation is based on the median residue level derived for strawberries from the submitted residue trials. For the remaining commodities, the input values were as derived in the MRL review (EFSA, 2014). Crops for which no uses were reported in the MRL review were excluded from the calculations. For sugar beet, a tentative MRL was derived in the MRL review but not implemented in the MRL regulation and therefore sugar beet was excluded from the exposure calculation assuming there are no authorised EU uses on this crop. For beetroot, a provisional conversion factor of 1.4 for risk assessment as derived by the EU pesticides peer review was applied to account for phenmedipham conjugates.

Since the current MRL application was submitted before the finalisation of the EU peer review of the renewal of the approval of phenmedipham, the consumer exposure assessment was undertaken in line with conclusions of the first approval of phenmedipham and the MRL review (European Commission, 2004; EFSA, 2014). It is reiterated that the renewal of the approval of phenmedipham under Regulation (EC) No 1107/2009, could not establish toxicological reference values for phenmedipham, since its genotoxicity potential was not clarified. Consequently, the non-dietary exposure assessment could not be conducted in the absence of toxicological reference values (EFSA, 2018b).

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; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|-----------|-------------------------|-------------------------|-----------------------|
| 0152000           | Strawberries | 0.3<sup>(+)</sup>       | (0.7)                   | Further risk management considerations required MRL is derived on the basis of 7 GAP compliant residue trials supporting the NEU use; one more trial would be required to complete the residue data set. Risk to consumers unlikely, according to the conclusions on the toxicity of phenmedipham from the first approval of the active substance under Directive 91/414/EEC. The present assessment does not consider the data gaps identified in the context of the renewal of the approval of phenmedipham under Regulation (EC) No 1107/2009, which prevented experts to derive toxicological reference values (TRVs) for phenmedipham, to derive the risk assessment residue definition for fruit crops and to conclude on the toxicity of relevant metabolites. The confirmatory data gap of the MRL review on the storage stability has been addressed. |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.

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

<sup>(+)</sup> The European Food Safety Authority identified some information on storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or, if that information is not submitted by that date, the lack of it.
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### Phenmedipham

| Input values | Toxicological reference values | Details – chronic risk assessment | Details – acute risk assessment |
|--------------|-------------------------------|---------------------------------|-------------------------------|
| Source of ADI: EC, 2004 | Year of evaluation: EC, 2004 | Source of ADI: EC, 2004 | Source of ADI: Year of evaluation |

### Details – Refined calculation mode

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

| Commodity | Highest contributor to ADI (in % of ADI) | Second contributor to ADI (in % of ADI) | Third contributor to ADI (in % of ADI) |
|-----------|-----------------------------------------|----------------------------------------|---------------------------------------|
| Bovine: Muscle/meat | 0.8% 0.24 0.2% | 0.2% 0.2% | 0.1% 0.2% |
| Swine: Muscle/meat | 0.7% 0.22 0.2% | 0.2% 0.2% | 0.1% 0.2% |
| Poultry: Muscle/meat | 0.7% 0.21 0.2% | 0.2% 0.2% | 0.1% 0.2% |
| Strawberries | 0.7% 0.20 0.2% | 0.2% 0.2% | 0.1% 0.2% |
| Beetroots | 0.6% 0.19 0.2% | 0.2% 0.2% | 0.1% 0.2% |
| Poultry: Fat tissue | 0.5% 0.14 0.1% | 0.2% 0.1% | 0.1% 0.1% |
| Sheep: Muscle/meat | 0.4% 0.13 0.1% | 0.2% 0.1% | 0.1% 0.1% |
| Bovine: Muscle/meat | 0.3% 0.11 0.1% | 0.2% 0.1% | 0.1% 0.1% |
| Poultry: Muscle/meat | 0.2% 0.11 0.1% | 0.2% 0.1% | 0.1% 0.1% |
| Bovine: Muscle/meat | 0.2% 0.07 0.1% | 0.2% 0.1% | 0.1% 0.1% |
| Strawberries | 0.2% 0.05 0.1% | 0.2% 0.1% | 0.1% 0.1% |
| Beetroots | 0.1% 0.01 0.0% | 0.2% 0.1% | 0.1% 0.1% |

### Conclusion

The long-term intake of residues of phenmedipham is unlikely to present a public health concern.
## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

| Commodity                          | Existing/proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|------------------------------------|-------------------------------|--------------------|-------------------------|-----------------------|
|                                    |                               |                    | Input value (mg/kg)     | Comment               |
|                                    |                               |                    | Comment                | Input value (mg/kg)   | Comment       |
| **Risk assessment residue definition:** phenmedipham (EFSA, 2014) |                               |                    |                         |                       |
| Strawberries                       | 0.7                           | Intended use       | 0.11                    | STMR-RAC              |                          |
| Beetroot                           | 0.15                          | EFSA (2014)        | 0.07                    | STMR-RAC (0.05)       | (tentative)* CF (1.4)(a) (EFSA, 2018b) |
| Spinach, beet leaves (chard), tarragon | 0.3                           | EFSA (2014)        | 0.01                    | STMR-RAC (tentative)  |                          |
| Herbs and edible flowers, except tarragon | 7                             | EFSA (2014)        | 0.22                    | STMR-RAC (tentative)  |                          |
| Sugar beet roots                   | 0.05*                         | EFSA (2014)        |                         | (b)                   | –                        |
| Meat, fat, liver, kidney of ruminants and swine; Poultry muscle, fat, liver; Eggs; Milk | 0.05*                         | EFSA (2014)        | 0.05                    | STMR-RAC (tentative)  |                          |

STMR-RAC: supervised trials median residue in raw agricultural commodity; CF-conversion factor.

(a): A provisional conversion factor of 1.4 as derived for sugar beet root from sugar beet metabolism studies during the EU pesticides peer review was applied to root crops to account for potential formation of phenmedipham glucoside conjugates in roots.

(b): Sugar beet use was assessed in the MRL review, resulting in tentative MRL of 0.15 mg/kg, which was not implemented in the MRL regulation. The existing MRL is set at the LOQ, thus, assuming that there are no authorised uses of phenmedipham on sugar beet in the EU, EFSA did not consider sugar beet in this exposure calculation.
Appendix E – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|------------------|-----------------------------------------------|---------------------------------|
| phenmedipham     | 3-[(methoxycarbonyl)amino]phenyl (3-methylphenyl)carbamate O=C(Oc1cccc(c1)NC(=O)OC)Nc1cc(C)ccc1 IDOWTHOLJBTAFI-UHFFFAOYSA-N | ![Phenmedipham Structure](image) |
| 3-methylaniline  | 3-methylaniline CC1=CC=CC(N)=C1 JJYPMNFTHTPTTDI-UHFFFAOYSA-N | ![3-Methylaniline Structure](image) |
| MHPC             | methyl (3-hydroxyphenyl)carbamate Oc1cccc(NC(=O)OC)c1 FFQQCJGNKKIRMD-UHFFFAOYSA-N | ![MHPC Structure](image) |
| 3-acetamidophenol| N-(3-hydroxyphenyl)acetamide Oc1cccc(NC(=O)c1 QLNWXBAGRTUKKI-UHFFFAOYSA-N | ![3-Azetamidophenol Structure](image) |

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

<sup>(a)</sup>: ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).

<sup>(b)</sup>: ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).