Evaluation of confirmatory data following the Article 12 MRL review for dimethenamid-P

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Abstract
The applicant BASF SE submitted a request to the competent national authority in Germany to evaluate the confirmatory data that were identified for dimethenamid-P in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. The data gap refers to the submission of a plant metabolism study investigating the fate of dimethenamid-P following foliar treatment with a short preharvest interval (PHI) in a leafy or bulb vegetable crop. The confirmatory data requirement is considered sufficiently addressed according to the conclusions of the peer review, which, based on available metabolism studies, proposed to modify the existing enforcement and risk assessment residue definitions in all plant commodities, by including additional dimethenamid-P metabolites ((2RS)-3-(2-((2,4-dimethylthiophen-3-yl)((2S)-1-methoxypropan-2-yl)amino)-2-oxoethanesulfanyl)-2-hydroxypropanoic acid (M30) and (2RS)-3-[(2-((2,4-dimethylthiophen-3-yl)((2S)-1-methoxypropan-2-yl)amino)-2-oxoethyl)sulfanyl]-2-hydroxypropanoic acid (M26). The residue data of metabolites M26 and M30 are currently not available for all authorised uses assessed in the MRL review. Should risk managers decide amending residue definitions, the existing EU MRLs would need to be revised accordingly. The consumer exposure as calculated by the MRL review was updated in two scenarios, using the existing and the new toxicological reference values as derived by the peer review. For the crops under consideration (spring onions, lettuce, escarole and herbs), indicative conversion factors were applied to account for possible metabolite burden. No consumer intake concerns were identified.

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Summary

In 2013, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for dimethenamid-P 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. A plant metabolism study investigating the fate of dimethenamid-P following a foliar treatment with a short preharvest interval (PHI) in a crop belonging to the class of leafy or bulb vegetables was requested as confirmatory data.

The tentative MRL proposals for the crops affected by the data gap have been implemented in the MRL legislation by Commission Regulation (EU) No 2015/552, including a footnote that indicated the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 8 April 2017.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, BASF SE submitted a formal application to the competent national authority in Germany (rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. In order to address the data gap, the applicant revised the Good Agricultural Practices (GAPs) for the crops for which tentative MRLs have been established: lettuce, spring onions and herbs. A new GAP on escarole was also reported. Furthermore, the applicant referred to new metabolism studies that have been assessed in the framework of the process of renewal of the approval for dimethenamid-P (in the following referred to as peer review process).

The evaluation report prepared by the RMS summarised the information submitted by the applicant. The application was submitted to the European Commission and forwarded to EFSA on 25 September 2018.

Based on the previously available and the new metabolism studies, the peer review proposed to modify the existing enforcement and risk assessment residue definitions in all plant commodities. It was suggested to include additional dimethenamid-P metabolites ((2RS)-3-[(2,4-dimethylthiophen-3-yl)[(2S)-1-methoxypropan-2-yl]amino]-2-oxoethanesulfonyl]-2-hydroxypropanoic acid (M30) and (2RS)-3-[(2,4-dimethylthiophen-3-yl)[(2S)-1-methoxypropan-2-yl]amino]-2-oxoethylsulfanyl]-2-hydroxypropanoic acid (M26)) in the residue definitions. However, so far, a formal decision on the amendment of the residue definition has not been taken, and therefore, the current residue definition established in Regulation (EC) No 396/2005 is still applicable.

The table below summarises the conclusions and recommendations derived on the basis of the assessment of confirmatory data submitted by the applicant.
### Current enforcement residue definition:

Dimethenamid, including other mixtures of constituent isomers including dimethenamid-P (sum of isomers)

| Code(a) | Commodity                          | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                                                                                 |
|--------|------------------------------------|-----------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0220040| Spring onions                      | 0.01* (ft 1)    | 0.01*        | The data gap identified by EFSA regarding metabolism study is considered addressed. Based on the new and previously available metabolism studies, the peer review proposed to modify the existing residue definitions for enforcement and risk assessment as 'dimethenamid (sum of stereoisomers) and metabolites M26 and M30, expressed as dimethenamid-P'. Since the modification of the residue definition will have an impact not only on the crops for which confirmatory data were requested, but for a wide range of crops with approved uses, further risk management discussions are required on the implementation of the new residue definitions. If the existing residue definition for enforcement is maintained, the MRLs for the crops under consideration are confirmed. The residue data on lettuce is acceptable to propose a new MRL in escarole, provided that the NEU use of dimethenamid-P on escarole is confirmed. The risk assessment performed in the framework of the MRL review was updated, taking into account the presence of M26 and M30 in leafy crops (lacking residue trials for the proposed new residue definition, indicative conversion factors were used to recalculate the input values for spring onions, lettuce, escarole and herbs). EFSA calculated two scenarios: while in scenario 1 the current ADI/ARfD was used, in scenario 2 an indicative risk assessment was performed, using new toxicological reference values derived in the peer review (not yet formally adopted). No consumer health concerns were identified (scenario 1: 1.5% of the ADI, max. 0.9% of ARfD for escarole and 0.3% of ARfD for lettuce; scenario 2: 0.8% of the ADI, max. 2.8% of ARfD for escarole and 0.9% of ARfD for lettuce). Given the wide margin of safety, it can be concluded that the existing uses of dimethenamid-P do not pose a risk to consumers.
| 0251020| Lettuces                           | 0.01* (ft 1)    | 0.01*        | Further risk management considerations required                                                                                                           |
| 0251030| Escarole/broad-leaved endives(c)   | 0.01* (default MRL) | 0.01* | Further risk management considerations required
| 0256000| Herbs and edible flowers (whole group) | 0.01* (ft 1)    | 0.01*        | Further risk management considerations required                                                                                                           |

MRL: maximum residue level; NEU: northern Europe; ADI: acceptable daily intake; ARfD: acute reference dose.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(c): The EMS notified a minor NEU use of dimethenamid-P on escarole. Provided that such a use is confirmed in the NEU, the existing residue data in lettuce is acceptable to derive an MRL for escarole.
*: Limit of quantification.
ft 1: The European Food Safety Authority identified some information on plant metabolism 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 8 April 2017, or, if that information is not submitted by that date, the lack of it.
Assessment

The review of existing maximum residue levels (MRLs) for the active substance dimethenamid-P according to Article 12 of Regulation (EC) No 396/2005\(^1\) (MRL review) has been performed in 2013 (EFSA, 2013). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified.

Following the MRL review, the existing MRLs have been modified in the MRL legislation by Commission Regulation (EU) No 2015/552\(^2\), including a footnote that specified the type of information that was identified as missing for the tentative MRLs. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 8 April 2017.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016), the applicant BASF SE submitted an application to the competent national authority in Germany (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 has amended the authorised Good Agricultural Practices (GAPs) for spring onions, lettuce and herbs by deleting the preharvest interval (PHI) since the active substance must be applied at an early development stage of the crop (BBCH 10–18) which does not require to specify a PHI. In Appendix A, the previously assessed GAPs and the adjusted GAPs are reported. Furthermore, the applicant referred to metabolism studies that have been assessed in the framework of the renewal of the approval of dimethenamid-P.

In addition, a GAP on escarole was reported, for which the existing MRL should be modified. The evaluating Member State (EMS) clarified that the applicant (BASF SE) is not the authorisation holder for escarole, but there might be a minor use registration in the northern Europe (NEU) requiring the MRL for escarole.

The RMS assessed the information and the arguments provided by the applicant in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 25 September 2018 (Germany, 2018). EFSA assessed the application as requested by the European Commission in accordance with Article 9 of Regulation (EC) No 396/2005.

EFSA based its assessment on the evaluation report submitted by the RMS (Germany, 2018), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2013) and the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance dimethenamid-P (EFSA, 2018).

For this application, the data requirements established in Regulation (EU) No 544/2011\(^3\) and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2015/552 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\(^4\).

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

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

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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) 2015/552 of 7 April 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,3-dichloropropene, bifenox, dimethenamid-P, prohexadione, tolyfluanid and trifluralin in or on certain products. OJ L 92, 8.4.2015, p. 20–85.

\(^3\) 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 data requirements for active substances. OJ L 92, 8.4.2015, p. 1–66.

\(^4\) 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. 127–175.
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 applicant did not submit a plant metabolism study investigating the fate of dimethenamid-P following a foliar treatment with a short PHI in a leafy or bulb vegetable crop as requested as confirmatory data.

Instead, the applicant referred to a new metabolism study with maize (foliar treatment) that was assessed under the peer review of dimethenamid-P and which was not available at the time of the MRL review. The new study provides information on the metabolism of dimethenamid-P and racemic dimethenamid-P in maize following the treatment of the crop at the rate of 1.3 kg/ha and 0.72 kg/ha, respectively (Germany, 2016). The samples of maize forage were analysed for residues 30 days after treatment with dimethenamid-P. In maize forage, metabolites (2RS)-3-(2-(2,4-dimethylthiophen-3-yl)\{[(2S)-1-methoxypropan-2-yl]amino\}-2-oxoethanesulfonyl)-2-hydroxypropanoic acid (M30) and (2RS)-3-[(2,4-dimethylthiophen-3-yl)\{[(2S)-1-methoxypropan-2-yl]amino\}-2-oxoethyl)sulfanyl]-2-hydroxypropanoic acid (M26) are the main components of the total radioactive residue (TRR), accounting for 17.9% (0.13 mg eq/kg)/18.5% (0.46 mg eq/kg) and 10.8% (0.08 mg eq/kg)/7% (0.18 mg eq/kg), when treated with dimethenamid-P and racemic dimethenamid-P, respectively. In maize grain harvested 81 days after the treatment, the active substance was found to be intensively metabolised; no parent compound was detected. There was no metabolites identification in maize grain.

According to the applicant, the results in maize forage following foliar treatment provide information on the metabolic profile expected in leafy parts of the crop treated close to harvesting. This proposal is in line with the conclusions of the peer review, where, on the basis of available metabolism studies with maize (foliar and soil treatment), sugar beet (foliar application) and soybean (soil application), a comparable metabolic pathway for all plant commodities was concluded.

Overall, the available plant metabolism studies demonstrate that residues of parent dimethenamid-P and its metabolites are all below 0.01 mg/kg in soybeans, sugar beet roots and maize grain; in soybean leaves and maize forage metabolites M26 (soybean leaves) and M30 (maize forage, DAT 30), accounted for more than 10% TRR. The presence of these metabolites was confirmed by certain residue trials submitted under the peer review, i.e. in spring onions (PHI 28–43), Chinese cabbage and curly kale (PHI 26–65) residues of metabolite M30 were above the limit of quantification (LOQ).

The peer review concluded that these metabolites are relevant plant metabolites to be included in the risk assessment and enforcement residue definitions for all plant commodities (EFSA, 2018).

EFSA concluded that the available maize metabolism study is sufficient to address the data gap for spring onions, herbs and lettuce as identified by the MRL review.

1.1.2. Nature of residues in rotational crops

New studies were not submitted and are not relevant.

1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Methods of analysis in plants

Not relevant for the current assessment.

1.1.5. Stability of residues in plants

Not relevant for the current assessment.

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5 The MRL review assessed metabolism of dimethenamid-P in maize and soybean following soil treatment and in sugar beet following foliar treatment (EFSA, 2013).
1.1.6. Proposed residue definitions

In the framework of the MRL review, the following residue definition for the risk assessment and enforcement was derived: ‘dimethenamid, including other mixtures of constituent isomers including dimethenamid-P (sum of isomers)’ (EFSA, 2013). The residue definition was considered tentative for some of the authorised uses in Europe (spring onions, lettuce and herbs) where consumable parts are harvested after foliar treatment with a short PHI.

The same residue definition is currently implemented in Regulation (EC) No 396/2005.

Based on the metabolism studies described under Section 1.1.1, and taking into account the toxicological relevance of metabolites, the experts performing the peer review of dimethenamid-P recently proposed to modify the residue definitions (enforcement and risk assessment) for plant commodities as ‘dimethenamid (sum of stereoisomers) and metabolites (2RS)-3-[(2-{(2,4-dimethylthiophen-3-yl)\{(2S)-1-methoxypropan-2-yl\}amino}-2-oxoethyl)sulfanyl]-2-hydroxypropanoic acid (M26) and (2RS)-3-[(2-{(2,4-dimethylthiophen-3-yl)\{(2S)-1-methoxypropan-2-yl\}amino}-2-oxoethanesulfonyl)-2-hydroxypropanoic acid (M30) expressed as dimethenamid-P’. These residue definitions are not yet formally adopted. The peer review also concluded that, based on structure similarity, the toxicological reference values of dimethenamid-P are applicable to metabolites M26 and M30, which are considered unlikely to be genotoxic.

If a decision is taken by risk managers to follow the recommendations of the peer review (EFSA, 2018) and to modify the residue definitions, a comprehensive revision of the existing MRLs would be required.

1.2. Magnitude of residues in plants

In the framework of the current assessment, the applicant proposed to modify the authorised GAPs for lettuce, chives and spring onions by deleting PHI intervals. For chives, in addition, another NEU GAP, involving split application, was reported (see Appendix A). The EMS also reported a new GAP on escarole which was not assessed previously.

**Spring onions, chives**

The deletion of the PHI interval and splitting of the application rate (only for chives) in the authorised GAP on spring onions and chives is not expected to affect the validity of trials assessed in the MRL review (no residue situation was observed). Thus, the adjusted GAPs are considered sufficiently supported by residue data. The available studies confirm that residues of parent dimethenamid-P above the LOQ are not expected in spring onions and chives.

**Lettuce, fresh herbs (except chives), escarole**

The adjusted GAP on lettuce is less critical than the authorised GAP assessed in the MRL review. The new reported GAP on escarole, which, according to the information from the EMS would support minor uses in the NEU, is identical to the GAP on lettuce reported in the framework of the current assessment.

New residue trials matching the adjusted GAP or the new GAP on escarole, have not been submitted. However, as residues of parent dimethenamid-P were below the LOQ of 0.01 mg/kg for a more critical GAP on lettuce assessed by the MRL review, it is concluded that available lettuce trials are valid to support the adjusted GAP on lettuce, the existing authorised GAP on herbs and the new GAP on escarole. The MRL of 0.01 mg/kg (at the LOQ) is thus confirmed for the existing residue definition in lettuce, herbs (except chives) and escarole.

It is noted that new metabolism studies confirm that in the crops under consideration metabolites are present at higher levels than parent, and thus shall be considered in the risk assessment. For spring onions, the residue trials assessed by the peer review support the adjusted GAP and provide information on metabolite levels. A conversion factor of 2.7 is derived for spring onions (extrapolated to chives) from the existing to the new risk assessment residue definition. For lettuce, herbs (except chives) and escarole in the absence of specific residue data, a conversion factor of 2.6 can be derived from the peer review residue trials on leafy brassica (Chinese cabbage, curly kale; GAP involving early treatment) to account for metabolites of M30 and M26.

2. Consumer risk assessment

New toxicological reference values were derived in the framework of the renewal of the approval of dimethenamid-P (EFSA, 2018). The new ADI and ARfD have not yet been adopted. Moreover, new
information available from metabolism studies would require consideration of dimethenamid-P metabolites M26 and M30 in the exposure assessment. The residue data on metabolites are currently not available for all crops on which the use of dimethenamid-P is authorised, but since the available residue trials assessed in the peer review indicate no residue situation in all crops, with exception of spring onions and leafy brassica, the lack of this information is not expected to underestimate the actual consumer exposure.

In the framework of the current assessment, EFSA updated the consumer exposure calculated in the MRL review with data on metabolites in the crops under consideration (scenario 1). In order to estimate the consumer exposure for the toxicological reference values proposed by the peer review, a second exposure scenario (scenario 2) was calculated, using new acceptable daily intake (ADI) and acute reference dose (ARfD) values. The scenario 2 is considered indicative as the new toxicological reference values are not yet enforced.

For lettuce, herbs, escarole and spring onions, indicative conversion factors of 2.6 and 2.7, derived from the peer review residue trials on leafy brassica and spring onions, respectively, were applied to the input values. For the remaining commodities, the input values for the chronic and acute exposure assessment were as reported in the MRL review. Those crops, on which the authorised uses have not been reported under the MRL review, were excluded from the exposure calculation.

Scenario 1

The calculated exposure was compared with the currently applicable toxicological reference values: ADI of 0.02 mg/kg body weight (bw) day and an ARfD of 0.25 mg/kg bw (European Commission, 2003). The highest calculated chronic exposure accounted for 1.5% of the ADI (UK toddler diet). No acute consumer intake concerns were identified for any of the crops, with a maximum individual highest exposure calculated from residues in escarole (0.9% of the ARfD) and lettuce (0.3% of the ARfD).

Scenario 2 (indicative)

The calculated exposure was compared with the toxicological reference values as derived by the recent EFSA peer review: ADI of 0.04 mg/kg bw day and the ARfD value of 0.08 mg/kg bw (EFSA, 2018). The toxicological reference values are not enforced yet. The calculated indicative chronic exposure accounted for a maximum 0.8% of the ADI (UK Toddler) and the highest acute exposure was calculated from the intake of escarole (2.8% of the ARfD) and lettuce (0.9% of the ARfD).

Although the contribution of dimethenamid metabolites in all crops from all authorised uses could not be assessed, given the wide margin of safety, it can be concluded that currently no risk of consumers is associated with the intake of crops containing dimethenamid-P residues when treated according to the authorised use patterns.

3. Conclusion and Recommendations

To address the data gaps, the applicant and the RMS referred to a new metabolism study on maize (foliar treatment), which was assessed for the renewal of the approval of dimethenamid-P, but not available for the MRL review. Along with other available metabolism studies, the peer review proposed to modify the existing enforcement and risk assessment residue definitions in all plant commodities, by including metabolites M26 and M30, and derived new toxicological reference values.

The residue data on metabolites M26 and M30 are currently not available for the authorised uses assessed in the MRL review. Since the modification of the residue definition will have an impact not only on the crops for which confirmatory data were requested, but for a wide range of crops with approved uses, further risk management discussions are required on the implementation of new residue definitions. It is noted that in the peer review a wide range of residue trials were assessed confirming the presence of metabolite M30 only in spring onions and leafy brassica, whereas for the remaining crops residues of dimethenamid-P and its metabolites M26 and M30 were below the LOQ.

If the existing residue definition is maintained, the tentative MRLs in spring onions, lettuce and herbs and a new MRL of 0.01 mg/kg (LOQ) in escarole, are confirmed.

New information available from metabolism studies requires consideration of dimethenamid-P metabolites M26 and M30 in the exposure assessment. The consumer exposure calculated by the MRL review was updated in two scenarios, using the existing and the new toxicological reference values. For the input values of spring onions, lettuce, escarole and herbs, indicative conversion factors as
derived from available peer review trials were applied to account for the metabolite burden. No consumer intake concerns were identified. Although the contribution of dimethenamid metabolites in all crops from all authorised uses could not be assessed, given the wide margin of safety, it can be concluded that no risk of consumers is currently associated with the intake of crops containing residues when treated according to the authorised use patterns.

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

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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement to risk assessment residue definition
DAR draft assessment report
DAT days after treatment
EC emulsifiable concentrate
EMS evaluating Member State
eq residue expressed as a.s. equivalent
GAP Good Agricultural Practice
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
InChiKey International Chemical Identifier Key
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LC–MS/MS liquid chromatography with tandem mass spectrometry
LOQ limit of quantification
MRL maximum residue level
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PHI preharvest interval
PRIMO (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RD residue definition
RMS: rapporteur Member State
SANCO: Directorate-General for Health and Consumers
SEU: southern Europe
SMILES: simplified molecular-input line-entry system
STMR: supervised trials median residue
TRR: total radioactive residue
## Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

| Crop and/or situation | NEU, SEU, MS or country | F, G or I(\(^{a}\)) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(\(^{d}\)) | Remarks |
|-----------------------|-------------------------|----------------------|-----------------------------------|-------------|-----------------|-----------------------------|-----------------|--------|
|                       |                         |                      |                                   |             | Method kind | Range of growth stages & season(\(^{c}\)) | No of min–max | g a.s./ hl | Water L/ha(min–max) | Rate | Unit | | |
| Lettuce               | NEU                     | F                    | Weeds                             | EC          | Foliar spray | 121.2.5 g/L               | 1               | 0.27      | kg/ha | 35    | GAP assessed under Article 12 MRL review (EFSA, 2013) |
|                       |                         |                      |                                   |             | Foliar spray | 720 g/L                  | 13–16           | 300      | 200–400 | 0.216 | kg/ha | n/a 10 days post-planting Adjusted GAP |
|                       | NEU                     | F                    | Weeds                             | EC          | Foliar spray | 720 g/L                  | 13–16           | 300      | 200–400 | 0.216 | kg/ha | n/a 10 days post-planting New GAP not reported for the MRL review |
| Escarole              | NEU                     | F                    | Weeds                             | EC          | Foliar spray | 720 g/L                  | 1               | 1.01     | kg/ha | 35    | GAP assessed under Article 12 MRL review (EFSA, 2013) |
|                       |                         |                      |                                   |             | Foliar spray | 720 g/L                  | 12–14           | 1,200    | 200–400 | 0.864 | kg/ha | n/a Adjusted GAP (the same GAP was assessed by the peer review (EFSA, 2018)) |
|                       | NEU                     | F                    | Weeds                             | EC          | Foliar spray | 720 g/L                  | 10–14           | 1,200    | 200–400 | 0.864 | kg/ha | n/a Adjusted GAP |
|                       | NEU                     | F                    | Weeds                             | EC          | Foliar spray | 720 g/L                  | 12–14           | 1,200    | 200–400 | 0.864 | kg/ha | n/a For use as fresh herb and/or bulb cultivation Adjusted GAP |
|                       | NEU                     | F                    | Weeds                             | EC          | Foliar spray | 720 g/L                  | 10–18           | 4 (in split appl.) | 5       | 1,200 | 200–400 | 0.864 | kg/ha | n/a Split applications 0.3+0.3+0.3+0.3 or 0.3+0.3+0.6 |
|                       | NEU                     | F                    | Weeds                             | EC          | Foliar spray | 720 g/L                  | 10–18           | 4 (in split appl.) | 5       | 1,200 | 200–400 | 0.864 | kg/ha | n/a Split applications 0.3+0.3+0.3+0.3 or 0.3+0.3+0.6 |
|                       | NEU                     | F                    | Weeds                             | EC          | Foliar spray | 720 g/L                  | 10–18           | 4 (in split appl.) | 5       | 1,200 | 200–400 | 0.864 | kg/ha | n/a Split applications 0.3+0.3+0.3+0.3 or 0.3+0.3+0.6 |

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

(\(^{a}\)): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(\(^{b}\)): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide 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 |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Root crops                        | Sugar beet  | Early post emergence (BBCH 10, then 9 and 21 days interval), 3 × 0.45 kg as/ha | 126 DAT: roots and leaves with tops | 3-14C-thienyl labelled racemic dimethenamid (EFSA, 2013, 2018) |
| Cereals/grass                     | Maize       | 1) early post-emergence 1 × 1.3 kg as/ha, BBCH 13-15 2) early post-emergence 1 × 0.72 kg as/ha, BBCH 13-15 | Forage: 30 DAT; Forage/husks and grain/cobs: 81 DAT; Mature plants: 120 DAT | 1) 3-14C-thienyl labelled racemic dimethenamid 2) 3-14C-thienyl dimethenamid (EFSA, 2018) |
| Pulses/oilseeds                   | Soybean     | Soil application, pre-emergence, 1 × 1 kg as/ha | Mature plants: 119 DAT | 2-14C-thienyl dimethenamid (EFSA, 2018). The study considered by the MRL review (1 × 1.34 kg as/ha) was considered as a supplementary study by the peer review and is not reported in the recent LOEP |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Radish      | Soil, 1 kg as/ha | 30, 120, 365 | 3-14C-thienyl dimethenamid (EFSA, 2013, 2018) |
| Carrot                              | Maize: 1.68/4.4 kg as/ha  Soya: 1.68/3.36 kg as/ha | 332 | Sown after harvest of maize (DAT 130) and soya (DAT 128) 3-14C-thienyl labelled racemic dimethenamid (EFSA, 2013, 2018) |
| Leafy crops                         | Spinach     | Soil, 1 kg as/ha | 30, 120, 365 | 3-14C-thienyl dimethenamid (EFSA, 2013, 2018) |
| Lettuce                             | Maize: 1.68/4.4 kg as/ha  Soya: 1.68/3.36 kg as/ha | 332 | Sown after harvest of maize (DAT 130) and soya (DAT 128) 3-14C-thienyl labelled racemic dimethenamid (EFSA, 2013, 2018) |
B.1.1.2. Stability of residues in plants

Not relevant.
### B.1.2. Magnitude of residues in plants

Not relevant

### B.2. Residues in livestock

Not relevant

### B.3. Consumer risk assessment

#### ARfD

| Scenario | 0.25 mg/kg bw (Regulation 03/84/EC; European Commission, 2003) |
|----------|---------------------------------------------------------------|
| **Scenario 2 (indicative)** | 0.08 mg/kg bw\(^7\) (EFSA, 2018) (not yet formally adopted) |

#### Highest IESTI, according to EFSA PRIMo

| Scenario | Escarole: 0.9% of the ARfD | Lettuce: 0.3% of the ARfD | Other commodities under consideration: < 0.2% of the ARfD |
|----------|---------------------------|---------------------------|-----------------------------------------------------------|
| **Scenario 2 (indicative)** | Escarole: 2.8% of the ARfD | Lettuce: 0.9% of the ARfD | Other commodities under consideration: < 0.5% of the ARfD |

#### Assumptions made for the calculations

The calculations are based on the highest residue levels expected in raw agricultural commodities from the authorised uses assessed in the MRL review (EFSA, 2013) and for the new use reported for escarole (Germany, 2018). The following conversion factors for risk assessment were applied: 2.7 for spring onions and chives and 2.6 for lettuce, escarole and herbs (except chives) to account for metabolites M26 and M30. The calculation for Scenario 2 is indicative since a formal decision on the toxicological reference values has not yet been taken.

#### ADI

| Scenario | 0.02 mg/kg bw per day (Regulation 03/84/EC; European Commission, 2003) |
|----------|--------------------------------------------------------------------------|
| **Scenario 2** | 0.04 mg/kg bw per day\(^8\) (EFSA, 2018) (not yet formally adopted) |

#### Highest IEDI, according to EFSA PRIMo

| Scenario | 1.5% of the ADI (UK Toddler diet) | Contribution of crops assessed: |
|----------|----------------------------------|---------------------------------|
| **Scenario 1** | Escarole: 0.03% of the ADI (NL child) | Lettuce: 0.006% of the ADI (IE adult diet) |
| **Scenario 2 (indicative)** | Escarole: 0.013% of the ADI (NL child) | Herbs: < 0.01% of the ADI |

| Scenario | 0.8% of the ADI (UK Toddler diet) | Contribution of crops assessed: |
|----------|----------------------------------|---------------------------------|
| **Scenario 1** | Lettuce: 0.035% of the ADI (ES adult diet) | Escarole: 0.003% of the ADI (IE adult diet) |
| **Scenario 2 (indicative)** | Escarole: 0.003% of the ADI (IE adult diet) | Herbs: < 0.01% of the ADI |

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\(^6\) Commission Directive 2003/84/EC of 25 September 2003 amending Council Directive 91/414/EEC to include flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam as active substances. OJ L 247, 30.9.2003, p. 20–25.

\(^7\) Not enforced yet.

\(^8\) Not enforced yet.
Assumptions made for the calculations

The calculations are based on the median residue levels expected in raw agricultural commodities from the authorised uses assessed in the MRL review (EFSA, 2013) and for the new use reported for escarole (Germany, 2018). The following conversion factors for risk assessment were applied: 2.7 for spring onions and chives and 2.6 for lettuce, escarole and herbs (except chives) to account for metabolites M26 and M30. The calculation for Scenario 2 is indicative since a formal decision on the toxicological reference values has not yet been taken.

B.4. Recommended MRLs

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------|----------------|--------------|----------------------------|
| 0220040 | Spring onions | 0.01* (ft 1) | 0.01* | Further risk management considerations required |
| 0251020 | Lettuces | 0.01* (ft 1) | 0.01* | Further risk management considerations required |
| 0251030 | Escarole/broad-leaved endives(c) | 0.01* (default MRL) | 0.01* | Further risk management considerations required |
| 0256000 | Herbs and edible flowers (whole group) | 0.01* (ft 1) | 0.01* | Further risk management considerations required |

Current enforcement residue definition: Dimethenamid, including other mixtures of constituent isomers including dimethenamid-P (sum of isomers)

The data gap identified by EFSA regarding metabolism study is considered addressed. Based on the new and previously available metabolism studies, the peer review proposed to modify the existing residue definitions for enforcement and risk assessment as "dimethenamid (sum of stereoisomers) and metabolites M26 and M30, expressed as dimethenamid-P". Since the modification of the residue definition will have an impact not only on the crops for which confirmatory data were requested, but for a wide range of crops with approved uses, further risk management discussions are required on the implementation of the new residue definitions. If the existing residue definition for enforcement is maintained, the MRLs for the crops under consideration are confirmed. The residue data on lettuce is acceptable to propose a new MRL in escarole, provided that the NEU use of dimethenamid-P on escarole is confirmed. The risk assessment performed in the framework of the MRL review was updated, taking into account the presence of M26 and M30 in leafy crops (lacking residue trials for the proposed new residue definition, indicative conversion factors were used to recalculate the input values for spring onions, lettuce, escarole and herbs).

EFSA calculated two scenarios: while in scenario 1 the current ADI/ARfD was used, in scenario 2 an indicative risk assessment was performed, using new toxicological reference values derived in the peer review (not yet formally adopted). No consumer health concerns were identified (scenario 1: 1.5% of the ADI, max. 0.9% of ARfD for escarole and 0.3% of ARfD for lettuce scenario 2: 0.8% of the ADI, max. 2.8% of ARfD for escarole and 0.9% of ARfD for lettuce).

Given the wide margin of safety, it can be concluded that the existing uses of dimethenamid-P do not pose a risk to consumers.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Dimethenamid-P

**Status of the active substance:** Included

| Code no. | LOQ (mg/kg bw): | Proposed LOQ: | ADI (mg/kg bw per day): | ARfD (mg/kg bw): | Source of ADI: | Source of ARfD: | Year of evaluation: |
|----------|----------------|---------------|------------------------|-----------------|----------------|-----------------|-------------------|
|          |                |               | 0.02                   | 0.25            | EC             | EC              | 2003              |

**Toxicological end points**

| TMDI (range) in % of ADI | minimum – maximum |
|--------------------------|--------------------|
| Commodity/group of commodities |
| 1.6 | 1.1 | Sugar beet (root) | 0.2 | Potatoes |
| 0.9 | 0.6 | Apples | 0.1 | Potatoes |
| 0.9 | 0.5 | Sugar beet (root) | 0.2 | Potatoes |
| 0.8 | 0.3 | Apples | 0.3 | Potatoes |
| 0.8 | 0.2 | Sweet potatoes | 0.1 | Maize |
| 0.7 | 0.2 | Potatoes | 0.1 | Maize |
| 0.6 | 0.2 | Potatoes | 0.1 | Maize |
| 0.5 | 0.2 | Potatoes | 0.1 | Maize |
| 0.5 | 0.2 | Potatoes | 0.0 | Lettuce |
| 0.4 | 0.2 | Potatoes | 0.0 | Lettuce |
| 0.4 | 0.2 | Potatoes | 0.1 | Apples |
| 0.4 | 0.2 | Potatoes | 0.0 | Lettuce |
| 0.4 | 0.2 | Potatoes | 0.1 | Apples |
| 0.4 | 0.2 | Potatoes | 0.0 | Lettuce |
| 0.3 | 0.2 | Potatoes | 0.1 | Apples |
| 0.3 | 0.2 | Potatoes | 0.1 | Apples |
| 0.3 | 0.2 | Sugar beet (root) | 0.1 | Potatoes |
| 0.2 | 0.1 | Potatoes | 0.0 | Lettuce |
| 0.2 | 0.1 | Lettuce | 0.0 | Lettuce |
| 0.2 | 0.1 | Lettuce | 0.0 | Lettuce |
| 0.2 | 0.1 | Lettuce | 0.0 | Lettuce |
| 0.1 | 0.1 | Potatoes | 0.0 | Potatoes |
| 0.1 | 0.1 | Potatoes | 0.0 | Potatoes |
| 0.1 | 0.1 | Potatoes | 0.0 | Potatoes |

#### Chronic risk assessment – refined calculations

**No of diets exceeding ADI:**

| Commodity/group of commodities |
|-------------------------------|
| 1.5 | UK Toddler |
| 0.9 | DE child |
| 0.9 | UK Infant |
| 0.8 | NL child |
| 0.8 | IE adult |
| 0.7 | WHO Cluster diet B |
| 0.6 | FR toddler |
| 0.6 | WHO cluster diet E |
| 0.5 | FR infant |
| 0.5 | PT General population |
| 0.5 | WHO regional European diet |
| 0.4 | WHO cluster diet D |
| 0.4 | SE general population 90th percentile |
| 0.4 | DK child |
| 0.4 | WHO Cluster diet F |
| 0.4 | UK vegetation |
| 0.4 | PL general population |
| 0.4 | UK Adult |
| 0.3 | LT adult |
| 0.3 | NL general |
| 0.3 | ES-chil |
| 0.2 | ES adult |
| 0.2 | IT kids/toddler |
| 0.2 | IT adult |
| 0.2 | FR all population |
| 0.2 | DK adult |
| 0.1 | FI adult |

#### Conclusion:

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

The acute risk assessment is based on the ARfD.

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

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

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

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

| Processed commodities | Unprocessed commodities |
|-----------------------|-------------------------|
| **Highest % of ARfD/ADI commodities** | **pTMRL/ threshold MRL (mg/kg)** |
| Scarole (broad-leaf) | 0.026/- |
| Potatoes | 0.01/- |
| Melons | 0.01/- |
| Apples | 0.01/- |
| Pears | 0.01/- |
| Sweet corn | 0.01/- |
| Lettuce | 0.026/- |
| Sugar beet (root) | 0.01/- |
| Peaches | 0.01/- |
| Cucumbers | 0.01/- |
| Sweet corn | 0.01/- |
| Swedes | 0.01/- |
| Sugar beet (root) | 0.01/- |
| Beetroot | 0.01/- |

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

| Processed commodities | Unprocessed commodities |
|-----------------------|-------------------------|
| **Highest % of ARfD/ADI commodities** | **pTMRL/ threshold MRL (mg/kg)** |
| Scarole (broad-leaf) | 0.026/- |
| Potatoes | 0.01/- |
| Melons | 0.01/- |
| Apples | 0.01/- |
| Pears | 0.01/- |
| Sweet corn | 0.01/- |
| Lettuce | 0.026/- |
| Sugar beet (root) | 0.01/- |
| Peaches | 0.01/- |
| Cucumbers | 0.01/- |
| Sweet corn | 0.01/- |
| Swedes | 0.01/- |
| Sugar beet (root) | 0.01/- |
| Beetroot | 0.01/- |

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

Conclusion:

For Dimethenamid-P, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.
### Dimethenamid-P

**Status of the active substance:** Included

**Code no.:** (no code provided)

**LOQ (mg/kg bw):** Proposed LOQ: 0.04

**Toxicological end points**

| ADI (mg/kg bw per day): | 0.04 |
|-------------------------|------|
| Proposed ADI:           | 0.08 |

**Source of ADI:** EFSA

**Year of evaluation:** 2018

**ARfD (mg/kg bw):**

| ARfD (mg/kg bw): | 0.08 |
|------------------|------|
| Proposed ARfD:   |      |

**Source of ARfD:** EFSA

**Year of evaluation:** 2018

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### Chronic risk assessment – refined calculations

#### TMDI values in % of ADI

| Commodity/group of commodities | UK Toddler | DE child | NL child | IE adult | WHO Regional European diet | WHO cluster diet B | WHO cluster diet E | WHO cluster diet D | SE general population 90th percentile | PT General population | DK child | WHO Cluster diet F | UK Vegetarian | PL general population | UK Adult | LT adult | NL general | ES child | ES adult | IT kids/toddler | IT adult | FR all population | DK adult | FI adult |
|-------------------------------|-----------|----------|----------|----------|---------------------------|-------------------|--------------------|-------------------|------------------------|---------------------|----------|------------------|--------------|------------------|---------|---------|-----------|----------|---------|----------------|--------|-------------|---------|--------|
| Commodity/group of commodities | 0.6       | 0.5      | 0.4      | 0.4      | 0.3                        | 0.3               | 0.2                | 0.2               | 0.1                     | 0.1                 | 0.1      | 0.1              | 0.1          | 0.1               | 0.1      | 0.1    | 0.1        | 0.1      | 0.1     | 0.1           | 0.1    | 0.1        |
| TMDI (range) in % of ADI      | 0.1 – 1.1 | 0.0 – 1.0 | 0.0 – 1.0 | 0.0 – 1.0 | 0.0 – 1.0                  | 0.0 – 1.0         | 0.0 – 1.0          | 0.0 – 1.0          | 0.0 – 1.0               | 0.0 – 1.0           | 0.0 – 1.0 | 0.0 – 1.0       | 0.0 – 1.0    | 0.0 – 1.0          | 0.0 – 1.0 | 0.0 – 1.0| 0.0 – 1.0   | 0.0 – 1.0 | 0.0 – 1.0| 0.0 – 1.0      | 0.0 – 1.0| 0.0 – 1.0  |
| No of diets exceeding ADI     | 0         | 0        | 0        | 0        |                           |                  |                    |                   |                         |                     | 1        |                  | 1            |                  |          |        |            |          |        |                |        |            |

#### TMDI (range) in % of ADI

| Commodity/group of commodities | UK Toddler | DE child | NL child | IE adult | WHO Regional European diet | WHO cluster diet B | WHO cluster diet E | WHO cluster diet D | SE general population 90th percentile | PT General population | DK child | WHO Cluster diet F | UK Vegetarian | PL general population | UK Adult | LT adult | NL general | ES child | ES adult | IT kids/toddler | IT adult | FR all population | DK adult | FI adult |
|-------------------------------|-----------|----------|----------|----------|---------------------------|-------------------|--------------------|-------------------|------------------------|---------------------|----------|------------------|--------------|------------------|---------|---------|-----------|----------|---------|----------------|--------|-------------|---------|--------|
| Commodity/group of commodities | 0.6       | 0.5      | 0.4      | 0.4      | 0.3                        | 0.3               | 0.2                | 0.2               | 0.1                     | 0.1                 | 0.1      | 0.1              | 0.1          | 0.1               | 0.1      | 0.1    | 0.1        | 0.1      | 0.1     | 0.1           | 0.1    | 0.1        |
| TMDI (range) in % of ADI      | 0.1 – 1.1 | 0.0 – 1.0 | 0.0 – 1.0 | 0.0 – 1.0 | 0.0 – 1.0                  | 0.0 – 1.0         | 0.0 – 1.0          | 0.0 – 1.0          | 0.0 – 1.0               | 0.0 – 1.0           | 0.0 – 1.0 | 0.0 – 1.0       | 0.0 – 1.0    | 0.0 – 1.0          | 0.0 – 1.0 | 0.0 – 1.0| 0.0 – 1.0   | 0.0 – 1.0 | 0.0 – 1.0| 0.0 – 1.0      | 0.0 – 1.0| 0.0 – 1.0  |

#### No of diets exceeding ADI

| Commodity/group of commodities | UK Toddler | DE child | NL child | IE adult | WHO Regional European diet | WHO cluster diet B | WHO cluster diet E | WHO cluster diet D | SE general population 90th percentile | PT General population | DK child | WHO Cluster diet F | UK Vegetarian | PL general population | UK Adult | LT adult | NL general | ES child | ES adult | IT kids/toddler | IT adult | FR all population | DK adult | FI adult |
|-------------------------------|-----------|----------|----------|----------|---------------------------|-------------------|--------------------|-------------------|------------------------|---------------------|----------|------------------|--------------|------------------|---------|---------|-----------|----------|---------|----------------|--------|-------------|---------|--------|
| Commodity/group of commodities | 0.6       | 0.5      | 0.4      | 0.4      | 0.3                        | 0.3               | 0.2                | 0.2               | 0.1                     | 0.1                 | 0.1      | 0.1              | 0.1          | 0.1               | 0.1      | 0.1    | 0.1        | 0.1      | 0.1     | 0.1           | 0.1    | 0.1        |
| TMDI (range) in % of ADI      | 0.1 – 1.1 | 0.0 – 1.0 | 0.0 – 1.0 | 0.0 – 1.0 | 0.0 – 1.0                  | 0.0 – 1.0         | 0.0 – 1.0          | 0.0 – 1.0          | 0.0 – 1.0               | 0.0 – 1.0           | 0.0 – 1.0 | 0.0 – 1.0       | 0.0 – 1.0    | 0.0 – 1.0          | 0.0 – 1.0 | 0.0 – 1.0| 0.0 – 1.0   | 0.0 – 1.0 | 0.0 – 1.0| 0.0 – 1.0      | 0.0 – 1.0| 0.0 – 1.0  |
| No of diets exceeding ADI     | 0         | 0        | 0        | 0        |                           |                  |                    |                   |                         |                     | 1        |                  | 1            |                  |          |        |            |          |        |                |        |            |

#### Conclusion:

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

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

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

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

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

### No of commodities for which ARfD/ADI is exceeded

| Commodity | pTMRL/Threshold MRL (mg/kg) | Commodity | pTMRL/Threshold MRL (mg/kg) | Commodity | pTMRL/Threshold MRL (mg/kg) | Commodity | pTMRL/Threshold MRL (mg/kg) |
|-----------|-----------------------------|-----------|-----------------------------|-----------|-----------------------------|-----------|-----------------------------|
| Scarole (broad-leaf) | 0.026/- | Scarole (broad-leaf) | 0.026/- | Pumpkins | 0.01/- | Pumpkins | 0.01/- |
| Potatoes | 0.01/- | Melons | 0.01/- | Melons | 0.01/- | Melons | 0.01/- |
| Melons | 0.01/- | Potatoes | 0.01/- | Potatoes | 0.01/- | Potatoes | 0.01/- |
| Pears | 0.01/- | Pears | 0.01/- | Leek | 0.026/- | Leek | 0.026/- |
| Sweet corn | 0.01/- | Sweet corn | 0.01/- | Courgettes | 0.01/- | Courgettes | 0.01/- |
| Lettuce | 0.026/- | Cucumbers | 0.01/- | Sugar beet (root) | 0.01/- | Sugar beet (root) | 0.01/- |
| Sugar beet (root) | 0.01/- | Swedes | 0.01/- | Swedes | 0.01/- | Swedes | 0.01/- |
| Peaches | 0.01/- | Peaches | 0.01/- | Peaches | 0.01/- | Peaches | 0.01/- |
| Cucumbers | 0.01/- | Cucumbers | 0.01/- | Cucumbers | 0.01/- | Cucumbers | 0.01/- |
| Head cabbage | 0.01/- | Head cabbage | 0.01/- | Head cabbage | 0.01/- | Head cabbage | 0.01/- |
| Apples | 0.01/- | Apples | 0.01/- | Apples | 0.01/- | Apples | 0.01/- |
| Head cabbage | 0.026/- | Leek | 0.026/- | Leek | 0.026/- | Leek | 0.026/- |
| Swedes | 0.01/- | Pears | 0.01/- | Pears | 0.01/- | Pears | 0.01/- |
| Courgettes | 0.01/- | Pumpkins | 0.01/- | Pumpkins | 0.01/- | Pumpkins | 0.01/- |
| Witloof | 0.01/- | Courgettes | 0.01/- | Courgettes | 0.01/- | Courgettes | 0.01/- |
| Fruit salad | 0.01/- | Witloof | 0.01/- | Witloof | 0.01/- | Witloof | 0.01/- |
| Onion | 0.01/- | Onion | 0.01/- | Onion | 0.01/- | Onion | 0.01/- |

### No of critical MRLs (IESTI 1)

| Commodity | pTMRL/Threshold MRL (mg/kg) |
|-----------|-----------------------------|
| Scarole (broad-leaf) | 0.026/- |
| Potatoes | 0.01/- |
| Melons | 0.01/- |
| Pears | 0.01/- |
| Sweet corn | 0.01/- |
| Lettuce | 0.026/- |
| Sugar beet (root) | 0.01/- |
| Peaches | 0.01/- |
| Cucumbers | 0.01/- |
| Head cabbage | 0.01/- |
| Apples | 0.01/- |
| Head cabbage | 0.026/- |
| Swedes | 0.01/- |
| Courgettes | 0.01/- |
| Witloof | 0.01/- |
| Fruit salad | 0.01/- |
| Onion | 0.01/- |

### No of critical MRLs (IESTI 2)

| Commodity | pTMRL/Threshold MRL (mg/kg) |
|-----------|-----------------------------|
| Scarole (broad-leaf) | 0.026/- |
| Potatoes | 0.01/- |
| Melons | 0.01/- |
| Pears | 0.01/- |
| Sweet corn | 0.01/- |
| Lettuce | 0.026/- |
| Sugar beet (root) | 0.01/- |
| Peaches | 0.01/- |
| Cucumbers | 0.01/- |
| Head cabbage | 0.01/- |
| Apples | 0.01/- |
| Head cabbage | 0.026/- |
| Swedes | 0.01/- |
| Courgettes | 0.01/- |
| Witloof | 0.01/- |
| Fruit salad | 0.01/- |
| Onion | 0.01/- |

### Conclusion

For Dimethenamid-P, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity.
### Appendix D – Input values for the exposure calculations

#### D.1. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Spring onions              | 0.027                   | STMR * CF (2.7)       | 0.027               | HR * CF (2.7)         |
| Lettuce, escarole          | 0.026                   | STMR * CF (2.6)       | 0.026               | HR * CF (2.6)         |
| Herbs (except chives)      | 0.026                   | STMR * CF (2.6)       | 0.026               | HR * CF (2.6)         |
| Chives                     | 0.027                   | STMR * CF (2.7)       | 0.027               | HR * CF (7)           |
| Other commodities of plant origin | STMR                     | EFSA reasoned opinion on the MRL review (EFSA, 2013) | HR                     | EFSA reasoned opinion on the MRL review (EFSA, 2013) |

STMR: supervised trials median residue; CF: conversion factor for enforcement to risk assessment residue definition; HR: highest residue; MRL: maximum residue level.
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-----------------------------------------------|---------------------------------|
| **Dimethenamid-P**              | (S)-2-chloro-\(N\)-(2,4-dimethyl-3-thienyl)-\(N\)-(2-methoxy-1-methylethyl)acetamide  |
|                                 | Cc1csc(C)c1N(C(=O)CCl)[C@@H]C(C)OC              |
|                                 | JLYFTQDENSOL-VIFVPBQESA-N                        |
| **Dimethenamid**                | (RS)-2-chloro-\(N\)-(2,4-dimethyl-3-thienyl)-\(N\)-(2-methoxy-1-methylethyl)acetamide  |
|                                 | Cc1csc(C)c1N(C(C)COC)C(=O)CCl                  |
|                                 | JLYFTQDENSOL-UHFFFAOYSA-N                       |
| **M656H026 (M26)**              | (2RS)-3-\{(2,4-dimethylthiophen-3-yl)[(2S)-1-methoxypropan-2-yl]amino\}-2-oxoethyl)sulfanyl\}-2-hydroxypropanoic acid |
|                                 | Cc1csc(C)c1N[H][COC]C(=O)CSC(O)C(=O)O            |
|                                 | OKPJQTITYFCQOXSUHJPEHSA-N                       |
| **M656PH030 (M30)**             | (2RS)-3-\{(2,4-dimethylthiophen-3-yl)[(2S)-1-methoxypropan-2-yl]amino\}-2-oxoethanesulfanyl\}-2-hydroxypropanoic acid |
|                                 | Cc1csc(C)c1N[H][COC]C(=O)CS(-O)CC(O)C(=O)O       |
|                                 | NBJGYUYXYOYKS-WJGGQSTASA-N                     |

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 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(c)</sup>: ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).