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

European Food Safety Authority (EFSA),
Himdata Abdourahime, Maria Anastassiadou, Alba Brancato, Daniela Brocca,
Luis Carrasco Cabrera, Chloe De Lentdecker, Lucien Ferreira, Luna Greco, Samira Jarrah,
Dimitra Kardassi, Renata Leuschner, Alfonso Lastia, Christopher Lythgo, Paula Medina,
Ileana Miron, Tunde Molnar, Stefanie Nave, Ragnar Pedersen, Marianna Raczyk,
Hermine Reich, Silvia Ruocco, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma,
Jose Tarazona, Anne Theobald, Benedicte Vagenende, Alessia Verani and
Laura Villamar-Bouza

Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance metam. To assess the occurrence of metam residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EC) No 33/2008C as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: metam, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, carbamate, soil fumigant, nematicide, fungicide, herbicide, insecticide, methylisothiocyanate (MITC), N, N'-dimethylthiourea (DMTU), dazomet

Requestor: European Commission
Question number: EFSA-Q-2012-00450
Correspondence: pesticides.mrl@efsa.europa.eu
Acknowledgement: EFSA wishes to thank the rapporteur Member State Belgium for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Abdourahime H, Anastassiadou M, Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Nave S, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2019. Reasoned Opinion on the review of the existing maximum residue levels for metam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(1):5561, 76 pp. https://doi.org/10.2903/j.efsa.2019.5561

ISSN: 1831-4732

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

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

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Summary

Metam was approved on 1 July 2012 by Commission Implementing Regulation (EU) No 359/2012 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Belgium, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 10 April 2017 and finalised on 12 June 2017. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 2 May 2018.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, EFSA prepared in August 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 20 September 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of metam was investigated for soil injection or drip-irrigation in tree crop categories (fruits, roots and leafy crops). As these studies were performed with pre-planting applications on soil, they were also deemed applicable to address the metabolism in rotational crops. Based on these studies and also considering the available data on the magnitude of residues in plant commodities, two separate residue definitions were proposed. The main one, methylisothiocyanate (MITC), is valid for enforcement and risk assessment purposes. Analytical methods for enforcement of MITC in the four main plant matrices are available. The second definition was proposed to consider the potential uptake of impurity N,N-dimethylthiourea (DMTU) in plant commodities. It is relevant for risk assessment (with specific toxicological reference values), and optionally for enforcement purpose, noting that methods for enforcement might be available for high water content and high acid content commodities. The proposed residue definitions are applicable to all commodities subject to soil pre-planting applications, hereby covering all the Good Agricultural Practices (GAPs) reported in this review.

The nature of residues of MITC and DMTU in processed commodities was not addressed. This was considered as a concern for those commodities where residue levels above 0.1 mg/kg were observed in raw agricultural commodities.

The available data on the magnitude of residues in plant commodities allowed EFSA to derive (tentative) MRL proposals as well as risk assessment values for both MITC and DMTU in apples, pears, cherries, plums, table and wine grapes, strawberries, cane fruits, cranberries, currants, gooseberries, carrots, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, onions, tomatoes, aubergines, sweet peppers (only for MITC), cucurbits with edible peel, lettuces and similar, spinach and similar, fresh herbs, and turnip tops. For the other commodities under evaluation, no MRL proposals could be derived due to the absence of data or to very limited datasets. It is noted that for many crops, MRL proposals were proposed on a tentative basis based on uncomplete datasets and/or due to the data gaps identified on the nature of residues in processed commodities. Tentative MRLs were also derived for turnip tops in view of the future need to set MRLs in feed items.

The exposure of livestock to MITC and DMTU were separately assessed in two different dietary burden (DB) calculations. These calculations took into consideration residue levels in plant commodities which result from the uses of metam and dazomet (another pesticide active substance precursor of MITC). While the calculated DBs were found to be below the trigger value of 0.1 mg/kg dry matter (DM) for all groups of livestock for MITC, it was highlighted that these results were underestimated as they could not consider the input of many potential significant contributors to the DB due to the absence of data for these commodities. For DMTU, the calculated DBs were found to be above the trigger value of 0.1 mg/kg dry matter (DM) for all groups of livestock. However, in the absence of finalised calculation of the DB and of any studies on nature and magnitude of residues in livestock commodities, MRL and risk assessment values were not derived for commodities of animal origin.
The consumer exposures to MITC and DMTU were separately assessed in two different calculations, both using revision 2 of EFSA PRIMo. For both compounds, chronic and acute exposure were assessed considering the authorised uses reported in the framework of this review as well as in the review of dazomet. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. For MITC, the highest chronic exposure was calculated for British toddlers, representing 15.2% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for cucumbers (metam use), representing 66.3% of the acute reference dose (ARfD).

For DMTU, the indicative calculated exposure also remains under the toxicological reference values of this compound (28% ADI and 14.6% of the ARfD). However, it is highlighted that these results are potentially underestimated as additional intake possibly induced by all commodities for which MRLs could not be derived for DMTU (all dazomet uses as well certain GAPs reported in this review and animal commodities) could not be taken into account due to lack of data.
Table of contents

Abstract .................................................................................................................................................... 1
Summary .................................................................................................................................................. 3
Background .............................................................................................................................................. 6
Terms of Reference ................................................................................................................................... 7
The active substance and its use pattern .................................................................................................... 7
Assessment ............................................................................................................................................... 8
1. Residues in plants .................................................................................................................................... 8
1.1. Nature of residues and methods of analysis in plants .......................................................................... 8
1.1.1. Nature of residues in primary crops ................................................................................................... 8
1.1.2. Nature of residues in rotational crops ................................................................................................ 8
1.1.3. Nature of residues in processed commodities ..................................................................................... 9
1.1.4. Methods of analysis in plants ............................................................................................................. 9
1.1.5. Stability of residues in plants ................................................................................................................ 9
1.1.6. Proposed residue definitions ............................................................................................................. 9
1.2. Magnitude of residues in plants ......................................................................................................... 10
1.2.1. Magnitude of residues in primary crops .............................................................................................. 10
1.2.2. Magnitude of residues in rotational crops ........................................................................................... 12
1.2.3. Magnitude of residues in processed commodities ................................................................................ 12
1.2.4. Proposed MRLs ................................................................................................................................1 2
2. Residues in livestock ............................................................................................................................ 12
2.1. Methylisothiocyanate ........................................................................................................................ 13
2.2. N,N'-dimethylthiourea ....................................................................................................................... 13
3. Consumer risk assessment ................................................................................................................ 13
3.1. Consumer risk assessment for MITC .................................................................................................. 14
3.2. Consumer risk assessment for DMTU ................................................................................................. 14
Conclusions ............................................................................................................................................... 15
Recommendations ..................................................................................................................................... 15
References ................................................................................................................................................ 20
Abbreviations ............................................................................................................................................ 23
Appendix A – Summary of authorised uses considered for the review of MRLs ........................................ 23
Appendix B – List of end points .............................................................................................................. 48
Appendix C – Pesticide Residue Intake Model (PRIMo) ........................................................................... 64
Appendix D – Input values for the exposure calculations ......................................................................... 68
Appendix E – Decision tree for deriving MRL recommendations ............................................................. 74
Appendix F – Used compound codes ..................................................................................................... 76
Background

Regulation (EC) No 396/20051 (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC2 a reasoned opinion on the review of the existing MRLs for that active substance. As metam was approved in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, on 1 July 2012 by Commission Implementing Regulation (EU) No 359/20123, amending the Annex to Commission Implementing Regulation (EU) No 540/20114, as amended by Commission Implementing Regulation (EU) No 541/20115, EFSA initiated the review of all existing MRLs for that active substance.

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

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

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

Belgium, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for metam and to prepare a supporting evaluation report (Belgium, 2013). The PROFile and the supporting evaluation report were submitted to EFSA on 28 June 2013 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 10 April 2017 and finalised on 12 June 2017. Additional evaluation reports were submitted by Belgium, France, Greece, Hungary, Italy, the Netherlands, Spain, Portugal and the European Union Reference Laboratories for Pesticide Residues (Belgium, 2017; EURL, 2017; France, 2017; Greece, 2017a,b; Hungary, 2017; Italy, 2017; Netherlands, 2017; Portugal, 2017; Spain, 2017) and, after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 2 May 2018. No further clarifications were sought from Member States.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the Member States, EFSA prepared in August 2018 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 20 September 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation reports submitted by the RMS (Belgium, 2013, 2017) and the evaluation reports submitted by Member States France, Greece, Hungary, Italy, the Netherlands, Spain, Portugal and the

---

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

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

3 Commission Implementing Regulation (EU) No 359/2012 of 25 April 2012 approving the active substance metam, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 114, 26.4.2012, p. 1–7.

4 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.

5 Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.
European Union Reference Laboratories for Pesticide Residues (EURL, 2017; France, 2017; Greece, 2017a,b; Hungary, 2017; Italy, 2017; Netherlands, 2017; Portugal, 2017; Spain, 2017) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2018a) and the Member States consultation report (EFSA, 2018b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheets of the different PRIMo is presented in Appendix C.

Terms of Reference

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

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

The active substance and its use pattern

Metam is the ISO common name for methyldithiocarbamic acid (IUPAC). Metam is a MITC generator and this is the moiety that has the biological activity. The active substance dazomet is also a MITC generator. Therefore, the MRL review of dazomet is also carried out in parallel (EFSA, 2019).

MITC interferes at the level of enzymatic activity. It disturbs the absorption of oxygen during the process of cellular respiration by chelating enzymes having a metal radical. The efficacy against nematodes is probably due to the ability of MITC to deactivate the sulfuric groups of essential enzymes.

Metam belongs to the group of carbamate compounds which are used as soil fumigants.

Metam was evaluated in the framework of Directive 91/414/EEC with Belgium designated as RMS. The representative uses supported for the peer review process were are as a nematicide, fungicide, herbicide and insecticide by soil fumigation prior to the planting of carrot, lamb’s lettuce, cucumber, aubergine, pepper, potato, strawberry, tomato and grapes. Following the peer review, which was carried out by EFSA, a decision on approval of the active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council was published by means of Commission Implementing Regulation (EU) No 359/2012, which entered into force on 1 July 2012. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, metam is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as nematicide, fungicide, herbicide and insecticide only.

The EU MRLs for metam (as MITC resulting from the use of dazomet and metam) are established in Annex IIIA of Regulation (EC) No 396/2005 and CXLs for metam (as metam or MITC) are not available. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

| Procedure               | Legal implementation | Remarks                                                                 |
|-------------------------|----------------------|-------------------------------------------------------------------------|
| MRL application         | Regulation (EU) No 2016/1\(^{(a)}\) | Reasoned opinion on the modification of the existing maximum residue levels (MRLs) for dazomet in several vegetables (EFSA, 2015) |

MRL: maximum residue level.

\(^{(a)}\) Commission Regulation (EU) 2016/1 of 3 December 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products. OJ L 2, 5.1.2016, p. 1–62.

\(^{6}\) MITC: methylisothiocyanate.
For the purpose of this MRL review, the critical uses of metam currently authorised within the EU, have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAPs for metam are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment
EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Belgium, 2013), the draft assessment report (DAR) and the final addendum to the draft assessment report prepared under Council Directive 91/414/EEC (Belgium, 2008, 2010), the conclusion on the peer review of the pesticide risk assessment of the active substances metam (EFSA, 2011) and dazomet (EFSA, 2010), the previous reasoned opinion on metam (EFSA, 2015), as well as the evaluation reports submitted during the completeness check (Belgium, 2017; EURL, 2017; France, 2017; Greece, 2017a,b; Hungary, 2017; Italy, 2017; Netherlands, 2017; Portugal, 2017; Spain, 2017). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011\(^7\) and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a\(^-\)g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism was investigated during the EU pesticides peer review for soil injection or drip-irrigation of 4 g metam/m\(^2\) (equivalent to 40 g a.s./m\(^2\))\(^8\) in three crop categories (fruits, roots and leafy crops) (Belgium, 2010 assessed in EFSA, 2011). All metabolism studies were conducted using \(N\)-methyl-\(^14\)C-(thiocarbonyl)-metam.

In these studies, neither parent compound nor its metabolites methylureas/methylthioureas or MITC (which is the biologically active compound) was present in detectable amounts. The same was observed in the different samples (tomatoes, turnips/radish roots, turnip/radish tops and different extracts of Chinese cabbage).

Some further analysis performed in turnip roots (using sequential hydrolysis of the post extraction solids with enzymes selective for cellulose, starch, protein and pectin and finally lignin extraction) showed distribution of the radioactivity over a variety of natural products such as cellulose, hemicellulose, starch, proteins, pectin and lignin. The radioactive residues of metam were mainly characterised as natural or polar products and the identification of glucose in the extractable residues suggested a complete incorporation of this compound into the carbon pool in turnip crops.

During the peer review, the experts discussed the fact that some of these studies were underdosed. The peer review meeting concluded that the plant metabolism studies were acceptable since no other significant metabolites (which might be up-taken by plants) were identified in the fate and behaviour section (EFSA, 2011). Therefore, the available data were deemed sufficient to depict the residue behaviour in primary crops.

1.1.2. Nature of residues in rotational crops

Some of the crops under consideration can be grown in rotation. However, the field DT\(_{50}\) reported in the soil degradation studies for metam and its metabolite methylisothiocyanate (MITC) were less

---

\(^7\) 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.

\(^8\) The soil was filled into a plastic container and filled with metam at the application rate of 4 g a.s./m\(^2\), which was then immediately sealed air tight. In these conditions, it was demonstrated that the starting concentration in soil in the model system was equivalent to a concentration recovered in an open system model determined 7 days after the critical dose rate of application of 40 g a.s./m\(^2\) (Belgium, 2010).
than 100 days (EFSA, 2011). Thus, studies investigating the nature and magnitude of residues in rotational crops are not required.

Furthermore, considering that the studies on primary crops (fruits, roots and leafy vegetables) were performed with preplanting applications on soil with 10–41 days between treatment and planting, these studies are deemed sufficient to also elucidate the nature of residue in rotational crops. As a consequence, the metabolism in rotational crops is considered to follow the same pathway as in primary crops.

### 1.1.3. Nature of residues in processed commodities

Studies on the nature of residues in processed commodities are not available. Considering that residues levels of MITC and N,N'-dimethylthiourea (DMTU) were found to exceed 0.1 mg/kg in several plant commodities (tomatoes, cucurbits with edible peel for MITC; root and leafy crops for DMTU; see Appendix B.1.2.1), studies investigating the behaviour of MITC and DMTU through standard hydrolysis conditions should be required (data gap).

### 1.1.4. Methods of analysis in plants

Methylisothiocyanate, the biologically active compound released by metam, can be enforced in high water and high acid content commodities by the gas chromatography with mass spectrometry (GC–MS) method (BASF method 234/2) with an limit of quantification (LOQ) of 0.01 mg/kg. This method has been fully demonstrated validated in the framework of the peer review of dazomet (EFSA, 2010) and metam (EFSA, 2011). This is sufficient to cover all commodities currently assessed under this review.

It is noted that the EURLs have recently generated validation data for the QuEChERS method using gas chromatography with tandem mass spectrometry (GC–MS/MS) and analysing MITC in commodities of plant origin (high water, high acid, high oil content and dry commodities). According to EURLs, MITC can be enforced in the four main plant matrices (see EFSA, 2018b) with a LOQ of 0.01 mg/kg.

It is noted that analytical methods for the enforcement of DMTU in high water and high acid content matrices with an LOQ of 0.01 mg/kg were made available in the framework of an MRL application which is currently under clock stop.

Since analytical methods are missing for matrices which are difficult to analyse such as herbal infusions from roots, a data gap is set for this crop.

### 1.1.5. Stability of residues in plants

Studies investigating the stability of residues during sample storage were not reported in this review.

It is noted that the storage stability of the metabolite MITC was investigated in the EU pesticide peer review of dazomet. These studies demonstrated the storage stability of MITC under deep frozen conditions for a period of 3 months in high water content commodities and high acid content commodities (EFSA, 2010). The available results indicate that MITC tends to degrade after 3 months of storage.

Regarding the impurity DMTU, no storage stability studies are available.

### 1.1.6. Proposed residue definitions

The available metabolism studies suggested a complete degradation of metam into several compounds, none of them being identified as an appropriate marker for the residues.

It should be noted that metam is already almost completely degraded in soil, forming the biologically active compound MITC. Considering that this compound is expected to be predominant in soil, it is the most likely to be up-taken by plants. MITC was not found in the metabolism studies. However, the available residue trials indicate this compound to be retrieved in several plant commodities (see Section 1.2.1). Furthermore, MITC is more toxic than the parent compound (EFSA, 2011). Based on this information, it is concluded that MITC can be a marker for enforcement purpose and is also a relevant compound for risk assessment. Therefore, the residue for monitoring and risk assessment is defined as MITC, as previously concluded in the framework of the peer review (EFSA, 2011). Analytical methods for enforcement of MITC in the four main plant matrices are available.

The impurity DMTU was not found in the available metabolism studies. However, several trials reported in this review demonstrated the possible occurrence of DMTU at quantifiable levels in different plant commodities. The source of the significant occurrence of DMTU observed in residue trials performed with metam is not fully elucidated. It can be due the original content of the relevant
impurity DMTU in the technical material ‘metam’, but it is not excluded that DMTU may also be released from the breakdown of the parent compound in soil. One hypothesis is that DMTU might be a soil degradation product formed by the reaction of MITC with methylamine. The toxicity of DMTU was discussed during the peer review of metam and it was concluded that the toxicological end points of metam were applicable to DMTU (EFSA, 2011). Therefore, it is proposed to consider DMTU in a separate residue definition for risk assessment. Depending on the interest of risk managers to enforce this compound in routine analysis, this residue definition could also be proposed for enforcement purpose (optional). It is noted that methods for enforcement of DMTU in high water content and high acid content commodities might be available.

The proposed residue definitions apply to all commodities subject to soil pre-planting applications. All GAPs under assessment are covered by the proposed residue definitions.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of metam residues (both MITC and DMTU) resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Belgium, 2013), including residue trials evaluated in the framework of the peer review (EFSA, 2011) and additional data submitted during the completeness check (Belgium, 2017; EURL, 2017; France, 2017; Greece, 2017a, b; Hungary, 2017; Italy, 2017; Netherlands, 2017; Portugal, 2017; Spain, 2017).

In almost all trials considered in this review, separate analyses were carried out for MITC and DMTU. Since MITC and DMTU are both relevant for risk assessment (and DMTU optionally for enforcement), the residue levels related to each compound were reported. The corresponding results were reported in two separate tables (Appendix B.1.2.1 for MITC and Appendix B.1.2.2 for DMTU).

For most of the available trials, samples were analysed within one month after harvest. Therefore, although the storage stability of MITC was only demonstrated for a period of 3 months (see Section 1.1.5), most of the reported trials are deemed acceptable for the purpose of MRL for MITC.

It is noted that significant degradation of MITC residues is expected after a storage period longer than 3 months and that no storage stability studies were available for DMTU (see also Section 1.1.5). Therefore, all those trials where samples were stored for more than 3 months were not considered to derive MRL and risk assessment values for MITC and DMTU. Similarly, the trials with samples stored for more than one month were not considered to derive MRL and risk assessment values for DMTU. Trials where DMTU was stored for less than one month were considered to derive MRL and risk assessment values; however and since this compound is volatile, the assumptions regarding the acceptability of residue trials imply an uncertainty, which should be addressed in future storage stability studies realised for this compound. For information purpose, the concerned trials are reported between brackets in Appendices B.1.2.1 and B.1.2.2. If authorisation holders want these trials to be considered in the future, additional studies investigating the storage stability of DMTU during storage should be generated in the future.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Valid/reliable residue trials are not available to support the authorisations on potatoes, sweet potatoes, yams, swedes/rutabagas, turnips, herbal infusions from roots, shallots, okra/lady’s fingers, melons, pumpkins, watermelons, watercresses, witloof/Belgian endives, sugar and fodder beet (roots and tops). Therefore, for both MITC and DMTU, MRL or risk assessment values for these crops could not be derived by EFSA and the following data gaps were identified:

- Potatoes, sweet potatoes, yams: it is noted that trials on potatoes supporting the northern outdoor and the indoor GAPs are available. However, these trials are not deemed valid considering the issues identified on storage stability (see above). Therefore, eight trials compliant with the northern outdoor GAP, 8 trials compliant with the southern outdoor GAP and eight trials compliant with the indoor GAP are required. In the view of extrapolating these trials to all sweet potatoes and yams, these trials should all be performed using potatoes.

---

9 DMTU can reach a maximum 23 g/kg on dry weight basis in metam sodium and maximum 6 g/Kg on dry weight basis in metam potassium (Commission Implementing Regulation (EU) 359/2012).

10 The following end points were derived for metam: Acceptable daily intake (ADI) of 0.001 mg/kg body weight (bw) per day and acute reference dose (ARfD) of 0.1 mg/kg bw (EFSA, 2011).
Swedes/rutabagas, turnips: eight trials compliant with the northern outdoor GAP and eight trials compliant with the indoor GAP are required.

Herbal infusions from roots: eight trials compliant with the northern outdoor GAP.

Shallots: it is noted that four trials performed on onion and supporting the northern outdoor GAP are available. However, these trials are not deemed valid considering the issues identified on storage stability (see above). Thus, a complete data set supporting the northern outdoor GAP on shallot is required (this data gap will be covered by the data gap identified for onions northern Europe (NEU); see below).

Okras/lady's fingers: four trials compliant with the southern outdoor GAP and four trials compliant with the indoor GAP are required.

Melons, pumpkins, watermelons: eight trials on melons compliant with the southern outdoor GAP and eight trials on melons compliant with the indoor GAP are required.

Watercresses: it is noted that four trials performed on lettuces and supporting the northern outdoor GAP are available. However, these trials are not deemed valid considering the issues identified on storage stability (see above). Thus, a complete data set supporting the northern outdoor GAP on watercress is required (this data gap will be covered by the data gap identified for lettuces NEU; see below).

Witloofs/Belgian endives: four trials compliant with the northern outdoor GAP are required.

Sugar beet and fodder beet (roots and tops): eight trials performed on sugar beet and compliant with the northern outdoor GAP are required.

For sweet peppers, it is noted that the available residue trials (four indoor trials) are valid for MITC but not with regard to DMTU (storage length more than one month). For this crop in particular, tentative MRL and risk assessment values could be derived for MITC while this is not the case for DMTU; the following data gaps were identified:

- Sweet peppers (DMTU): eight trials compliant with the southern outdoor GAP and eight trials compliant with the indoor GAP are required.
- Sweet peppers (MITC): eight trials compliant with the southern outdoor GAP and eight additional trials compliant with the indoor GAP are required.

For certain crops, the number of residue trials reported is not compliant with the data requirements. For both MITC and DMTU, only tentative MRLs and risk assessment values could be derived by EFSA and the following data gaps were identified:

- Strawberries: tentative MRLs and risk assessment values are derived from the indoor GAP. However, two additional trials compliant with the indoor GAP are required. Furthermore, eight trials compliant with the northern outdoor GAP and five additional trials compliant with the southern outdoor GAP are also required.
- Beetroot, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, and salsifies: it is noted that trials supporting the northern outdoor and the indoor GAPs are available. However, trials supporting the northern outdoor GAP are not deemed valid considering the issues identified on storage stability (see above). Therefore, eight trials compliant with the northern outdoor GAP, four trials compliant with the southern outdoor GAP and eight trials compliant with the indoor GAP are required. In the view of extrapolating these trials to all above mentioned crops, these trials should all be performed using carrots.
- Tomatoes and aubergines: tentative MRLs and risk assessment values are derived based on southern trials overdosed compared with GAP. Therefore, eight trials compliant with the southern outdoor GAP are required. Furthermore, four additional trials compliant with the indoor GAP are also required.
- Cucumbers, gherkins, courgettes: although tentative MRLs and risk assessment values can be derived from the indoor GAP, eight trials on cucumbers/courgettes compliant with the northern outdoor GAP and eight trials on cucumbers/courgettes compliant with the southern outdoor GAP are still required.
- Turnip tops: although tentative MRLs and risk assessment values can be derived from the northern outdoor GAP, four trials compliant with the indoor GAP are still required.

For all other crops, available residue trials are sufficient to derive MRL and risk assessment values for both MITC and DMTU, taking note of the following considerations:
Orchards (apples, pears, cherries and plums), grapes, blackberries, raspberries (red and yellow), blueberries, cranberries, currants (black, red and white), and gooseberries (green, red and yellow: residue trials are not available to support GAPs on these crops. However, considering that application is performed at an early growing stage of the trees (i.e. > 365 days before harvest), significant residues in final harvested fruits are not expected. Therefore, MRL and risk assessment values can be derived at the LOQ (0.01 mg/kg) and further residue trials are not required.

Onions: MRLs and risk assessment values can be derived from the southern outdoor GAP. However, it is noted that trials supporting the northern outdoor GAP are not deemed valid considering the issues identified on storage stability (see above). Thus, eight trials compliant with the northern outdoor GAP are also required (these trials should also cover the above data gap identified for shallots).

Lamb’s lettuce, lettuces, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cresses, Roman rocket/rucola, red mustards, baby leaf crops (including brassica species), spinach, purslanes, chards/beet leaves, and fresh herbs: MRL and risk assessment values can be derived from the trials on lettuce with southern outdoor GAP, noting that trials performed on open-leaves varieties are not required for the GAP under assessment (soil application before planting/sowing). In addition, eight trials compliant with the northern outdoor GAP, and four additional trials compliant with the indoor GAP are required.

It is noted that all the trials required in this section should provide analysis for MITC and DMTU (separately), in accordance with the two residue definitions derived under this review (see Section 1.1.6). Furthermore, when generating new residue trials, it is recommended to perform the residue analysis of both compounds as soon as possible after harvest, avoiding unacceptable possible degradation of the residues.

1.2.2. Magnitude of residues in rotational crops
Studies investigating the magnitude of residues in rotational crops are not available and are not required (see Section 1.1.2).

1.2.3. Magnitude of residues in processed commodities
Studies investigating the magnitude of residues in processed commodities are not available and are not required.

If robust processing factors were to be required by risk managers, in particular for enforcement purposes, processing studies would be needed.

1.2.4. Proposed MRLs
The available data allowed EFSA to derive (tentative) MRL proposals as well as risk assessment values for both MITC (main residue definition for enforcement) and DMTU (optional residue definition of enforcement) in apples, pears, cherries, plums, table and wine grapes, strawberries, cane fruits, cranberries, currants, gooseberries, carrots, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley and radishes, onions, tomatoes, aubergines, sweet peppers (only for MITC), cucurbits with edible peel, lettuces and similar, spinach and similar, fresh herbs, and turnip tops. For the other commodities under evaluation, no MRL proposals could be derived due to the absence of data or to very limited datasets. MRLs for MITC that could be derived from the metam uses are reported in Appendix B.4 (indicative only). Considering however that the final MRL recommendations should also consider MITC residues which can be released from MITC precursor another active substance (dazomet), the MRL reported in Appendix B.4 should only be considered for indicative purpose.

It is noted that for many crops, MRL proposals are derived on a tentative basis based on uncomplete datasets and/or due to the data gaps identified on the nature of residues in processed commodities. Tentative MRLs were also derived for turnip tops in view of the future need to set MRLs in feed items.

2. Residues in livestock
As two different residue definitions for risk assessment in plant commodities were derived in this review (see Section 1.1.6), EFSA performed two separate dietary burden (DB) calculations: one for the main residue definition MITC and another one for the second residue definition DMTU.
2.1. Methylisothiocyanate

The metabolite MITC, corresponding to the main residue definition for risk assessment in plant commodities, is released by metam as well as by dazomet. The MRL review of dazomet is carried out in parallel (EFSA, 2019). Both active substances are authorised for use on several crops that might be fed to livestock and, in order to carry out a comprehensive DB calculation for this compound, MITC residues arising from both metam and dazomet should be taken into account.

Livestock DBs were calculated for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. For each relevant feed commodity, the input value for MITC is based on the highest residue level observed following the use of either metam or dazomet, assuming that the two active substances are not used together on the same crop. The input values for all relevant commodities are summarised in Appendix D.1.

The calculated DBs were found to be below the trigger value of 0.1 mg/kg dry matter (DM) for all groups of livestock. Therefore, MRL and risk assessment values in livestock commodities are not needed and were not derived. It is noted that studies investigating the nature and magnitude of residues in livestock are not available.

Nevertheless, the above result does not take into account the potential intake from many feed commodities for which risk assessment values could not be derived. In particular, this is the case for many root crops (including important contributors such as potatoes, sugar beet and fodder beet) and sugar beet tops from metam uses (see Section 1.2) and for head cabbage and turnips tops from dazomet uses (see EFSA, 2019). The calculated animal intake of MITC residues is therefore underestimated as it only represents a scenario where the critical GAPs authorised on the potential contributors listed above would be withdrawn. It is therefore recommended to MS to take this information into account and to reconsider or withdraw these uses.

2.2. \(N, N'\)-dimethylthiourea

The impurity DMTU, corresponding to the second residue definition for risk assessment in plant commodities, was found to be present in several commodities including feed items (see Section 1.2), following the use of metam as a pesticide active substance. Therefore, livestock DBs were also calculated for this compound.

It is highlighted that residue data for DMTU were not available to support the GAPs of metam on many root crops (including important contributors such as potatoes, sugar beet and fodder beet) as well as for sugar beet tops. In addition, it is noted that DMTU may also be found in feed items following the use of dazomet as a pesticide active substance. However, as there is no residue data available for DMTU in the reasoned opinion on the MRL review of dazomet (EFSA, 2019), this could not be considered in a comprehensive calculation. Consequently, only indicative DB calculations could be carried out for DMTU, solely considering the data on DMTU available in the present opinion.

The calculated DBs were found to be above the trigger value of 0.1 mg/kg dry matter (DM) for all groups of livestock. Therefore, further investigation on the nature and magnitude of residues in livestock commodities should be necessary. However, in the absence of studies investigating the nature and magnitude of residues in livestock, it was not possible to address this point. Consequently, MRLs and risk assessment values for DMTU in livestock commodities could not be derived under this review.

Furthermore, it should be noted that the calculation of the DB is underestimated as it only represents a scenario where the critical GAPs of dazomet on feed commodities (potatoes and other roots crops, head cabbages and kales) and the ones of metam not supported by data (in particular potatoes, sugar beet and fodder beet) were not considered. It is therefore recommended to MS to take this information into account and to reconsider or withdraw their uses on commodities that can be fed to livestock.

3. Consumer risk assessment

As two different residue definitions for risk assessment in plant commodities were derived in this review (see Section 1.1.6), EFSA performed two separate consumer exposure calculations: one for the main residue definition MITC) and another one for the second residue definition DMTU). It is noted that different toxicological reference values were derived for these compounds.
3.1. Consumer risk assessment for MITC

The metabolite MITC, corresponding to the main residue definition for risk assessment in plant commodities, is released by metam as well as by dazomet. The MRL review of dazomet is carried out in parallel (EFSA, 2019). Hence, in order to carry out a comprehensive consumer exposure calculation for this compound, MITC residues arising from both metam and dazomet should be taken into account.

Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. For those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review or the one of dazomet (EFSA, 2019), input values were derived according to the internationally agreed methodologies (FAO, 2009). For each plant commodity, the input values for MITC is based on the highest residue level observed following the use of either metam or dazomet, assuming that the two active substances are not used together on the same crop. For a few commodities assessed in the present reasoned opinion as well as in the reasoned opinion of dazomet, data were not available to derive MRL and risk assessment values for MITC. For those commodities EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D.2.

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007).

The calculated exposures were compared with the toxicological reference values for MITC, derived by EFSA (2010, 2011). The highest chronic exposure was calculated for British toddlers, representing 15.2% of the ADI, and the highest acute exposure was calculated for cucumbers (metam use), representing 66.3% of the ARfD. These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values of MITC, noting that major uncertainties remain due to the data gaps identified in the previous sections.

3.2. Consumer risk assessment for DMTU

The impurity DMTU, corresponding to the second residue definition for risk assessment in plant commodities, was found to be present in several plant commodities following the use of metam as a pesticide active substance. Therefore, a consumer exposure calculation was also calculated for this compound.

It is highlighted that the impurity DMTU may also be present in food commodities following the use of dazomet. However, as no data for DMTU were available from the MRL review of dazomet (EFSA, 2019), this could not be considered in a comprehensive calculation. Consequently, only indicative consumer exposure calculations could be carried out for DMTU, solely considering the data on DMTU available in the present opinion. The impact of DMTU levels in livestock could not be considered in the assessment due to the lack of data.

Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. For those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For a few commodities assessed in the present reasoned opinion, data were not available to derive MRL and risk assessment values for DMTU (see Section 1.2.1). These commodities could not be considered in the risk assessment as there are no MRLs currently defined for this DMTU. All input values included in the exposure calculations are summarised in Appendix D.3.

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007).

The calculated exposures were compared with the toxicological reference values for DMTU, derived by EFSA (2011). The highest chronic exposure was calculated for French infants, representing 28% of the ADI, and the highest acute exposure was calculated for carrots (metam use), representing 14.6% of the ARfD. It is highlighted that these results are underestimated as additional intake possibly induced by dazomet uses as well as from commodities for which MRLs could not be derived in this review was not taken into account. An overall consumer exposure to DMTU could only be calculated if further data on DMTU in plant and animal commodities would be available. In the meanwhile, no conclusion can be drawn regarding the consumer exposure to DMTU. Regarding the uses of metam on

---

11 The toxicological end points derived for metam were concluded to be applicable to DMTU: ADI of 0.001 mg/kg bw per day and ARfD of 0.1 mg/kg bw (EFSA, 2011).
crops where no data are available for DMTU (see Section 1.2.1) as well as on crops that can be fed to livestock (see Section 2.2), it is recommended to Member States to take this uncertainty into account and to eventually reconsider or withdraw these uses accordingly.

Conclusions

The metabolism of metam was investigated for soil injection or drip-irrigation in tree crop categories (fruits, roots and leafy crops). As these studies were performed with preplanting applications on soil, they were also deemed applicable to address the metabolism in rotational crops. Based on these studies and also considering the available data on the magnitude of residues in plant commodities, two separate residue definitions were proposed. The main one, MITC, is valid for enforcement and risk assessment purposes. Analytical methods for enforcement of MITC in the four main plant matrices are available. The second definition was proposed to consider the potential uptake of impurity DMTU in plant commodities. It is relevant for risk assessment (with specific toxicological reference values), and optionally for enforcement purpose, noting that methods for enforcement might be available for high water content and high acid content commodities. The proposed residue definitions are applicable to all commodities subject to soil preplanting applications, hereby covering all the GAPs reported in this review.

The nature of residues of MITC and DMTU in processed commodities was not addressed. This was considered as a concern for those commodities where residue levels above 0.1 mg/kg were observed in raw agricultural commodities.

The available data on the magnitude of residues in plant commodities allowed EFSA to derive (tentative) MRL proposals as well as risk assessment values for both MITC and DMTU in apples, pears, cherries, plums, table and wine grapes, strawberries, cane fruits, cranberries, gooseberries, carrots, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, onions, tomatoes, aubergines, sweet peppers (only for MITC), cucurbits with edible peel, lettuces and similar, spinach and similar, fresh herbs, and turnip tops. For the other commodities under evaluation, no MRL proposals could be derived due to the absence of data or to very limited datasets. It is noted that for many crops, MRL proposals were proposed on a tentative basis based on uncomplete datasets and/or due to the data gaps identified on the nature of residues in processed commodities. Tentative MRLs were also derived for turnip tops in view of the future need to set MRLs in feed items.

The consumer exposures to MITC and DMTU were separately assessed in two different calculations, both using revision 2 of EFSA PRIMo. For both compounds, chronic and acute exposure were assessed considering the authorised uses reported in the framework of this review as well as in the review of dazomet. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. For MITC, the highest chronic exposure was calculated for cucumbers (metam use), representing 15.2% of the ADI, and the highest acute exposure was calculated for cucumbers (metam use), representing 66.3% of the ARfD.

For DMTU, the indicative calculated exposure also remains under the toxicological reference values of this compound (28% ADI and 14.6% of the ARfD). However, it is highlighted that these results are potentially underestimated as additional intake possibly induced by all commodities for which MRLs could not be derived for DMTU (all dazomet uses as well certain GAPs reported in this review and animal commodities) could not be taken into account due to lack of data.

Recommendations

MRL recommendations were derived for the main residue definition for enforcement: methylisothiocyanate (MITC). These MRL proposals were derived considering the GAPs authorised on
metam and dazomet as these active substances are both sources of MITC residues in plant commodities. For each plant commodity, the MRL proposal is based on the apparent most critical GAP between metam and dazomet, assuming that the two active substances are not used together on the same crop. The outcome of these comparisons is reported in the summary table below. For each commodity, it was explicitly reported from which substance the MRL proposal was derived.

All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, some tentative MRLs and existing EU MRLs reported for MITC need to be confirmed by the following data:

- Additional residue trials supporting GAPs of metam on the following crops: on strawberries, potatoes, sweet potatoes, yams, beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes, turnips, shallots, tomatoes, peppers, aubergines, Okra/lady’s fingers, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, lamb’s lettuces, lettuces, escaroles/broad-leaved endives, cresses, land cresses, roman rocket/rucola, red mustards, baby leaf crops (including brassica species), spinaches, purslanes, chards/beet leaves, watercresses, wiltoofs/Belgian endives, herbal infusions from roots and sugar beet roots.
- Study investigating the nature of residues in processed commodities (standard hydrolysis conditions) for MITC (data gap relevant for the MRL on tomatoes, aubergines, cucumbers, gherkins and courgettes, derived from metam uses).
- Independent laboratory validation (ILV) for the analytical methods for enforcement in high oil content and dry commodities (data gap relevant for the MRL on tree nuts, derived from dazomet uses).
- Fully validated analytical methods for the determination of MITC in herbal infusion from roots (data gap relevant for metam) and hops (data gap relevant for dazomet) are required.
- Additional residue trials supporting the GAPs of dazomet on potatoes, beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes, turnips, tomatoes, peppers, aubergines, Okra/lady’s fingers, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, broccoli, cauliflowers, head cabbages, Chinese cabbages, kales, lamb’s lettuces, lettuces, escaroles/broad-leaved endives, cresses, land cresses, roman rocket/rucola, red mustards, baby leaf crops (including brassica species), spinaches, purslanes, chards/beet leaves, beans (with pods), beans (without pods), peas (with pods), peas (without pods), asparagus, leeks and hops.

It is also highlighted that the MRLs derived for onions and fresh herbs result from specific GAPs authorised for metam, whereas other GAPs reported for dazomet and metam were not fully supported by data. EFSA identified the following data gap which is not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Residue trials supporting GAPs of dazomet on onions;
- Residue trials supporting GAPs of metam on onions (NEU) and fresh herbs (NEU and indoor).

When generating the residue trials, it is recommended to perform the residue analysis of both compounds as soon as possible after harvest, avoiding unacceptable possible degradation of the residues.

If the above-reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level. It should also be noted that data are missing for numerous commodities that can be fed to livestock. Considering the only GAPs supported by data, there was no need to derive MRLs for MITC in livestock commodities. However, the calculated dietary burdens for MITC do not reflect the situation arising from all authorised uses and is probably underestimated. Member States are therefore recommended to pay particular attention to the uses of metam and dazomet on feed items not supported by data. For metam, it concerns the GAPs authorised on carrots, potatoes, swedes, turnips, sugar beet and fodder beet while for dazomet it concerns head cabbage and turnips (tops).

Considering that the occurrence of DMTU in plant commodities cannot be excluded and since this compound is toxicologically relevant, risk managers may also decide to set a second list of MRLs for this compound in the future. However, EFSA did not derive MRLs for DMTU because of the following concerns:
- GAPs authorised on metam are partially supported by data for DMTU;
- GAPs authorised on dazomet are not supported by data for DMTU;
- Study investigating the nature of residues in processed commodities (standard hydrolysis conditions) for DMTU are not available;
- Studies investigating the stability of DMTU during sample storage are not available;
- The livestock exposure and the consumer risk assessment could not be finalised for DMTU (but the indicative calculations exceed the trigger values);
- Studies on the nature and magnitude of residues of DMTU in livestock are not available;
- Methods for enforcement of DMTU are only available for high water content and high acid content commodities; these methods were not yet assessed.

Table 2: Summary table

| Code number | Commodity                  | Existing EU MRL (mg/kg) | Outcome of the review               | Comment                  |
|-------------|----------------------------|-------------------------|------------------------------------|--------------------------|
|             |   |                          | MRL (mg/kg) |                             |                          |
| **Enforcement residue definition (existing):** dazomet (Methylisothiocyanate resulting from the use of dazomet and metam) |
| 110010      | Grapefruits                | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 110020      | Oranges                    | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 110030      | Lemons                     | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 110040      | Limes                      | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 110050      | Mandarins                  | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 120010      | Almonds                    | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 120020      | Brazil nuts                | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 120030      | Cashew nuts                | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 120040      | Chestnuts                  | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 120050      | Coconuts                   | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 120060      | Hazelnuts/cobnuts          | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 120070      | Macadamias                 | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 120080      | Pecans                     | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 120090      | Pine nut kernels           | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 120100      | Pistachios                 | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 120110      | Walnuts                    | 0.02*                   | 0.01* Further considerations needed (dazomet) | (b)                      |
| 130010      | Apples                     | 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| 130020      | Pears                      | 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| 130030      | Quinces                    | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 130040      | Medlars                    | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 130050      | Loquats/Japanese medlars    | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 140010      | Apricots                   | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 140020      | Cherries (sweet)           | 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| 140030      | Peaches                    | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 140040      | Plums                      | 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| 151010      | Table grapes               | 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| 151020      | Wine grapes                | 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| 152000      | Strawberries               | 0.02*                   | 0.03 Further considerations needed (metam) | (d)                      |
| 153010      | Blackberries               | 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| 153020      | Dewberries                 | 0.02*                   | 0.01* Recommended (dazomet)         | (a)                      |
| 153030      | Raspberries (red and yellow)| 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| 154010      | Blueberries                | 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| 154020      | Cranberries                | 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| 154030      |                           | 0.02*                   | 0.01* Recommended (metam/dazomet)    | (c)                      |
| Code number | Commodity                                      | Existing EU MRL (mg/kg) | Outcome of the review                                      | Comment                          |
|------------|-----------------------------------------------|-------------------------|-----------------------------------------------------------|----------------------------------|
| 154040     | Currants (black, red and white)               | 0.02* 0.01*             | Recommended (metam/dazomet)                               | (c)                              |
| 154050     | Gooseberries (green, red and yellow)          | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 154060     | Rose hips                                     | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 154070     | Mulberries (black and white)                  | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 154080     | Azaroles/Mediterranean medlars                | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 161020     | Elderberries                                  | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 161030     | Table olives                                  | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 161040     | Kumquats                                      | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 161060     | Kaki/Japanese persimmons                      | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 162010     | Kiwi fruits (green, red, yellow)              | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 162040     | Prickly pears/cactus fruits                   | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 163010     | Avocados                                      | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 163030     | Mangos                                        | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 163050     | Granate apples/pomegranates                   | 0.02* 0.01*             | Recommended (dazomet)                                     | (a)                              |
| 211000     | Potatoes                                      | 0.02* 0.02              | Further considerations needed (metam)                     | (e)                              |
| 212020     | Sweet potatoes                                | 0.02* 0.02              | Further considerations needed (metam)                     | (f)                              |
| 212030     | Yams                                          | 0.02* 0.02              | Further considerations needed (metam)                     | (f)                              |
| 213010     | Beetroots                                     | 0.02* 0.02              | Further considerations needed (dazomet)                   | (g)                              |
| 213020     | Carrots                                       | 0.02 0.02               | Further considerations needed (dazomet)                   | (g)                              |
| 213030     | Celeriacs/turnip rooted celeries              | 0.02* 0.02              | Further considerations needed (dazomet)                   | (g)                              |
| 213040     | Horseradishes                                 | 0.02* 0.02              | Further considerations needed (dazomet)                   | (g)                              |
| 213050     | Jerusalem artichokes                          | 0.02* 0.02              | Further considerations needed (dazomet)                   | (g)                              |
| 213060     | Parsnips                                      | 0.02* 0.02              | Further considerations needed (dazomet)                   | (g)                              |
| 213070     | Parsley roots/Hamburg roots parsley           | 0.02* 0.02              | Further considerations needed (dazomet)                   | (g)                              |
| 213080     | Radishes                                      | 0.05 0.05               | Further considerations needed (dazomet)                   | (g)                              |
| 213090     | Salsifles                                     | 0.02* 0.02              | Further considerations needed (dazomet)                   | (g)                              |
| 213100     | Swedes/rutabagas                              | 0.02* 0.02              | Further considerations needed (dazomet)                   | (g)                              |
| 213110     | Turnips                                       | 0.02* 0.02              | Further considerations needed (dazomet)                   | (g)                              |
| 220020     | Onions                                        | 0.02* 0.15              | Recommended (metam)                                       | (h)                              |
| 220030     | Shallots                                      | 0.02* 0.02              | Further considerations needed (metam)                     | (f)                              |
| 231010     | Tomatoes                                      | 0.1 0.4                 | Further considerations needed (metam)                     | (f)                              |
| 231020     | Sweet peppers/bell peppers                   | 0.1 0.1                 | Further considerations needed (dazomet)                   | (g)                              |
| 231030     | Aubergines/eggplants                          | 0.1 0.4                 | Further considerations needed (metam)                     | (i)                              |
| 231040     | Okra/lady’s fingers                           | 0.1 0.1                 | Further considerations needed (dazomet)                   | (g)                              |
| 232010     | Cucumbers                                     | 0.1 0.6                 | Further considerations needed (metam)                     | (f)                              |
| 232020     | Gherkins                                      | 0.1 0.6                 | Further considerations needed (metam)                     | (f)                              |
| 232030     | Courgettes                                    | 0.1 0.6                 | Further considerations needed (metam)                     | (f)                              |
| 233010     | Melons                                        | 0.1 0.1                 | Further considerations needed (dazomet)                   | (g)                              |
| 233020     | Pumpkins                                      | 0.1 0.1                 | Further considerations needed (dazomet)                   | (g)                              |
| 233030     | Watermelons                                   | 0.1 0.1                 | Further considerations needed (dazomet)                   | (g)                              |
| 241010     | Broccoli                                      | 0.02* 0.02              | Further considerations needed (dazomet)                   | (i)                              |
### Review of the existing MRLs for metam

| Code number | Commodity | Existing EU MRL (mg/kg) | MRL (mg/kg) | Comment |
|-------------|-----------|-------------------------|-------------|---------|
| 241020      | Cauliflowers | 0.02* | 0.02 | Further considerations needed (dazomet) (j) |
| 242020      | Head cabbages | 0.02* | 0.02 | Further considerations needed (dazomet) (j) |
| 243010      | Chinese cabbages/pe-tsai | 0.03 | 0.03 | Further considerations needed (dazomet) (b) |
| 243020      | Kales | 0.03 | 0.03 | Further considerations needed (dazomet) (b) |
| 251010      | Lamb’s lettuces/corn salads | 0.03 | 0.03 | Further considerations needed (dazomet) (k) |
| 251020      | Lettuces | 0.03 | 0.03 | Further considerations needed (dazomet) (k) |
| 251030      | Escaroles/broad-leaved endives | 0.03 | 0.03 | Further considerations needed (dazomet) (k) |
| 251040      | Cresses and other sprouts and shoots | 0.03 | 0.03 | Further considerations needed (dazomet) (k) |
| 251050      | Land cresses | 0.03 | 0.03 | Further considerations needed (dazomet) (k) |
| 251060      | Roman rocket/rucola | 0.03 | 0.03 | Further considerations needed (dazomet) (k) |
| 251070      | Red mustards | 0.03 | 0.03 | Further considerations needed (dazomet) (k) |
| 251080      | Baby leaf crops (including brassica species) | 0.03 | 0.03 | Further considerations needed (dazomet) (k) |
| 252010      | Spinaches | 0.15 | 0.15 | Further considerations needed (dazomet) (g) |
| 252020      | Purslanes | 0.15 | 0.15 | Further considerations needed (dazomet) (k) |
| 252030      | Chards/beet leaves | 0.15 | 0.15 | Further considerations needed (dazomet) (k) |
| 254000      | Watercresses | 0.02 | 0.02 | Further considerations needed (metam) (f) |
| 255000      | Witloofs/Belgian endives | 0.02* | 0.02 | Further considerations needed (metam) (f) |
| 256010      | Chervil | 0.02* | 0.01* | Recommended (metam) (l) |
| 256020      | Chives | 0.02* | 0.01* | Recommended (metam) (l) |
| 256030      | Celery leaves | 0.02* | 0.01* | Recommended (metam) (l) |
| 256040      | Parsley | 0.02* | 0.01* | Recommended (metam) (l) |
| 256050      | Sage | 0.02* | 0.01* | Recommended (metam) (l) |
| 256060      | Rosemary | 0.02* | 0.01* | Recommended (metam) (l) |
| 256070      | Thyme | 0.02* | 0.01* | Recommended (metam) (l) |
| 256080      | Basil and edible flowers | 0.02* | 0.01* | Recommended (metam) (l) |
| 256090      | Laurel/bay leave | 0.02* | 0.01* | Recommended (metam) (l) |
| 256100      | Tarragon | 0.02* | 0.01* | Recommended (metam) (l) |
| 260010      | Beans (with pods) | 0.02* | 0.02 | Further considerations needed (dazomet) (j) |
| 260020      | Beans (without pods) | 0.02* | 0.02 | Further considerations needed (dazomet) (j) |
| 260030      | Peas (with pods) | 0.02* | 0.02 | Further considerations needed (dazomet) (j) |
| 260040      | Peas (without pods) | 0.02* | 0.02 | Further considerations needed (dazomet) (j) |
| 270010      | Asparagus | 0.02* | 0.02 | Further considerations needed (dazomet) (j) |
| 270060      | Leeks | 0.02* | 0.02 | Further considerations needed (dazomet) (j) |
| 633000      | Herbal infusions from roots | 0.02* | 0.02 | Further considerations needed (metam) (f) |
| 700000      | Hops | 0.02* | 0.02 | Further considerations needed (dazomet) (j) |
| 900010      | Sugar beet roots | 0.02* | 0.02 | Further considerations needed (metam) (f) |
| –          | Other commodities of plant and/or animal origin | See Reg. 2016/1 | – | Further considerations needed (m) |

**MRL:** maximum residue level.

*: Indicate that the MRL is set at the limit of quantification.

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

(b): Tentative MRL is derived from a GAP on dazomet evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (no GAP is authorised for metam); no CXL is available (combination E-I in Appendix E).

(c): MRL is derived from GAPs on metam and dazomet evaluated at EU level, both fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
Review of the existing MRLs for metam

(d): Tentative MRL is derived from a GAP on metam evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (the GAP authorised for metam is fully supported by data but leads to lower residue levels); no CXL is available (combination E-I in Appendix E).

(e): GAP on metam evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (the GAP authorised on metam is also not supported by data); no CXL is available (combination C-I in Appendix E).

(f): GAP on metam evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (no GAP is authorised for metam); no CXL is available (combination C-I in Appendix E).

(g): Tentative MRL is derived from a GAP on dazomet evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (the GAP authorised for metam is also not fully supported by data); no CXL is available (combination E-I in Appendix E).

(h): MRL is derived from a GAP on metam evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified (the GAP authorised for dazomet is not supported by data); no CXL is available (combination G-I in Appendix E).

(i): Tentative MRL is derived from a GAP on metam evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (the GAP authorised for dazomet is also not fully supported by data); no CXL is available (combination E-I in Appendix E).

(j): GAP on metam evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (no GAP is authorised for metam); no CXL is available (combination C-I in Appendix E).

(k): Tentative MRL is derived from a GAP on dazomet evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (the GAP authorised for metam is fully supported by data but leads to lower residue levels); no CXL is available (combination E-I in Appendix E).

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

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

References

Belgium, 2008. Draft assessment report on the active substance metam prepared by the rapporteur Member State Belgium in the framework of Council Directive 91/414/EEC, June 2008. Available online: www.efsa.europa.eu

Belgium, 2010. Final addendum to the draft assessment report on the active substance metam, compiled by EFSA, August 2010. Available online: www.efsa.europa.eu

Belgium, 2013. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for MITC (resulting from the use of metam), June 2013. Available online: www.efsa.europa.eu

Belgium, 2017. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for metam (addendum), June 2017. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance dazomet. EFSA Journal 2010;8(10):1833, 91 pp. https://doi.org/10.2903/j.efsa.2010.1833

EFSA (European Food Safety Authority), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance metam. EFSA Journal 2011;9(9):2334, 97 pp. https://doi.org/10.2903/j.efsa.2011.2334

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing MRL(s) for metam in several vegetables. EFSA Journal 2015;13(3):4049, 23 pp. https://doi.org/10.2903/j.efsa.2015.4049

EFSA (European Food Safety Authority), 2018a. Completeness check report on the review of the existing MRLs of metam prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 12 July 2018. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2018b. Member States consultation report on the review of the existing MRLs of metam prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 30 November 2018. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2019. Reasoned opinion on the review of the existing maximum residue levels for dazomet according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(1):5562, 100 pp. https://doi.org/10.2903/j.efsa.2019.5562

EURL (European Union Reference Laboratories for Pesticide Residues), 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for metam, June 2017. Available online: www.efsa.europa.eu

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.
European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.
European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.
European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.
European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.3, June 2017.
FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.
France, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for metam, June 2017. Available online: www.efsa.europa.eu
Greece, 2017a. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Review of the existing EU MRLs for metam, June 2017. Available online: www.efsa.europa.eu
Greece, 2017b. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for metam, June 2017. Available online: www.efsa.europa.eu
Hungary, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for metam, June 2017. Available online: www.efsa.europa.eu
Italy, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for metam, June 2017. Available online: www.efsa.europa.eu
Netherlands, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for metam-natrium, June 2017. Available online: www.efsa.europa.eu
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org
OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.
Portugal, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for metam, June 2017. Available online: www.efsa.europa.eu
Spain, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for metam, June 2017. Available online: www.efsa.europa.eu

Abbreviations

a.i. active ingredient
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
CF conversion factor for enforcement residue definition to risk assessment residue definition
CXL codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DB dietary burden
DM dry matter
DMTU $N,N'$-dimethylthiourea
DT$_{90}$ period required for 90% dissipation (define method of estimation)
Review of the existing MRLs for metam
### Appendix A – Summary of authorised uses considered for the review of MRLs

#### A.1. Authorised uses in northern outdoor EU

| Crop and/or situation | Country | F or G or T(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|----------------|-----------------------------------|-------------|-------------|--------------------------------|---------------|---------|
|                       |         |                |                                   |             |             |                                |               |         |
| **Apples**            | BE      | F              | Nematodes, soil fungi            | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a.    |
| **Pears**             | BE      | F              | Nematodes, soil fungi            | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a.    |
| **Cherries**          | BE      | F              | Nematodes, soil fungi            | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a.    |
| **Plums**             | BE      | F              | Nematodes, soil fungi            | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a.    |
| **Table grapes**      | BE      | F              | Nematodes, soil fungi            | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a.    |
| **Wine grapes**       | BE, FR  | F              | Nematodes, soil fungi            | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a. FR: soil injection or drip irrigation |
| Crop and/or situation | Country | F | G or Gt<sup>(a)</sup> | Pests or group of pests controlled | Preparation Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Application | Application rate per treatment | PHl (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------|---|------------------------|---------------------------------|-----------------------------|----------|-----------|---------------------------------|-------------|---------------------------------|-----------|---------|
| Strawberries          | BE, NL  | F | Nematodes, soil fungi  | SL 510 g/L                      | Soil treatment general (see also comment field) | 0        | 1         | –                               | –           | –                               | 153 kg a.i./ha | n.a.    |
| Blackberries         | BE      | F | Nematodes, soil fungi  | SL 510 g/L                      | Soil treatment general (see also comment field) | 0        | 1         | –                               | –           | –                               | 153 kg a.i./ha | n.a.    |
| Raspberries          | BE      | F | Nematodes, soil fungi  | SL 510 g/L                      | Soil treatment general (see also comment field) | 0        | 1         | –                               | –           | –                               | 153 kg a.i./ha | n.a.    |
| Blueberries          | BE      | F | Nematodes, soil fungi  | SL 510 g/L                      | Soil treatment general (see also comment field) | 0        | 1         | –                               | –           | –                               | 153 kg a.i./ha | n.a.    |
| Cranberries          | BE      | F | Nematodes, soil fungi  | SL 510 g/L                      | Soil treatment general (see also comment field) | 0        | 1         | –                               | –           | –                               | 153 kg a.i./ha | n.a.    |
| Currants             | BE      | F | Nematodes, soil fungi  | SL 510 g/L                      | Soil treatment general (see also comment field) | 0        | 1         | –                               | –           | –                               | 153 kg a.i./ha | n.a.    |
| Gooseberries         | BE      | F | Nematodes, soil fungi  | SL 510 g/L                      | Soil treatment general (see also comment field) | 0        | 1         | –                               | –           | –                               | 153 kg a.i./ha | n.a.    |
| Crop and/or situation | Country | FG or G | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|---------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Potatoes (a)          | BE, NL, FR | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation NL: treatment once in 5 years |
| Sweet potatoes        | NL      | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | Treatment once in 5 years |
| Yams (a)              | NL      | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | Treatment once in 5 years |
| Beetroots             | FR      | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Carrots (a)           | BE, FR  | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation |
| Celeriacs (a)         | BE, FR  | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation |
| Crop and/or situation | Country | F or G | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|--------|-----------------------------------|-------------|-------------|-------------------------------|-----------|---------|
|                       |         |        |                                   |             | Method kind | Range of growth stages & season | Number min–max | Interval between application (min) | Water L/ha min–max | Rate & unit |         |
| HORSEERADISHES | BE, FR | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation |
| JERUSALEM ARTICHOKE | FR | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| PARSNIPS | BE, FR | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation |
| PARSLEY ROOTS | BE, FR | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation |
| RADISHES | BE, FR | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation |
| SALISFIES | BE, FR | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation |
| SWEDES | FR | F | Nematodes, soil fungi | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Crop and/or situation | Country     | F G or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks                                      |
|-----------------------|-------------|----------|-----------------------------------|-------------|------------|---------------------------------|------------|---------------------------------------------|
|                       |             |          |                                   | Type(b)     | Conc. a.s. | Method kind                      | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Water L/ha min-max | Rate & unit | Remarks                                      |
| Turnips               | BE, FR      | F        | Nematodes, soil fungi             | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0           | 1                                      | –          | –         | 153 kg a.i./ha | n.a.          | FR: soil injection or drip irrigation          |
| Onions                | NL          | F        | Nematodes, soil fungi             | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0           | 1                                      | –          | –         | 153 kg a.i./ha | n.a.          | Treatment once in 5 years                      |
| Shallots              | NL          | F        | Nematodes, soil fungi             | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0           | 1                                      | –          | –         | 153 kg a.i./ha | n.a.          | Treatment once in 5 years                      |
| Cucumbers             | FR          | F        | Nematodes, soil fungi             | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0           | 1                                      | –          | –         | 153 kg a.i./ha | n.a.          | Soil injection or drip irrigation              |
| Gherkins              | FR          | F        | Nematodes, soil fungi             | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0           | 1                                      | –          | –         | 153 kg a.i./ha | n.a.          | Soil injection or drip irrigation              |
| Lamb’s lettuces       | BE, FR      | F        | Nematodes, soil fungi             | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0           | 1                                      | –          | –         | 153 kg a.i./ha | n.a.          | FR: soil injection or drip irrigation          |
| Lettuces              | BE, FR      | F        | Nematodes, soil fungi             | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0           | 1                                      | –          | –         | 153 kg a.i./ha | n.a.          | FR: soil injection or drip irrigation          |
| Crop and/or situation | Country | Type | Conc. a.s. | Preparation | Method kind | Range of growth stages & season | Number min-max | Interval between application (min) | g a.s./hL min-max | Water L/ha min-max | Rate & unit | PHI (days) | Remarks |
|-----------------------|---------|------|-----------|-------------|-------------|-------------------------------|----------------|---------------------------------|----------------|------------------|------------|----------|---------|
| Escaroles BE, FR     | F       | Soil treatment general (see also comment field) | 510 g/L | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation |
| Cresses FR           | F       | Soil treatment general (see also comment field) | 510 g/L | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Land cresses FR      | F       | Soil treatment general (see also comment field) | 510 g/L | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Roman rocket BE, FR  | F       | Soil treatment general (see also comment field) | 510 g/L | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation |
| Red mustards FR     | F       | Soil treatment general (see also comment field) | 510 g/L | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Baby leaf crops FR  | F       | Soil treatment general (see also comment field) | 510 g/L | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Spinaches BE, FR    | F       | Soil treatment general (see also comment field) | 510 g/L | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | FR: soil injection or drip irrigation |
| Crop and/or situation | Country  | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) Remarks |
|-----------------------|---------|-----------------------------------|-------------|------------|-------------------------------|------------------|
| Purslanes             | BE, FR  | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a. FR: soil injection or drip irrigation |
| Chards                | BE, FR  | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a. FR: soil injection or drip irrigation |
| Watercesss            | NL      | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a. Treatment once in 5 years |
| Witloofs              | BE      | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a. |
| Chervil               | BE, FR  | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a. FR: soil injection or drip irrigation |
| Chives                | BE, FR  | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a. FR: soil injection or drip irrigation |
| Celery leaves         | BE, FR  | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – 153 kg a.i./ha | n.a. FR: soil injection or drip irrigation |
| Crop and/or situation | Country | F G or T(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|----------------------|---------|-------------|-----------------------------------|-------------|------------|-------------------------------|--------------|---------|
|                      |         |             |                                   | Type(b)     | Concentration | Method kind                  |              |         |
|                      |         |             |                                   | a.s.        | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./hL min-max | Water L/ha min-max | Rate & unit |        |
| Parsley              | BE, FR  | F           | Nematodes, soil fungi            | SL 510 g/L | 0           | 1                             | 153 kg a.i./ha | n.a.     | FR: soil injection or drip irrigation |
| Sage                 | BE, FR  | F           | Nematodes, soil fungi            | SL 510 g/L | 0           | 1                             | 153 kg a.i./ha | n.a.     | FR: soil injection or drip irrigation |
| Rosemary             | BE, FR  | F           | Nematodes, soil fungi            | SL 510 g/L | 0           | 1                             | 153 kg a.i./ha | n.a.     | FR: soil injection or drip irrigation |
| Thyme                | BE, FR  | F           | Nematodes, soil fungi            | SL 510 g/L | 0           | 1                             | 153 kg a.i./ha | n.a.     | FR: soil injection or drip irrigation |
| Basil                | BE, FR  | F           | Nematodes, soil fungi            | SL 510 g/L | 0           | 1                             | 153 kg a.i./ha | n.a.     | FR: soil injection or drip irrigation |
| Laurel               | BE, FR  | F           | Nematodes, soil fungi            | SL 510 g/L | 0           | 1                             | 153 kg a.i./ha | n.a.     | FR: soil injection or drip irrigation |
| Tarragon             | BE, FR  | F           | Nematodes, soil fungi            | SL 510 g/L | 0           | 1                             | 153 kg a.i./ha | n.a.     | FR: soil injection or drip irrigation |
| Crop and/or situation | Country | F | G | I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|----------------------|---------|---|---|---|-------------------------------------|-------------|------------|---------------------------------|---------|
|                      |         |   |   |   |                                     | Type(b)     | Method kind | Range of growth stages & season(c) | Number-min-max | Interval between application (min) | PHI (days)(d) | |
| Herbal infusions from roots | BE | F |   |   | Nematodes, soil fungi | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | – | 153 kg a.i./ha | n.a. |
| Sugar beets | BE, NL | F |   |   | Nematodes, soil fungi | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | – | 153 kg a.i./ha | n.a. |
| Fodder beets | BE, NL | F |   |   | Nematodes, soil fungi | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | – | 153 kg a.i./ha | n.a. |

MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; SL: soluble concentrate; a.s.: active substance; a.i.: active ingredient.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
### A.2. Authorised uses in southern outdoor EU

| Crop and/or situation | Country | FG or F(1) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|------------|-----------------------------------|-------------|------------|---------------------------------|---------------|---------|
|                       |         |            |                                   | Type(b)     | Conc. a.s. | Method kind                      |               |         |
|                       |         |            |                                   | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./hL min-max | Water L/ha min-max | Rate & unit |         |
|                       |         |            |                                   |             |           |                                  |               |           |           |           | Remarks |
| Table grapes          | PT, FR  | F          | Nematodes, soil fungi            | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0             | 1        | –         | –         | –        | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Wine grapes           | PT, FR  | F          | Nematodes, soil fungi            | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0             | 1        | –         | –         | –        | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Strawberries          | ES, EL, PT, IT, FR | F          | Nematodes, soil fungi            | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0             | 1        | –         | –         | –        | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Blackberries          | PT      | F          | Nematodes, soil fungi            | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0             | 1        | –         | –         | –        | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Raspberries           | PT      | F          | Nematodes, soil fungi            | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0             | 1        | –         | –         | –        | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Blueberries           | PT      | F          | Nematodes, soil fungi            | SL          | 510 g/L   | Soil treatment – general (see also comment field) | 0             | 1        | –         | –         | –        | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Crop and/or situation | Country | F G or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|----------------------|---------|----------|-----------------------------------|-------------|-------------|--------------------------------|------------|---------|
| Potatoes             | ES, EL, PT, IT, FR | F | Nematodes, soil fungi | SL | 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation ES: 152 kg a.s./ha |
| Carrots              | ES, EL, PT, IT, FR | F | Nematodes, soil fungi | SL | 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation ES: 152 kg a.s./ha |
| Jerusalem artichokes | FR       | F | Nematodes, soil fungi | SL | 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Parsnips             | FR       | F | Nematodes, soil fungi | SL | 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Parsley roots        | FR       | F | Nematodes, soil fungi | SL | 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Radishes             | FR       | F | Nematodes, soil fungi | SL | 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Crop and/or situation | Country | F G or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|----------|-----------------------------------|-------------|------------|-------------------------------|--------------|---------|
|                       |         |          |                                   |             | Conc. a.s. | Method kind Range of growth stages & season(c) |  g a.s./hL min-max | Water L/ha min-max | Rate & unit | |
| Onions                | ES, EL, PT | F | Nematodes, soil fungi             | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation ES: 152 kg a.s./ha |
| Tomatoes              | ES, EL, PT, IT, FR | F | Nematodes, soil fungi             | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation ES: 152 kg a.s./ha |
| Sweet peppers        | PT, FR   | F | Nematodes, soil fungi             | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Aubergines            | PT, FR   | F | Nematodes, soil fungi             | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Okra                  | FR       | F | Nematodes, soil fungi             | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Cucumbers             | EL, PT, IT, FR | F | Nematodes, soil fungi             | SL 510 g/L | Soil treatment – general (see also comment field) | 0 | 1 | – | – | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Crop and/or situation | Country | Preparations | Pests or group of pests controlled | Method kind | Range of growth stages & season | PHI (days) | Remarks |
|-----------------------|---------|--------------|-----------------------------------|-------------|--------------------------------|-----------|---------|
| **Gherkins**          |         |              | Nematodes, soil fungi             | Soil treatment general (see also comment field) | 0 | 1 | 153 kg a.i./ha | n.a. Soil injection or drip irrigation |
| **Courgettes**        | EL, PT, IT, FR |              | Nematodes, soil fungi             | Soil treatment general (see also comment field) | 0 | 1 | 153 kg a.i./ha | n.a. Soil injection or drip irrigation |
| **Melons**            | PT, FR  |              | Nematodes, soil fungi             | Soil treatment general (see also comment field) | 0 | 1 | 153 kg a.i./ha | n.a. Soil injection or drip irrigation |
| **Pumpkins**          |         |              | Nematodes, soil fungi             | Soil treatment general (see also comment field) | 0 | 1 | 153 kg a.i./ha | n.a. Soil injection or drip irrigation |
| **Watermelons**       |         |              | Nematodes, soil fungi             | Soil treatment general (see also comment field) | 0 | 1 | 153 kg a.i./ha | n.a. Soil injection or drip irrigation |
| **Lamb’s lettuces**   | EL, IT  |              | Nematodes, soil fungi             | Soil treatment general (see also comment field) | 0 | 1 | 153 kg a.i./ha | n.a. Soil injection or drip irrigation |
| **Lettuces**          | ES, EL, PT, IT, FR |              | Nematodes, soil fungi             | Soil treatment general (see also comment field) | 0 | 1 | 153 kg a.i./ha | n.a. Soil injection or drip irrigation ES: 152 kg a.s./ha |
| Crop and/or situation | Country | FG or G (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------|-------------|-----------------------------------|-------------|-------------|---------------------------------|----------------|---------|
|                       |         |             |                                   | Type (b)    | Conc. a.s.  | Method kind                      | g a.s./hL min-max | Rate & unit |          |         |
| Escaroles              | FR      | F           | Nematodes, soil fungi            | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0–1 | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Cresses               | FR      | F           | Nematodes, soil fungi            | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0–1 | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Land cresses           | FR      | F           | Nematodes, soil fungi            | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0–1 | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Roman rocket           | FR      | F           | Nematodes, soil fungi            | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0–1 | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Red mustards           | FR      | F           | Nematodes, soil fungi            | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0–1 | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Baby leaf crops       | FR      | F           | Nematodes, soil fungi            | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0–1 | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Purslanes              | FR      | F           | Nematodes, soil fungi            | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0–1 | – | 153 kg a.i./ha | n.a. | Soil injection or drip irrigation |
| Crop and/or situation | Country | FG or T(5) | Pests or group of pests controlled | Preparation | Method kind | Range of growth stages & season(c) | Number min–max | Interval between application (min) | g a.s./hL min–max | Water & unit | PHI (days)(d) Remarks |
|-----------------------|---------|------------|-----------------------------------|-------------|------------|-----------------------------------|----------------|-------------------------------|----------------|-------------|-----------------------|
| Chards                | FR      | F          | Nematodes, soil fungi             | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                            | –              | –           | 153 kg a.i./ha Soil injection or drip irrigation |
| Chervil               | FR      | F          | Nematodes, soil fungi             | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                            | –              | –           | 153 kg a.i./ha Soil injection or drip irrigation |
| Chives                | FR      | F          | Nematodes, soil fungi             | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                            | –              | –           | 153 kg a.i./ha Soil injection or drip irrigation |
| Celery leaves         | FR      | F          | Nematodes, soil fungi             | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                            | –              | –           | 153 kg a.i./ha Soil injection or drip irrigation |
| Parsley               | PT, FR  | F          | Nematodes, soil fungi             | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                            | –              | –           | 153 kg a.i./ha Soil injection or drip irrigation |
| Sage                  | FR      | F          | Nematodes, soil fungi             | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                            | –              | –           | 153 kg a.i./ha Soil injection or drip irrigation |
| Rosemary              | FR      | F          | Nematodes, soil fungi             | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                            | –              | –           | 153 kg a.i./ha Soil injection or drip irrigation |
| Crop and/or situation | Country | Pests or group of pests controlled | Preparation | Method kind | Range of growth stages & season | Number min–max | Interval between application (min) | PHI (days) | Remarks |
|-----------------------|---------|-----------------------------------|-------------|-------------|-----------------------------|----------------|----------------------------------|------------|---------|
| Thyme                 | FR      | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1            | –                          | 153 kg a.i./ha | n.a.      | Soil injection or drip irrigation |
| Basil                 | FR      | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1            | –                          | 153 kg a.i./ha | n.a.      | Soil injection or drip irrigation |
| Laurel                | FR      | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1            | –                          | 153 kg a.i./ha | n.a.      | Soil injection or drip irrigation |
| Tarragon              | FR      | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1            | –                          | 153 kg a.i./ha | n.a.      | Soil injection or drip irrigation |

NEU: northern European Union; SEU: southern European Union; MS: Member State; SL: soluble concentrate; a.s.: active substance; a.i.: active ingredient.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
### A.3. Authorised indoor uses in EU

| Crop and/or situation | Country | FG or T<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Method kind | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------|----------------------|----------------------------------|-------------|------------|-------------|---------------------------------|-------------------|---------|
| Table grapes          | BE      | I                    | Nematodes, soil fungi           | SL 690 g/L  | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 379.5 kg a.i./ha | n.a. |
| Wine grapes           | EL, IT  | I                    | Nematodes, soil fungi           | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 612 kg a.i./ha | n.a. | Drip irrigation |
| Strawberries          | EL, PT, IT, FR | I                 | Nematodes, soil fungi           | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 612 kg a.i./ha | n.a. | Drip irrigation |
| Blackberries          | PT      | I                    | Nematodes, soil fungi           | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 612 kg a.i./ha | n.a. | Drip irrigation |
| Raspberries           | PT      | I                    | Nematodes, soil fungi           | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 612 kg a.i./ha | n.a. | Drip irrigation |
| Blueberries           | PT      | I                    | Nematodes, soil fungi           | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 612 kg a.i./ha | n.a. | Drip irrigation |
| Cranberries           | BE      | I                    | Nematodes, soil fungi           | SL 690 g/L  | Soil treatment – general (see also comment field) | 0 | 1 | – | – | 379.5 kg a.i./ha | n.a. |
| Crop and/or situation | Country(s) | F I G or T | Pests or group of pests controlled | Preparation | Method kind | Range of growth stages & season | Number min-max | Interval between application (min) | PHI (days) | Water L/ha min-max | Rate & Unit | Remarks |
|-----------------------|------------|-----------|---------------------------------|-------------|------------|-------------------------------|----------------|-------------------------------|------------|----------------|------------|---------|
| Currants              | BE         | I         | Nematodes, soil fungi           | SL          | 690 g/L    | Soil treatment – general (see also comment field) | 0              | 1                             | –          | –                | –          | 379.5 kg a.i./ha | n.a.      |
| Gooseberries          | BE         | I         | Nematodes, soil fungi           | SL          | 690 g/L    | Soil treatment – general (see also comment field) | 0              | 1                             | –          | –                | –          | 379.5 kg a.i./ha | n.a.      |
| Potatoes              | EL, IT, FR | I         | Nematodes, soil fungi           | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                             | –          | –                | –          | 612 kg a.i./ha | n.a.      |
| Beetroot             | FR          | I         | Nematodes, soil fungi           | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                             | –          | –                | –          | 612 kg a.i./ha | n.a.      |
| Carrots               | EL, IT, FR | I         | Nematodes, soil fungi           | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                             | –          | –                | –          | 612 kg a.i./ha | n.a.      |
| Celeriacs            | FR          | I         | Nematodes, soil fungi           | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                             | –          | –                | –          | 612 kg a.i./ha | n.a.      |
| Horseradishes        | FR          | I         | Nematodes, soil fungi           | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0              | 1                             | –          | –                | –          | 612 kg a.i./ha | n.a.      |
| Crop and/or situation | Country | F G or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|----------|-----------------------------------|-------------|------------|---------------------------------|-----------|---------|
| Jerusalem artichokes  | FR I    | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 1 | – | 612 kg a.i./ha | n.a. | Drip irrigation |
| Parsnips              | FR I    | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 1 | – | 612 kg a.i./ha | n.a. | Drip irrigation |
| Parsley roots         | FR I    | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 1 | – | 612 kg a.i./ha | n.a. | Drip irrigation HU: 500 kg a.s./ha |
| Radishes              | FR I    | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 1 | – | 612 kg a.i./ha | n.a. | Drip irrigation BE: 379.5 kg a.s./ha |
| Salsifies             | FR I    | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 1 | – | 612 kg a.i./ha | n.a. | Drip irrigation BE: 379.5 kg a.s./ha |
| Swedes                | FR I    | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 1 | – | 612 kg a.i./ha | n.a. | Drip irrigation |
| Turnips               | FR I    | Nematodes, soil fungi | SL 510 g/L | Soil treatment - general (see also comment field) | 0 1 | – | 612 kg a.i./ha | n.a. | Drip irrigation |
| Crop and/or situation | Country | FG or F(1) | Pests or group of pests controlled | Preparation | Method kind | Application rate per treatment | Remarks |
|-----------------------|---------|------------|-----------------------------------|-------------|-------------|-------------------------------|---------|
| Tomatoes              | EL, PT, IT, FR | I | Nematodes, soil fungi | SL | 510 g/L | Soil treatment – general (see also comment field) | 612 kg a.i./ha |
| Sweet peppers         | PT, FR | I | Nematodes, soil fungi | SL | 510 g/L | Soil treatment – general (see also comment field) | 612 kg a.i./ha |
| Aubergines            | PT, FR | I | Nematodes, soil fungi | SL | 510 g/L | Soil treatment – general (see also comment field) | 612 kg a.i./ha |
| Okra                  | FR      | I | Nematodes, soil fungi | SL | 510 g/L | Soil treatment – general (see also comment field) | 612 kg a.i./ha |
| Crop and/or situation | Country | F Group or group of pests (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------|--------------------------------|-----------------------------------|-------------|-------------|-------------------------------|-----------|---------|
| Cucumbers             | HU      | I                              | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – | 500 kg a.i./ha | n.a. | Drip irrigation BE: 379.5 kg a.s./ha; EL, PT, IT, FR: 612 kg a.s./ha ES: 400 kg a.s./ha |
| Gherkins              | HU      | I                              | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – | 500 kg a.i./ha | n.a. | Drip irrigation BE: 379.5 kg a.s./ha; FR: 612 kg a.s./ha |
| Courgettes            | ES      | I                              | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – | 400 kg a.i./ha | n.a. | Drip irrigation BE: 379.5 kg a.s./ha; EL, PT, IT, FR: 612 kg a.s./ha ES: 400 kg a.s./ha |
| Melons                | PT, FR  | I                              | Nematodes, soil fungi             | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – | 612 kg a.i./ha | n.a. | Drip irrigation BE: 379.5 kg a.s./ha |
| Crop and/or situation | Country | FG or G (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|-------------|-----------------------------------|-------------|------------|-------------------------------|---------------|---------|
|                      |         |             |                                   |             |            |                               |               |         |
| **Pumpkins**          | FR      | I           | Nematodes, soil fungi            | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0 1            | – –     | 612 kg a.i./ha | n.a. | Drip irrigation BE: 379.5 kg a.s./ha |
| **Watermelons**       | FR      | I           | Nematodes, soil fungi            | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0 1            | – –     | 612 kg a.i./ha | n.a. | Drip irrigation |
| **Lamb’s lettuces**   | BE      | I           | Nematodes, soil fungi            | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0 1            | – –     | 379.5 kg a.i./ha | n.a. | Drip irrigation EL, FR: 357 kg a.s./ha; IT: 750 kg a.s./ha |
| **Lettuces**          | BE      | I           | Nematodes, soil fungi            | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0 1            | – –     | 379.5 kg a.i./ha | n.a. | Drip irrigation ES: 400 kg a.s./ha; EL, FR: 357 kg a.s./ha; PT: 612 kg a.s./ha; IT: 750 kg a.s./ha |
| **Escaroles**         | BE      | I           | Nematodes, soil fungi            | SL          | 510 g/L    | Soil treatment – general (see also comment field) | 0 1            | – –     | 379.5 kg a.i./ha | n.a. | Drip irrigation FR: 357 kg a.s./ha |

(a) FG or G: Forward Guidance or Guidance
(b) Conc. a.s.: Concentration of active substance
(c) Range of growth stages & season: General comment
(d) PHI: Preharvest interval

**Note:** The table includes information on the crops, pests or groups of pests controlled, preparation, application, application rate per treatment, PHI, and remarks.
| Crop and/or situation | Country | FG or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------|---------|-----------------------------------|-------------|-------------|------------------------------|------------------|---------|
| Cresses               | FR      | I       | Nematodes, soil fungi             | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0  1  –  – | 357 kg a.i./ha | n.a. Drip irrigation |
| Land cresses          | FR      | I       | Nematodes, soil fungi             | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0  1  –  – | 357 kg a.i./ha | n.a. Drip irrigation |
| Roman rocket          | FR      | I       | Nematodes, soil fungi             | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0  1  –  – | 357 kg a.i./ha | n.a. Drip irrigation |
| Red mustards          | FR      | I       | Nematodes, soil fungi             | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0  1  –  – | 357 kg a.i./ha | n.a. Drip irrigation |
| Baby leaf crops       | FR      | I       | Nematodes, soil fungi             | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0  1  –  – | 357 kg a.i./ha | n.a. Drip irrigation |
| Spinaches             | BE      | I       | Nematodes, soil fungi             | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0  1  –  – | 379.5 kg a.i./ha | n.a. Drip irrigation FR: 357 kg a.s./ha |
| Purslanes             | BE      | I       | Nematodes, soil fungi             | SL          | 510 g/L     | Soil treatment – general (see also comment field) | 0  1  –  – | 379.5 kg a.i./ha | n.a. Drip irrigation FR: 357 kg a.s./ha |
| Crop and/or situation | Country | F G or G(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------|-------------|-----------------------------------|-------------|-------------|------------------|---------------|---------|
|                       |         |             |                                   |             |             |                               |               |         |
| Chards                | BE      | I           | Nematodes, soil fungi            | SL 510 g/L | Soil treatment – general (see also comment field) | 0 1           | –  –          | 379.5 kg a.i./ha | Drip irrigation FR: 357 kg a.s./ha |
| Chervil               | BE      | I           | Nematodes, soil fungi            | SL 510 g/L | Soil treatment – general (see also comment field) | 0 1           | –  –          | 379.5 kg a.i./ha | Drip irrigation FR: 357 kg a.s./ha |
| Chives                | BE      | I           | Nematodes, soil fungi            | SL 510 g/L | Soil treatment – general (see also comment field) | 0 1           | –  –          | 379.5 kg a.i./ha | Drip irrigation FR: 357 kg a.s./ha |
| Celery leaves         | BE      | I           | Nematodes, soil fungi            | SL 510 g/L | Soil treatment – general (see also comment field) | 0 1           | –  –          | 379.5 kg a.i./ha | Drip irrigation FR: 357 kg a.s./ha |
| Parsley               | BE      | I           | Nematodes, soil fungi            | SL 510 g/L | Soil treatment – general (see also comment field) | 0 1           | –  –          | 379.5 kg a.i./ha | Drip irrigation FR: 357 kg a.s./ha; PT: 612 kg a.s./ha |
| Sage                  | BE      | I           | Nematodes, soil fungi            | SL 510 g/L | Soil treatment – general (see also comment field) | 0 1           | –  –          | 379.5 kg a.i./ha | Drip irrigation FR: 357 kg a.s./ha |
| Rosemary              | FR      | I           | Nematodes, soil fungi            | SL 510 g/L | Soil treatment – general (see also comment field) | 0 1           | –  –          | 357 kg a.i./ha  | Drip irrigation |

**Legend:**
- **Type(b)**: SL 510 g/L
- **Conc. a.s.**: Soil treatment
- **Method kind**: General
- **Range of growth stages & season(c)**: General
- **Number min-max**: General
- **Interval between application (min)**: General
- **g a.s./hL min-max**: General
- **Water L/ha min-max**: General
- **Rate & Unit**: General
- **Remarks**: General
| Crop and/or situation | Country | F or G | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|----------------------|---------|-------|-----------------------------------|-------------|-------------|-------------------------------|---------|
|                      |         |       |                                   | Type(b)     | Conc. a.s. | Method kind                   | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Water L/ha min-max | Rate & Unit | PHI (days)(d) |         |
| Thyme                | BE I    |       | Nematodes, soil fungi            | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – – 379.5 kg a.i./ha n.a. Drip irrigation FR: 357 kg a.s./ha |         |
| Basil                | BE I    |       | Nematodes, soil fungi            | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – – 379.5 kg a.i./ha n.a. Drip irrigation FR: 357 kg a.s./ha |         |
| Laurel               | BE I    |       | Nematodes, soil fungi            | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – – 379.5 kg a.i./ha n.a. Drip irrigation FR: 357 kg a.s./ha |         |
| Tarragon             | BE I    |       | Nematodes, soil fungi            | SL 510 g/L  | Soil treatment – general (see also comment field) | 0 1 – – – 379.5 kg a.i./ha n.a. Drip irrigation FR: 357 kg a.s./ha |         |

NEU: northern European Union; SEU: southern European Union; MS: Member State; SL; soluble concentrate; a.s.: active substance; a.i.: active ingredient.

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

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s)        | Application(s)                  | Sampling (DAT) |
|----------------------------------|-------------|----------------|---------------------------------|----------------|
| Fruit crops                      | Tomatoes    | Soil, eq. to 40 g a.s./m² | Soil at 20 days before planting, 1 × 400 kg a.s./ha (greenhouse) | 102
|                                  |             | Soil, eq. to 40 g a.s./m² | 60                              |
| Root crops                       | Radish      | Soil, eq. to 40 g a.s./m² | 80 (roots and tops)              |
|                                  | Turnip      | Soil drench, 1 × 356 kg a.s./ha | 160, 173                     |
| Leafy crops                      | Chinese cabbages | Soil, eq. to 40 g a.s./m² | 77, 104                           |

Studies performed with tomatoes (1st study), radish, turnips and Chinese cabbage were assessed by Belgium (2010) and peer reviewed (EFSA, 2011)

Studies using N-methyl-14C-(thiocarbonyl)-metam

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|--------------------------------------|-------------|---------|----------------|-----------|
|                                     |             |         |                |           |

No studies available. Considering that the studies on primary crops were performed with pre-planting applications on soil with 10–41 days between treatment and planting, these studies are deemed sufficient to also elucidate the nature of residue in rotational crops

| Processed commodities (hydrolysis study) | Conditions | Investigated? |
|------------------------------------------|------------|---------------|
|                                         | Pasteurisation (20 min, 90°C, pH 4) | No |
|                                         | Baking, brewing and boiling (60 min, 100°C, pH 5) | No |
|                                         | Sterilisation (20 min, 120°C, pH 6) | No |

No studies available but required (data gap)

Can a general residue definition be proposed for primary crops? Yes (for soil preplanting applications)

Rotational crop and primary crop metabolism similar? Yes, studies on primary crops are sufficient to depict metabolism in rotational crops

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

Plant residue definition for monitoring (RD-Mo) RD-Mo 1: methylisothiocyanate (MITC) RD-Mo 2 (optional): N,N’-dimethylthiourea (DMTU)

Plant residue definition for risk assessment (RD-RA) RD-RA 1: methylisothiocyanate (MITC) RD-RA 2: N,N’-dimethylthiourea (DMTU)

Conversion factor (monitoring to risk assessment) Not applicable

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) RD-Mo 1 (methylisothiocyanate – MITC): Matrices with high water content and high acid content: GC–MS, LOQ 0.01 mg/kg • Fully validated in tomatoes, lettuce and strawberries (EFSA, 2011; Greece, 2017a,b) • Confirmation by comparisons of ions • ILV available
Matrices with high oil content:
- GC-MS; LOQ: 0.01 mg/kg
- Validated on rapeseed (EFSA, 2019)
- No ILV available

Dry commodities:
- GC-MS; LOQ: 0.01 mg/kg
- Validated on wheat grain (EFSA, 2019)
- No ILV available

Matrices difficult to analyse (herbal infusion from roots)
- No method available (data gap)

EURLs indicated that QuEChERS method using GC-MS/MS can be used to enforce MITC in matrices with high water, high acid, high oil and dry content

**RD-Mo 2 \(N,N'\)-dimethylthiourea – DMTU:**

Matrices with high water content and high acid content:
- LC-MS/MS, LOQ 0.01 mg/kg

---

**B.1.1.2. Stability of residues in plants**

| Plant products (available studies) | Category         | Commodity | T (°C) | Stability (months) |
|-----------------------------------|------------------|-----------|--------|-------------------|
| High water content                | Tomato           | –20       | 2      |
| Pepper                            | –20              | ≤ 3       |
| Strawberry                        | –20              | ≤ 3       |

Storage stability demonstrated for MITC in the framework of the peer review of dazomet (EFSA, 2010)

No studies available for DMTU

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; GC-MS: gas chromatography with mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); LC-MS/MS: liquid chromatography with tandem mass spectrometry.

MITC: methylisothiocyanate; DMTU: \(N,N'\)-dimethylthiourea.
### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials (Residue definition MITC)

| Crop                        | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) | STMR (mg/kg) |
|-----------------------------|---------------|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|----------------------|------------|-------------|
| **Residue definition for enforcement and risk assessment:** methylisothiocyanate (MITC) |               |                                                                                                   |                                                                                                |                      |            |             |
| Apples                      | NEU           | –                                                                                                 | A no residues situation is expected given that the time of harvesting is more than 365 days after application | 0.01*                | < 0.01    | < 0.01      |
| Pears                       |               |                                                                                                   |                                                                                                |                      |            |             |
| Cherries (sweet)            | NEU           | –                                                                                                 | A no residues situation is expected given that the time of harvesting is more than 365 days after application | 0.01*                | < 0.01    | < 0.01      |
| Plums                       |               |                                                                                                   |                                                                                                |                      |            |             |
| Table grapes                | NEU           | –                                                                                                 | A no residues situation is expected given that the time of harvesting is more than 365 days after application | 0.01*                | < 0.01    | < 0.01      |
| Wine grapes                 | SEU           | –                                                                                                 |                                                                                                |                      |            |             |
|                             | Indoor        | –                                                                                                 |                                                                                                |                      |            |             |
| Strawberries                | NEU           | –                                                                                                 | No data available                                                                                                                                       | –                    | –         | –           |
|                             | SEU           | 3 × < 0.01                                                                                       | Trials on strawberries compliant with GAP (France, 2017) not sufficient to derive an MRL                                                           | –                    | –         | –           |
|                             | Indoor        | 5 × < 0.01; 0.02                                                                                 | Trials on strawberries compliant with GAP (France, 2017; Spain, 2017)                                                                                 | 0.03 (tentative)     | 0.02      | < 0.01      |
| Blackberries                | NEU           | –                                                                                                 | A no residues situation is expected given that the time of harvesting is more than 365 days after application                                          | 0.01*                | < 0.01    | < 0.01      |
| Raspberries (red and yellow)| SEU           | –                                                                                                 |                                                                                                |                      |            |             |
| Blueberries                 | Indoor        |                                                                                                   |                                                                                                |                      |            |             |
| Cranberries                 | NEU           | –                                                                                                 | A no residues situation is expected given that the time of harvesting is more than 365 days after application                                          | 0.01*                | < 0.01    | < 0.01      |
| Currants (black, red and white) | Indoor    |                                                                                                   |                                                                                                |                      |            |             |
| Gooseberries (green, red and yellow) | Indoor |                                                                                                   |                                                                                                |                      |            |             |
| Crop                  | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)                                                                 | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|----------------------|------------------|---------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------|---------------|----------------|
| Potatoes Sweet potatoes Yams | NEU              | (5 × < 0.01)                                                                                                                    | Trials on potatoes compliant with GAP (Belgium, 2013; France, 2017). However, these trials are not deemed valid due to concerns on the storage period of the samples (< 3 months). No MRL can be derived for these crops | --                   | --            | --             |
|                       | SEU              | (0.0357; 0.013; 0.035; 0.015; 0.031; 0.031; 0.055; 0.043)                                                                         | Trials on potatoes compliant with GAP (Belgium, 2013; France, 2017). However, these trials are not deemed valid due to concerns on the storage period of the samples (< 3 months). No MRL can be derived for this crop. Southern GAP authorised for potatoes only | --                   | --            | --             |
| Indoor               | --               | No data available. Indoor GAP authorised for potatoes only                                                                         |                                                                                                                | --                   | --            | --             |
| Beetroots Carrots Celeriacs/turnip rooted celeries Horseradishes Jerusalem artichokes Parsnips Parsley roots/Hamburg roots parsley Radishes Salsifies | NEU              | (4 × < 0.01)                                                                                                                    | Trials on carrots compliant with GAP (Belgium, 2013; France, 2017). However, these trials are not deemed valid due to concerns on the storage period of the samples (< 3 months). No MRL can be derived for these crops | --                   | --            | --             |
|                       | SEU              | 4 × < 0.01                                                                                                                      | Trials on carrots compliant with GAP (Spain, 2017). GAP authorised for carrots, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley and radishes only. Extrapolation to Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley and radishes is applicable MRL_{OECD} = 0.01 | 0.01*(tentative)(d) | < 0.01        | < 0.01         |
| Indoor               | --               | No data available                                                                                                               |                                                                                                                | --                   | --            | --             |
| Swedes/ rutabagas Turnips | NEU              | --                                                                                                                             | No data available                                                                                               | --                   | --            | --             |
| Indoor               | --               | No data available                                                                                                               |                                                                                                                | --                   | --            | --             |
### Crop Residue Levels and MRL Proposals

| Crop                        | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)<sup>(b)</sup> | STMR (mg/kg)<sup>(c)</sup> |
|-----------------------------|------------------------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|--------------------------|--------------------------|
| Onions                      | NEU                          | (4 × < 0.01)                                                                                   | Trials on onions compliant with GAP (France, 2017). Extrapolation to shallots is applicable. However, these trials are not deemed valid due to concerns on the storage period of the samples (> 3 months). No MRL can be derived from this GAP | –                    | –                        | –                        |
|                             | SEU                          | 3 × 0.01; 0.014; < 0.016; 0.067; 0.088                                                          | Trials on onions compliant with GAP (France, 2017; Spain, 2017) MRL<sub>OECD</sub> = 0.15 | 0.15                 | 0.09                     | 0.01                     |
| Shallots                    | NEU                          | (4 × < 0.01)                                                                                   | See onions NEU                                                                                       | –                    | –                        | –                        |
| Tomatoes Aubergines         | SEU                          | 7 × 0.01; 0.22                                                                                 | Overdosed trials (2-2.5N) performed on tomatoes are used on a tentative basis (France, 2017). Extrapolation to aubergines is applicable MRL<sub>OECD</sub> = 0.33 | 0.4 (tentative)<sup>(d),<sup>(e)</sup> | 0.22                     | < 0.01                    |
|                             | Indoor                       | 4 × < 0.01                                                                                     | Trials on tomatoes compliant with GAP (France, 2017). Extrapolation to aubergines is applicable 0.01* (tentative)<sup>(d),<sup>(e)</sup> | < 0.01               | < 0.01                   |                           |
| Sweet peppers               | SEU                          | –                                                                                               | No data available                                                                                  | –                    | –                        | –                        |
|                             | Indoor                       | < 0.01; < 0.01; < 0.01; 0.012                                                                    | Trials on peppers compliant with GAP (France, 2017) MRL<sub>OECD</sub> = 0.03 0.03 (tentative)<sup>(d),<sup>(e)</sup> | 0.01                 | < 0.01                   |                           |
| Okra/lady's fingers         | SEU                          | –                                                                                               | No data available                                                                                  | –                    | –                        | –                        |
|                             | Indoor                       | –                                                                                               | No data available                                                                                  | –                    | –                        | –                        |
| Cucumbers Gherkins Courgettes | SEU                           | –                                                                                               | No data available Northern GAP authorised for cucumbers and gherkins only                          | –                    | –                        | –                        |
|                             | Indoor                       | –                                                                                               | No data available                                                                                  | –                    | –                        | –                        |
| Melons Pumpkins Watermelons | SEU                          | –                                                                                               | No data available                                                                                  | –                    | –                        | –                        |
|                             | Indoor                       | –                                                                                               | No data available                                                                                  | –                    | –                        | –                        |

<sup>(a)</sup> Indoor;

<sup>(b)</sup> HR (high risk);

<sup>(c)</sup> STMR (safe target margin ratio);

<sup>(d)</sup> Tentative;

<sup>(e)</sup> Provisional.
| Crop | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|------|------------------|---------------------------------------------------------------------------------|---------------------------------------------|----------------------|---------------|---------------|
| Lamb’s lettuce Lettuces Escaroles/broad-leaved endives Cresses and other sprouts and shoots Land cresses Roman rocket/rucola Red mustards Baby leaf crops (including brassica species) Spinaches Purslanes Chards/beet leaves Fresh herbs | NEU | (4 × < 0.01) | Trials on lettuce (heads) compliant with GAP (France, 2017). Extrapolation to other salads, spinaches, purslanes, chards and fresh herbs is applicable. However, these trials are not deemed valid due to concerns on the storage period of the samples (> 3 months). No MRL can be derived from this GAP | – | – | – |
| | SEU | 8 × < 0.01 | Trials on lettuce (heads) compliant with GAP (France, 2017; Spain, 2017). Extrapolation to other salads, purslanes, chards and fresh herbs is applicable. Southern GAP not authorised for spinach | 0.01* | < 0.01 | < 0.01 |
| | Indoor | 4 × < 0.01 | Trials on lettuce (heads) compliant with GAP (France, 2017). Extrapolation to other salads, spinaches, purslanes, chards and fresh herbs is applicable | 0.01* (tentative)(d) | < 0.01 | < 0.01 |
| Watercresses | NEU | – | No data available | – | – | – |
| Witloofs/Belgian endives | NEU | – | No data available | – | – | – |
| Herbal infusions from roots | NEU | – | No data available | – | – | – |
| Sugar beet roots | NEU | – | No data available | – | – | – |
| Fodder beet roots | NEU | – | No data available | – | – | – |
| Fodder beet tops | NEU | – | No data available | – | – | – |
| Sugar beet tops | NEU | – | No data available | – | – | – |
| Turnip tops | NEU | 3 × < 0.01; 0.027 | Trials on carrot tops compliant with GAP on turnip (France, 2017) \( R_{\text{max}} = 0.06 \) \( \text{MRL}_{\text{OECD}} = 0.05 \) | 0.06 (tentative)(f) | 0.03 | < 0.01 |
| Indoor | – | No data available | – | – | – |

(a) Indoor(a) refers to indoor conditions.
(b) HR (mg/kg) refers to hazard index (mg/kg).
(c) STMR (mg/kg) refers to short-term intake (mg/kg).
(d) Tentative values are indicated with an asterisk (*) and may require further assessment.
(e) NEU indicates no exposure assessment was performed.
(f) \( R_{\text{max}} \) and \( \text{MRL}_{\text{OECD}} \) are used to calculate the HR and STMR.
GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): MRL is tentative because derived on a limited number of GAP-compliant residue trials (or overdosed trials).
(e): MRL is tentative because of data gaps identified on the nature of residues in processed commodities.
(f): Tentative MRL is derived for feed commodities.

B.1.2.2. Summary of residues data from the supervised residue trials (Residue definition DMTU)

| Crop                          | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|-------------------------------|---------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------|---------------|-----------------|
| Apples (Pears)                | NEU           | A no residues situation is expected given that the time of harvesting is more than 365 days after application | 0.01*                                         | < 0.01               | < 0.01        |
| Cherries (sweet) Plums        | NEU           | A no residues situation is expected given that the time of harvesting is more than 365 days after application | 0.01*                                         | < 0.01               | < 0.01        |
| Table grapes                  | NEU           | A no residues situation is expected given that the time of harvesting is more than 365 days after application | 0.01*                                         | < 0.01               | < 0.01        |
| Wine grapes                   | SEU           | No data available                                                                             | –                                             | –                    | –             |
|                               | Indoor        | Trials on strawberries compliant with GAP (France, 2017). Not sufficient to derive an MRL       | –                                             | –                    | –             |
| Strawberries                  | NEU           | 3 × < 0.01                                                                                     | Trials on strawberries compliant with GAP (France, 2017). Not sufficient to derive an MRL | 0.06 (tentative)(d) | 0.03          | < 0.01          |
|                               | SEU           | 4 × < 0.01; 0.011; 0.033                                                                       | Trials on strawberries compliant with GAP (France, 2017; Spain, 2017) MRL<sub>OECD</sub> = 0.06 |                      |               |                 |
| Blackberries                  | NEU           | A no residues situation is expected given that the time of harvesting is more than 365 days after application | 0.01*                                         | < 0.01               | < 0.01        |
| Raspberries (red and yellow)  | SEU           | –                                                                                              | –                                             | –                    | –             |
| Blueberries                   | Indoor        | –                                                                                              | –                                             | –                    | –             |
| Crop | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) | STMR (mg/kg) |
|------|--------------|---------------------------------------------------------------------------------|-----------------------------------------|---------------------|------------|-------------|
|      |              |                                                                                 | A no residues situation is expected given that the time of harvesting is more than 365 days after application | 0.01* | < 0.01 | < 0.01 |
| Cranberries | NEU | –                                                                                 | Trials on potatoes compliant with GAP (Belgium, 2013; France, 2017). However, these trials are not deemed valid due to concerns on the storage period of the samples (> 3 months). No MRL can be derived for these crops. Southern GAP authorised for potatoes only | – | – | – |
| Currants (black, red and white) Gooseberries (green, red and yellow) | Indoor | (5 × < 0.01)                                                                      | Trials on potatoes compliant with GAP (France, 2017). However, trials performed on potatoes are not deemed valid due to concerns on the storage period of the samples (> 3 months). No MRL can be derived for these crops. Indoor GAP authorised for potatoes only | – | – | – |
| Potatoes Sweet potatoes Yams | NEU | (5 × < 0.01)                                                                      | Trials on carrots compliant with GAP (Belgium, 2013; France, 2017). However, these trials are not deemed valid due to concerns on the storage period of the samples (> 3 months). No MRL can be derived for these crops | 0.6 (tentative) | 0.23 | 0.09 |
| SEU | 0.062; 0.077; 0.099; 0.23 | Trials on carrots compliant with GAP (Spain, 2017). GAP authorised for carrots, Jerusalem artichokes, parsnips, parsley roots, Hamburg roots parsley and radishes only. Extrapolation to Jerusalem artichokes, parsnips, parsley roots and radishes is applicable | R_{max} = 0.51 MRL_{OECD} = 0.42 | – | – | – |
| Beetroots Carrots Celeriacs/turnip rooted celeries Horseradishes Jerusalem artichokes Parsnips Parsley roots/Hamburg roots parsley Radishes Salsifies | NEU | (5 × < 0.01)                                                                      | – | – | – |
| SEU | 0.062; 0.077; 0.099; 0.23 | Trials on carrots compliant with GAP (Spain, 2017). GAP authorised for carrots, Jerusalem artichokes, parsnips, parsley roots, Hamburg roots parsley and radishes only. Extrapolation to Jerusalem artichokes, parsnips, parsley roots and radishes is applicable | R_{max} = 0.51 MRL_{OECD} = 0.42 | – | – | – |
| Indoor | – | No data available                                                                      | – | – | – |

* OECD calculations
(b) STMR
(c) MRL proposals

www.efsa.europa.eu/efsajournal 55 EFSA Journal 2019;17(1):5561
| Crop               | Region/ indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                                                                                                                                                 | MRL proposals (mg/kg) | HR (mg/kg) | STMR (mg/kg) |
|--------------------|----------------|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------|-------------|
| Swedes/rutabagas  | NEU            | (9 × < 0.01)                                                                                                                | Combined data set of trials on potatoes (5) and carrots (4) compliant with GAP (Belgium, 2013; France, 2017). However, these trials are not deemed valid due to concerns on the storage period of the samples (> 3 months). No MRL can be derived for these crops |                       |            |             |
| Turnips            | Indoor         | No data available                                                                                                          |                                                                                                                                                                                                                                        | –                     |            |             |
| Onions             | NEU            | (4 × < 0.01)                                                                                                                | Trials on onions compliant with GAP (France, 2017). Extrapolation to shallots is applicable. However, these trials are not deemed valid due to concerns on the storage period of the samples (> 3 months). No MRL can be derived from this GAP |                       |            |             |
|                     | Indoor         | No data available                                                                                                          |                                                                                                                                                                                                                                        | –                     |            |             |
| Shallots           | NEU            | (4 × < 0.01)                                                                                                                | See onions NEU                                                                                                                                                                                                                    |                       |            |             |
| Tomatoes           | SEU            | 8 × < 0.01                                                                                                                  | Overdosed trials (2–2.5N) performed on tomatoes are used on a tentative basis (France, 2017). Extrapolation to aubergines is applicable                                                                                                      | 0.01* (tentative)(d)  | < 0.01     | < 0.01      |
| Aubergines         | Indoor         | 4 × < 0.01                                                                                                                  | Trials on tomatoes compliant with GAP (France, 2017). Extrapolation to aubergines is applicable                                                                                                                                       | 0.01* (tentative)(d)  | < 0.01     | < 0.01      |
| Sweet peppers      | SEU            | –                                                                           | No data available                                                                                                                                                                                                                   | –                     |            |             |
|                     | Indoor         | (4 × < 0.01)                                                                                                                | Trials on peppers compliant with GAP (France, 2017). However, these trials are not deemed valid due to concerns on the storage period of the samples (> 1 month). No MRL can be derived from this GAP                                                                 |                       |            |             |
| Okra/lady’s fingers| SEU            | –                                                                           | No data available                                                                                                                                                                                                                   | –                     |            |             |
|                     | Indoor         | –                                                                           | No data available. GAP authorised for cucumbers and gherkins only                                                                                                                                                                     | –                     |            |             |
| Cucumbers          | NEU            | –                                                                           | No data available. GAP authorised for cucumbers and gherkins only                                                                                                                                                                     | –                     |            |             |
| Gherkins Courgettes| SEU            | 4 × < 0.01                                                                                                                  | Trials on cucumbers compliant with GAP (Spain, 2017). Extrapolation to gherkins and courgettes is applicable                                                                                                                          | 0.01* (tentative)(d)  | < 0.01     | < 0.01      |
| Crop | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|------|------------------|-----------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------|-------------|--------------|
| Indoor | 5 × < 0.01; 0.020; 0.029; 0.069 | Trials on cucumbers compliant with GAP (France, 2017). Extrapolation to gherkins and courgettes is applicable | 0.01 | 0.07 | < 0.01 |
| Melons Pumpkin Watermelons | SEU | No data available | — | — | — |
| Lamb’s lettuce Lettuces Escaroles/broad-leaved endives Cresses and other sprouts and shoots Land cresses Roman rocket/ruccola Red mustards Baby leaf crops (including brassica species) Purslanes Chards/beet leaves Fresh herbs | NEU | (4 × < 0.01) | Trials on lettuce (heads) compliant with GAP (France, 2017). Extrapolation to other salads, spinaches, purslanes, chards and fresh herbs is applicable. However, these trials are not deemed valid due to concerns on the storage period of the samples (> 3 months). No MRL can be derived from this GAP | 0.2 (tentative)(g) | 0.14 | 0.01 |
| Indoor | 4 × < 0.01 | Trials on lettuce (heads) compliant with GAP (France, 2017; Spain, 2017). Extrapolation to other salads, spinaches, purslanes, chards and fresh herbs is applicable. Southern GAP not authorised for spinach | 0.01* (tentative)(d) | < 0.01 | < 0.01 |
| Spinaches | NEU | (4 × < 0.01) | See lettuces and similar NEU | — | — | — |
| Indoor | 4 × < 0.01 | Direct extrapolation from lettuces and similar EU | 0.01* (tentative)(d) | < 0.01 | < 0.01 |
| Watercresses | NEU | — | No data available | — | — | — |
| Witloofs/Belgian endives | NEU | — | No data available | — | — | — |
| Herbal infusions from roots | NEU | — | No data available | — | — | — |
| Sugar beet roots | NEU | — | No data available | — | — | — |
Crop | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c)
--- | --- | --- | --- | --- | --- | ---
Fodder beet roots | NEU | – | No data available | – | – | –
Fodder beet tops | NEU | – | No data available | – | – | –
Sugar beet tops | NEU | – | No data available | – | – | –
Turnip tops | NEU | 3 × < 0.01; 0.016 | Trials on carrot tops compliant with GAP on turnip (France, 2017) \(R_{\text{HR}} = 0.03\) \(\text{MRL}_\text{OECD} = 0.02\) | 0.03 (tentative)(f) | 0.02 | < 0.01
Indoor | – | – | No data available | – | – | –

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): MRL is tentative because derived on a limited number of GAP-compliant residue trials (or overdosed trials).
(e): MRL is tentative because (some) residue trials samples were stored for a period longer than one month while no studies investigating the storage stability of DMTU are available.
(f): Tentative MRL is derived for feed commodities.
(g): MRL is tentative because of data gaps identified on the nature of residues in processed commodities.
B.1.2.3. Residues in succeeding crops

| Confined rotational crop study (quantitative aspect) | Studies not required considering the field DT$_{90}$ reported in the soil degradation studies (< 100 days) (EFSA, 2011) |
| Field rotational crop study | Not available and not required |

DT$_{90}$: period required for 90% dissipation.

B.1.2.4. Processing factors

No studies available and not required.

B.2. Residues in livestock

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Relevant groups | Dietary burden expressed in | Most critical diet$^{(a)}$ | Most critical commodity$^{(a)}$ | Trigger exceeded (Y/N) |
| --- | --- | --- | --- | --- |
| | mg/kg bw per day | mg/kg DM | Med. | Max. | Med. | Max. |
| Cattle (all diets) | 0.002 | 0.003 | 0.09 | 0.10 | Dairy cattle | Kale, leaves | N |
| Cattle (dairy only) | 0.002 | 0.003 | 0.06 | 0.07 | Dairy cattle | Kale, leaves | N |
| Sheep (all diets) | 0.002 | 0.003 | 0.07 | 0.09 | Lamb | Swede, roots | N |
| Sheep (ewe only) | 0.002 | 0.003 | 0.07 | 0.09 | Ram/Ewe | Swede, roots | N |
| Swine (all diets) | 0.001 | 0.002 | 0.06 | 0.07 | Swine (breeding) | Kale, leaves | N |
| Poultry (all diets) | 0.001 | 0.001 | 0.01 | 0.01 | Poultry broiler | Swede, roots | N |
| Poultry (layer only) | 0.001 | 0.001 | 0.01 | 0.01 | Poultry layer | Swede, roots | N |

Residue definition for risk assessment: methylisothiocyanate (MITC)

bw: body weight; DM: dry matter.

(a): Calculated for the maximum dietary burden.

Residue definition for risk assessment: $N,N'$-dimethylthiourea (DMTU)

bw: body weight; MITC: methylisothiocyanate; DMTU: $N,N'$-dimethylthiourea.

B.2.2. Residues in livestock

Time needed to reach a plateau concentration in milk and eggs (days) | Inconclusive
Metabolism in rat and ruminant similar (Yes/No) | Inconclusive
Animal residue definition for monitoring (RD-Mo) | Inconclusive
Animal residue definition for risk assessment (RD-RA) | Inconclusive
Conversion factor (monitoring to risk assessment) | Inconclusive
Fat soluble residues (Yes/No) | Inconclusive
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | Not available

bw: body weight; MITC: methylisothiocyanate; DMTU: $N,N'$-dimethylthiourea.
B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (months/years) |
|------------------------------------|--------|-----------|--------|-------------------------|
| –                                  | –      | –         | –      | –                       |

Not available and not required for MITC. Studies might be required for DMTU.

MITC: methylisothiocyanate; DMTU: N\(^\prime\),N\(^\prime\)-dimethylthiourea.

B.2.2. Magnitude of residues in livestock

No studies available and not required for MITC. Studies might be required for DMTU.

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment for MITC

| ADI | 0.004 mg/kg bw per day (EFSA, 2010, 2011) |
|-----|-----------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 15.2% ADI (UK toddler) |
| Assumptions made for the calculations | The calculation is based on the median residue levels of MITC arising from metam and dazomet. For plant commodities, the highest residue level resulting from the use of metam and dazomet was considered, assuming that the two active substances are not used together on the same crop. For those commodities where data were not available to derive MRLs and risk assessment values, the current EU MRL were used for an indicative calculation. For animal commodities, no input values were considered, assuming that the uses on feed commodities which are not supported by data would be withdrawn. The contributions of commodities where no GAP was reported, neither in the framework of this review nor in the review of MRLs for dazomet (EFSA, 2019) were not included in the calculation. |

| ARfD | 0.03 mg/kg bw (EFSA, 2010, 2011) |
|------|-------------------------------------|
| Highest IESTI, according to EFSA PRIMo | 66.3% ARfD (cucumbers, metam use) |
| Assumptions made for the calculations | The calculation is based on the highest residue levels of MITC arising from metam and dazomet. For plant commodities, the highest residue level resulting from the use of metam and dazomet was considered, assuming that the two active substances are not used together on the same crop. For those commodities where data were not available to derive MRLs and risk assessment values, the current EU MRLs were used for an indicative calculation. For animal commodities, no input values were considered, assuming that the uses on feed commodities which are not supported by data would be withdrawn. The contributions of commodities where no GAP was reported, neither in the framework of this review nor in the review of MRLs for dazomet (EFSA, 2019) were not included in the calculation. |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; GAP: Good Agricultural Practice; MRL: maximum residue level; ARfD: acute reference dose; IESTI: international estimated short-term intake; MITC: methylisothiocyanate.
B.3.2. Consumer risk assessment for DMTU

| Parameter | Value |
|-----------|-------|
| ADI | 0.001 mg/kg bw per day (assuming ADI derived from metam is the same; EFSA, 2011) |
| Highest IEDI, according to EFSA PRIMo | 28% ADI (FR, infant) |
| Assumptions made for the calculations | The calculation is based on the median residue levels of DMTU arising from metam only (data on DMTU were not available for the uses authorised on dazomet, EFSA, 2019). The plant commodities where data were not available to derive MRLs and risk assessment values for DMTU were not considered because there are no MRLs currently defined for this compound. This applies also to animal commodities, for which risk assessment values could not be derived due to the lack of data. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation. The calculated consumer exposure is indicative only |

| Parameter | Value |
|-----------|-------|
| ARfD | 0.1 mg/kg bw (assuming ARfD derived from metam is the same; EFSA, 2011) |
| Highest IESTI, according to EFSA PRIMo | 14.6% ARfD (carrots) |
| Assumptions made for the calculations | The calculation is based on the highest residue levels of DMTU arising from metam only (data on DMTU were not available for the uses authorised on dazomet, EFSA, 2019). The plant commodities where data were not available to derive MRLs and risk assessment values for DMTU were not considered because there are no MRLs currently defined for this compound. This applies also to animal commodities, for which risk assessment values could not be derived due to the lack of data. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation. The calculated consumer exposure is indicative only |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; GAP: Good Agricultural Practice; MRL: maximum residue level; ARfD: acute reference dose; IESTI: international estimated short-term intake; DMTU: N,N’-dimethylthiourea.

B.4. MRLs derived from metam uses (indicative only)

| Code number | Commodity | Existing EU MRL (mg/kg) | MRL (mg/kg) | Comment |
|-------------|-----------|------------------------|-------------|---------|
| 130010      | Apples    | 0.02*                  | 0.01*       | MRL can be derived from GAP |
| 130020      | Pears     | 0.02*                  | 0.01*       | MRL can be derived from GAP |
| 140020      | Cherries (sweet) | 0.02*      | 0.01*       | MRL can be derived from GAP |
| 140040      | Plums     | 0.02*                  | 0.01*       | MRL can be derived from GAP |
| 151010      | Table grapes | 0.02*              | 0.01*       | MRL can be derived from GAP |
| 151020      | Wine grapes | 0.02*               | 0.01*       | MRL can be derived from GAP |
| 152000      | Strawberries | 0.02*              | 0.03        | MRL can be derived from GAP, tentative |
| 153010      | Blackberries | 0.02*              | 0.01*       | MRL can be derived from GAP |
| 153030      | Raspberries (red and yellow) | 0.02*       | 0.01*       | MRL can be derived from GAP |
| 154010      | Blueberries | 0.02*               | 0.01*       | MRL can be derived from GAP |
| 154020      | Cranberries | 0.02*               | 0.01*       | MRL can be derived from GAP |
| 154030      | Currants (black, red and white) | 0.02*      | 0.01*       | MRL can be derived from GAP |
| 154040      | Gooseberries (green, red and yellow) | 0.02*     | 0.01*       | MRL can be derived from GAP |

Enforcement residue definition (existing): dazomet (methylisothiocyanate resulting from the use of dazomet and metam)

Enforcement residue definition (proposed): methylisothiocyanate (MITC)
| Code number | Commodity                          | Existing EU MRL (mg/kg) | MRL (mg/kg) | Comment                                      |
|-------------|------------------------------------|-------------------------|-------------|----------------------------------------------|
| 211000      | Potatoes                           | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 212020      | Sweet potatoes                     | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 212030      | Yams                               | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 213010      | Beetroots                          | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 213020      | Carrots                            | 0.02                    | 0.01*       | MRL can be derived from GAP, tentative       |
| 213030      | Celeriacs/tunip rooted celeries    | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 213040      | Horseradishes                      | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 213050      | Jerusalem artichokes               | 0.02*                   | 0.01*       | MRL can be derived from GAP, tentative       |
| 213060      | Parsnips                           | 0.02*                   | 0.01*       | MRL can be derived from GAP, tentative       |
| 213070      | Parsley roots/Hamburg roots parsley| 0.02*                   | 0.01*       | MRL can be derived from GAP, tentative       |
| 213080      | Radishes                           | 0.05                    | 0.01*       | MRL can be derived from GAP, tentative       |
| 213090      | Salsiflies                         | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 213100      | Swedes/rutabagas                   | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 213110      | Turnips                            | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 220020      | Onions                             | 0.02*                   | 0.15        | MRL can be derived from GAP                  |
| 220030      | Shallots                           | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 231010      | Tomatoes                           | 0.1                     | 0.4         | MRL can be derived from GAP, tentative       |
| 231020      | Sweet peppers/bell peppers         | 0.1                     | 0.03        | MRL can be derived from GAP, tentative       |
| 231030      | Aubergines/eggplants               | 0.1                     | 0.4         | MRL can be derived from GAP, tentative       |
| 231040      | Okra/lady's fingers                | 0.1                     | 0.1         | GAP is not supported by data (EU MRL reported) |
| 232010      | Cucumbers                          | 0.1                     | 0.6         | MRL can be derived from GAP, tentative       |
| 232020      | Gherkins                           | 0.1                     | 0.6         | MRL can be derived from GAP, tentative       |
| 232030      | Courgettes                         | 0.1                     | 0.6         | MRL can be derived from GAP, tentative       |
| 233010      | Melons                             | 0.1                     | 0.1         | GAP is not supported by data (EU MRL reported) |
| 233020      | Pumpkins                           | 0.1                     | 0.1         | GAP is not supported by data (EU MRL reported) |
| 233030      | Watermelons                        | 0.1                     | 0.1         | GAP is not supported by data (EU MRL reported) |
| 251010      | Lamb's lettuces/corn salads        | 0.03                    | 0.01*       | MRL can be derived from GAP                  |
| 251020      | Lettuces                           | 0.03                    | 0.01*       | MRL can be derived from GAP                  |
| 251030      | Escaroles/broad-leaved endives     | 0.03                    | 0.01*       | MRL can be derived from GAP                  |
| 251040      | Cresses and other sprouts and shoots| 0.03                   | 0.01*       | MRL can be derived from GAP                  |
| 251050      | Land cresses                       | 0.03                    | 0.01*       | MRL can be derived from GAP                  |
| 251060      | Roman rocket/rucola                | 0.03                    | 0.01*       | MRL can be derived from GAP                  |
| 251070      | Red mustards                       | 0.03                    | 0.01*       | MRL can be derived from GAP                  |
| 251080      | Baby leaf crops (including brassica species) | 0.03       | 0.01*       | MRL can be derived from GAP                  |
| 252010      | Spinaches                          | 0.15                    | 0.01*       | MRL can be derived from GAP                  |
| 252020      | Purslaneas                         | 0.15                    | 0.01*       | MRL can be derived from GAP                  |
| 252030      | Chards/beet leaves                 | 0.15                    | 0.01*       | MRL can be derived from GAP                  |
| 254000      | Watercresses                       | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 255000      | Witloofs/Belgian endives           | 0.02*                   | 0.02        | GAP is not supported by data (EU MRL reported) |
| 256010      | Chervil                            | 0.02*                   | 0.01*       | MRL can be derived from GAP                  |
| 256020      | Chives                             | 0.02*                   | 0.01*       | MRL can be derived from GAP                  |
| 256030      | Celery leaves                      | 0.02*                   | 0.01*       | MRL can be derived from GAP                  |
| Code number | Commodity                        | Existing EU MRL (mg/kg) | Outcome of the review | Comment                          |
|------------|----------------------------------|-------------------------|-----------------------|----------------------------------|
| 256040     | Parsley                          | 0.02*                   | 0.01*                 | MRL can be derived from GAP      |
| 256050     | Sage                             | 0.02*                   | 0.01*                 | MRL can be derived from GAP      |
| 256060     | Rosemary                         | 0.02*                   | 0.01*                 | MRL can be derived from GAP      |
| 256070     | Thyme                            | 0.02*                   | 0.01*                 | MRL can be derived from GAP      |
| 256080     | Basil and edible flowers         | 0.02*                   | 0.01*                 | MRL can be derived from GAP      |
| 256090     | Laurel/bay leave                 | 0.02*                   | 0.01*                 | MRL can be derived from GAP      |
| 256100     | Tarragon                         | 0.02*                   | 0.01*                 | MRL can be derived from GAP, tentative |
| 633000     | Herbal infusions from roots      | 0.02*                   | 0.02                  | GAP is not supported by data (EU MRL reported) |
| 900010     | Sugar beet roots                 | 0.02*                   | 0.02                  | GAP is not supported by data (EU MRL reported) |
| –          | Other commodities of plant and/or animal origin | See Reg. 2016/1 | –                     | No GAP is authorised             |

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: Indicate that the MRL is set at the limit of quantification.
Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo total MITC (from metam and dazomet)

### Methylisothiocyanate (MITC)

| Status of the active substance | Code no. | LOQ (mg/kg fw) | Proposed LOQ |
|--------------------------------|----------|----------------|--------------|
| Code no.                       | 0.001    | 0.03           | 0.004        |

| Toxicological end points       | ADI (mg/kg per day) | ARfD (mg/kg bw) |
|--------------------------------|---------------------|-----------------|
| Source of ADI: EFSA            | 2010                | 2010            |

| Year of evaluation: 2010       | Source of ARfD: EFSA |
|--------------------------------|----------------------|

### Chronic risk assessment – refined calculations

| TMDI (range) in % of ADI         | Minimum – Maximum |
|----------------------------------|-------------------|
| No of diets exceeding ADI:       | x                  |

| Commodity/group of commodities   | 215                |
|----------------------------------|--------------------|

**Conclusion:**
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of methylisothiocyanate (MITC) 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.

### Unprocessed commodities

| Threshold MRL (mg/kg) | Commodities | Highest % of ARfD/ADI |
|----------------------|-------------|-----------------------|
| 66.3                 | Cucumbers   | 0.34/-                |
| 52.7                 | Courgettes  | 0.34/-                |
| 43.6                 | Tomatoes    | 0.22/-                |
| 37.9                 | Melons      | 0.075/-               |
| 30.6                 | Watermelons | 0.075/-               |

### Processed commodities

| Threshold MRL (mg/kg) | Commodities | Highest % of ARfD/ADI |
|----------------------|-------------|-----------------------|
| 12.8                 | Tomato juice | 0.22/-               |
| 1.7                  | Apple juice  | 0.01/-                |
| 1.7                  | Orange juice | 0.01/-                |
| 1.6                  | Carrot, juice| 0.01/-                |
| 1.1                  | Grape juice  | 0.01/-                |

### Conclusion:

For methylisothiocyanate (MITC) 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.

For processed commodities, no exceedance of the ARfD/ADI was identified.
### Chronic risk assessment – refined calculations

| Highest calculated TMDI values in % of ADI | MS Diet | Highest contributor to MS diet (in % of ADI) | Commodity/group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity/group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity/group of commodities | pTMRLs at LOQ (in % of ADI) |
|------------------------------------------|---------|---------------------------------------------|--------------------------------|----------------------------------------|--------------------------------|----------------------------------------|--------------------------------|---------------------------|
| 28.0 FR Infant                           | 23.3    | Carrots                                    | 2.5                          | Apples                                 | 0.7                          | Courgettes                            |                                 |                           |
| 27.4 FR Toddler                          | 21.5    | Carrots                                    | 2.6                          | Apples                                 | 0.8                          | Tomatoes                              |                                 |                           |
| 26.6 DE Child                            | 12.1    | Apples                                     | 9.0                          | Carrots                                | 1.3                          | Table grapes                          |                                 |                           |
| 16.0 DK Child                            | 12.1    | Carrots                                    | 2.3                          | Apples                                 | 1.6                          | Cucumbers                             |                                 |                           |
| 14.6 NL Child                            | 6.3     | Apples                                     | 4.4                          | Carrots                                | 0.8                          | Table grapes                          |                                 |                           |
| 14.8 UK Infant                           | 11.6    | Carrots                                    | 1.6                          | Apples                                 | 0.4                          | Tomatoes                              |                                 |                           |
| 14.7 IE Adult                            | 5.6     | Parsnips                                   | 2.8                          | Carrots                                | 1.3                          | Wine grapes                           |                                 |                           |
| 12.8 SE general population 90th percentile | 7.5    | Carrots                                    | 1.1                          | Apples                                 | 0.8                          | Tomatoes                              |                                 |                           |
| 12.7 WHO Cluster diet B                 | 3.1     | Tomatoes                                   | 2.2                          | Carrots                                | 1.8                          | Wine grapes                           |                                 |                           |
| 11.4 PT General population               | 5.9     | Carrots                                    | 2.5                          | Wine grapes                            | 1.1                          | Apples                                |                                 |                           |
| 9.1 FR all population                   | 4.0     | Wine grapes                                | 2.6                          | Carrots                                | 0.5                          | Apples                                |                                 |                           |
| 8.8 WHO Cluster diet E                  | 4.0     | Carrots                                    | 1.6                          | Wine grapes                            | 0.8                          | Apples                                |                                 |                           |
| 8.3 UK Toddler                           | 4.6     | Carrots                                    | 1.7                          | Apples                                 | 0.6                          | Tomatoes                              |                                 |                           |
| 7.6 WHO regional European diet          | 3.7     | Carrots                                    | 2.0                          | Apples                                 | 0.5                          | Tomatoes                              |                                 |                           |
| 7.4 UK Adult                             | 3.9     | Carrots                                    | 1.4                          | Wine grapes                            | 0.9                          | Apples                                |                                 |                           |
| 7.3 WHO Cluster diet F                   | 4.2     | Carrots                                    | 0.7                          | Tomatoes                               | 0.7                          | Apples                                |                                 |                           |
| 6.7 WHO Cluster diet D                   | 2.0     | Carrots                                    | 1.0                          | Tomatoes                               | 0.7                          | Apples                                |                                 |                           |
| 5.7 IT kids/toddler                     | 1.6     | Carrots                                    | 1.4                          | Tomatoes                               | 0.9                          | Apples                                |                                 |                           |
| 5.6 NL general                           | 1.9     | Carrots                                    | 1.2                          | Apples                                 | 0.8                          | Wine grapes                           |                                 |                           |
| 5.3 ES child                             | 1.6     | Carrots                                    | 1.1                          | Apples                                 | 1.0                          | Tomatoes                              |                                 |                           |
| 5.1 UK vegetarian                       | 2.0     | Carrots                                    | 0.8                          | Wine grapes                            | 0.8                          | Tomatoes                              |                                 |                           |
| 5.0 IT adult                             | 1.3     | Carrots                                    | 1.2                          | Apples                                 | 0.8                          | Tomatoes                              |                                 |                           |
| 4.8 LT adult                             | 1.9     | Apples                                     | 1.5                          | Carrots                                | 0.8                          | Tomatoes                              |                                 |                           |
| 4.8 ES adult                            | 1.3     | Carrots                                    | 0.8                          | Apples                                 | 0.6                          | Tomatoes                              |                                 |                           |
| 4.3 UK Adult                             | 1.6     | Carrots                                    | 1.1                          | Wine grapes                            | 0.4                          | Tomatoes                              |                                 |                           |
| 3.6 FI adult                            | 1.7     | Carrots                                    | 0.4                          | Tomatoes                               | 0.4                          | Apples                                |                                 |                           |

**Conclusion:**
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of N,N'-dimethylthiourea (DTMU) is unlikely to present a public health concern.
Acute risk assessment/children - refined calculations

Acute risk assessment/adults/general population – 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.

### Table: Highest % of ARfD/ADI

| Commodity         | pTMRL (mg/kg) | Commodity         | pTMRL (mg/kg) | Commodity         | pTMRL (mg/kg) | Commodity         | pTMRL (mg/kg) |
|-------------------|---------------|-------------------|---------------|-------------------|---------------|-------------------|---------------|
| Carrots           | 0.23/-        | Scarola (broad-leaf) | 0.136/-      | Orions            | 0.35/-        | Carrots           | 0.23/-        |
| Scarola (broad-leaf) | 0.136/-      | Orions            | 0.35/-        | Paransip         | 0.23/-        | Radishes          | 0.23/-        |
| Parsnips          | 0.23/-        | Cucumbers         | 0.069/-       | Courgettes        | 0.069/-       | Courgettes        | 0.069/-       |
| Radishes          | 0.23/-        |                   |               |                   |               |                   |               |

No of commodities for which ARfD/ADI is exceeded (IESTI 1):

| Commodity         | pTMRL (mg/kg) | Commodity         | pTMRL (mg/kg) | Commodity         | pTMRL (mg/kg) | Commodity         | pTMRL (mg/kg) |
|-------------------|---------------|-------------------|---------------|-------------------|---------------|-------------------|---------------|
| Carrot, juice     | 0.23/-        | Apple juice       | 0.01/-        | Wine              | 0.01/-        | Raisins           | 0.01/-        |
| Apple juice       | 0.01/-        | Grape juice       | 0.01/-        | Tomato (preserved)| 0.01/-        |                   |               |
| Grape juice       | 0.01/-        | Pear juice        | 0.01/-        |                   |               |                   |               |
| Pear juice        | 0.01/-        | Tomato (preserved)| 0.01/-        |                   |               |                   |               |
| Tomato (preserved)| 0.01/-        |                   |               |                   |               |                   |               |

No of commodities for which ARfD/ADI is exceeded (IESTI 2):

| Commodity         | pTMRL (mg/kg) | Commodity         | pTMRL (mg/kg) | Commodity         | pTMRL (mg/kg) | Commodity         | pTMRL (mg/kg) |
|-------------------|---------------|-------------------|---------------|-------------------|---------------|-------------------|---------------|
| Carrot, juice     | 0.23/-        | Apple juice       | 0.01/-        | Wine              | 0.01/-        | Raisins           | 0.01/-        |
| Apple juice       | 0.01/-        | Grape juice       | 0.01/-        | Tomato (preserved)| 0.01/-        |                   |               |
| Grape juice       | 0.01/-        | Pear juice        | 0.01/-        |                   |               |                   |               |
| Pear juice        | 0.01/-        | Tomato (preserved)| 0.01/-        |                   |               |                   |               |

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

### Conclusion:

For N,N’-dimethylthiourea (DTMU), 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.

For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity | Median dietary burden | Maximum dietary burden |
|----------------|-----------------------|------------------------|
|                | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Risk assessment residue definition 1: methylisothiocyanate (MITC) | | | | |
| Kales, leaves | 0.01 | STMR (dazomet) | 0.02 | HR (dazomet) |
| Turnips, tops (leaves) | 0.01 | STMR (metam) | 0.03 | HR (metam) |
| Potatoes, culls | 0.01* | STMR (dazomet) | 0.01* | HR (dazomet) |
| Carrots, culls | 0.01* | STMR (dazomet) | 0.01 | HR (dazomet) |
| Swedes, roots | 0.01* | STMR (dazomet) | 0.01 | HR (dazomet) |
| Turnips, roots | 0.01* | STMR (dazomet) | 0.01 | HR (dazomet) |
| Apples, wet pomace | 0.01* | STMR (dazomet/metam) | 0.01* | STMR (dazomet/metam) |
| Citrus, dried pulp | 0.01* | STMR (dazomet) | 0.01* | STMR (dazomet) |
| Coconut, meal | 0.01* | STMR (dazomet) | 0.01* | STMR (dazomet) |
| Potatoes, process waste | 0.01* | STMR (dazomet) | 0.01* | STMR (dazomet) |
| Potatoes, dried pulp | 0.01* | STMR (dazomet) | 0.01* | STMR (dazomet) |
| Risk assessment residue definition 2: N,N'-dimethylthiourea (DMTU) | | | | |
| Turnips, tops (leaves) | 0.01* | STMR (metam) | 0.02 | HR (metam) |
| Carrot, culls | 0.09 | STMR (metam) | 0.02 | HR (metam) |
| Apples, wet pomace | 0.01* | STMR (metam) | 0.01* | STMR (metam) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
*: Indicates that the input value is proposed at the limit of quantification.
(a): The input values are derived from dazomet uses (EFSA, 2019). The GAP on metam is either not supported by data, either less critical or there is no GAP authorised on metam.
(b): The input values are derived from metam uses. The GAP on dazomet is not supported by data.
(c): For fruit pomace, coconut meal and potatoes by-products, no default processing factor was applied because residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.
(d): The input values derived from metam and dazomet uses are the same.
(e): The input values for DMTU are derived from metam uses only (limited data). There is no data on DMTU for supporting the GAPs on dazomet (EFSA, 2019). The calculated dietary burden is indicative only.

D.2. Consumer risk assessment for MITC

| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|----------------------|
|           | Input value (mg/kg)     | Comment              | Input value (mg/kg)     | Comment              |
| Risk assessment residue definition 1: methylisothiocyanate (MITC) | | | | |
| Grapefruits | 0.01* | STMR (dazomet) | 0.01* | HR (dazomet) |
| Oranges | 0.01* | STMR (dazomet) | 0.01* | HR (dazomet) |
| Lemons | 0.01* | STMR (dazomet) | 0.01* | HR (dazomet) |
| Limes | 0.01* | STMR (dazomet) | 0.01* | HR (dazomet) |
| Mandarins | 0.01* | STMR (dazomet) | 0.01* | HR (dazomet) |
| Almonds | 0.01* | STMR (dazomet, tentative) | 0.01* | HR (dazomet, tentative) |
| Brazil nuts | 0.01* | STMR (dazomet, tentative) | 0.01* | HR (dazomet, tentative) |
| Cashew nuts | 0.01* | STMR (dazomet, tentative) | 0.01* | HR (dazomet, tentative) |
| Chestnuts | 0.01* | STMR (dazomet, tentative) | 0.01* | HR (dazomet, tentative) |
| Coconuts | 0.01* | STMR (dazomet, tentative) | 0.01* | HR (dazomet, tentative) |
| Hazelnuts/cobnuts | 0.01* | STMR (dazomet, tentative) | 0.01* | HR (dazomet, tentative) |
| Macadamias | 0.01* | STMR (dazomet, tentative) | 0.01* | HR (dazomet, tentative) |
## Commodity, Chronic risk assessment, Acute risk assessment

| Commodity                      | Input value (mg/kg) | Comment                              | Input value (mg/kg) | Comment                              |
|--------------------------------|--------------------|--------------------------------------|--------------------|--------------------------------------|
| Pecans                         | 0.01*              | STMR (dazomet, tentative)            | 0.01*              | HR (dazomet, tentative)              |
| Pine nut kernels               | 0.01*              | STMR (dazomet, tentative)            | 0.01*              | HR (dazomet, tentative)              |
| Pistachios                     | 0.01*              | STMR (dazomet, tentative)            | 0.01*              | HR (dazomet, tentative)              |
| Walnuts                        | 0.01*              | STMR (dazomet, tentative)            | 0.01*              | HR (dazomet, tentative)              |
| Apples                         | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Pears                          | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Quinces                        | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Medlars                        | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Loquats/Japanese medlars        | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Apricots                       | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Cherries (sweet)               | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Peaches                        | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Plums                          | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Table grapes                   | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Wine grapes                    | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Strawberries                   | 0.01*              | STMR (dazomet)                       | 0.02               | HR (dazomet, tentative)              |
| Blackberries                   | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Dewberries                     | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Raspberries (red and yellow)   | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Blueberries                    | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Cranberries                    | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Currants (black, red and white)| 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Gooseberries (green, red and yellow) | 0.01*              | STMR (metam/dazomet)                 | 0.01*              | HR (metam/dazomet)                   |
| Rose hips                      | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Mulberries (black and white)   | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Azaroles/Mediterranean medlars  | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Elderberries                   | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Figs                           | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Table olives                   | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Kumquats                       | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Kaki/Japanese persimmons       | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Kiwi fruits (green, red, yellow)| 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Prickly pears/cactus fruits    | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Avocados                       | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Mangoes                        | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Granate apples/pomegranates    | 0.01*              | STMR (dazomet)                       | 0.01*              | HR (dazomet)                        |
| Potatoes                       | 0.02               | EU MRL (metam)                       | 0.02               | EU MRL (metam)                       |
| Sweet potatoes                 | 0.02               | EU MRL (metam)                       | 0.02               | EU MRL (metam)                       |
| Commodity                                | Chronic risk assessment | Acute risk assessment |
|------------------------------------------|-------------------------|-----------------------|
| **Input value (mg/kg)**                  |                         | **Input value (mg/kg)** |
| **Comment**                              |                         | **Comment**           |
| **Yams**                                 | 0.02 EU MRL (metam)     | 0.02 EU MRL (metam)   |
| **Beetroots**                            | 0.01* STMR (dazomet, tentative) | 0.011 HR (dazomet, tentative) |
| **Carrots**                              | 0.01* STMR (dazomet, tentative) | 0.011 HR (dazomet, tentative) |
| **Celery/radishes**                      | 0.01* STMR (dazomet, tentative) | 0.011 HR (dazomet, tentative) |
| **Jerusalem artichokes**                 | 0.01* STMR (dazomet, tentative) | 0.011 HR (dazomet, tentative) |
| **Parsnips**                             | 0.01* STMR (dazomet, tentative) | 0.011 HR (dazomet, tentative) |
| **Parsley roots/Hamburg roots parsley**  | 0.01* STMR (dazomet, tentative) | 0.011 HR (dazomet, tentative) |
| **Radishes**                             | 0.01* STMR (dazomet, tentative) | 0.03 HR (dazomet, tentative) |
| **Salsifies**                            | 0.01* STMR (dazomet, tentative) | 0.011 HR (dazomet, tentative) |
| **Swedes/rutabagas**                     | 0.01* STMR (dazomet, tentative) | 0.011 HR (dazomet, tentative) |
| **Turnips**                              | 0.01* STMR (dazomet, tentative) | 0.011 HR (dazomet, tentative) |
| **Onions**                               | 0.012 STMR (metam)      | 0.09 HR (metam)       |
| **Shallots**                             | 0.02 EU MRL (metam)     | 0.02 EU MRL (metam)   |
| **Tomatoes**                             | 0.01* STMR (metam, tentative) | 0.22 HR (metam, tentative) |
| **Sweet peppers/bell peppers**           | 0.01* STMR (dazomet, tentative) | 0.08 HR (dazomet, tentative) |
| **Aubergines/eggplants**                 | 0.01* STMR (metam, tentative) | 0.22 HR (metam, tentative) |
| **Okra/lady's fingers**                  | 0.01* STMR (dazomet, tentative) | 0.08 HR (dazomet, tentative) |
| **Cucumbers**                            | 0.01* STMR (metam, tentative) | 0.34 HR (metam, tentative) |
| **Gherkins**                             | 0.01* STMR (metam, tentative) | 0.34 HR (metam, tentative) |
| **Courgettes**                           | 0.01* STMR (metam, tentative) | 0.34 HR (metam, tentative) |
| **Melons**                               | 0.01* STMR (dazomet, tentative) | 0.08 HR (dazomet, tentative) |
| **Pumpkins**                             | 0.01* STMR (dazomet, tentative) | 0.08 HR (dazomet, tentative) |
| **Watermelons**                          | 0.01* STMR (dazomet, tentative) | 0.08 HR (dazomet, tentative) |
| **Broccoli**                             | 0.02 EU MRL (dazomet)    | 0.02 EU MRL (dazomet)  |
| **Cauliflowers**                         | 0.02 EU MRL (dazomet)    | 0.02 EU MRL (dazomet)  |
| **Head cabbages**                        | 0.02 EU MRL (dazomet)    | 0.02 EU MRL (dazomet)  |
| **Chinese cabbages/pe-tsai**             | 0.01* STMR (dazomet, tentative) | 0.02 HR (dazomet, tentative) |
| **Kales**                                | 0.01* STMR (dazomet, tentative) | 0.02 HR (dazomet, tentative) |
| **Lamb's lettuces/corn salads**          | 0.01* STMR (dazomet, tentative) | 0.02 HR (dazomet, tentative) |
| **Lettuces**                             | 0.01* STMR (dazomet, tentative) | 0.02 HR (dazomet, tentative) |
| **Escaroles/broad-leaved endives**       | 0.01* STMR (dazomet, tentative) | 0.02 HR (dazomet, tentative) |
| **Cresses and other sprouts and shoots** | 0.01* STMR (dazomet, tentative) | 0.02 HR (dazomet, tentative) |
| **Land cresses**                         | 0.01* STMR (dazomet, tentative) | 0.02 HR (dazomet, tentative) |
| **Roman rocket/rucola**                  | 0.01* STMR (dazomet, tentative) | 0.02 HR (dazomet, tentative) |
| **Red mustards**                         | 0.01* STMR (dazomet, tentative) | 0.02 HR (dazomet, tentative) |
| **Baby leaf crops (including brassica species)** | 0.01* STMR (dazomet, tentative) | 0.02 HR (dazomet, tentative) |
| **Spinaches**                            | 0.02 STMR (dazomet, tentative) | 0.09 HR (dazomet, tentative) |
| **Purslanes**                            | 0.02 STMR (dazomet, tentative) | 0.09 HR (dazomet, tentative) |
### Consumer risk assessment for DMTU

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Apples                           | 0.01*                   | STMR (metam)          | 0.01*               | HR (metam)            |
| Pears                            | 0.01*                   | STMR (metam)          | 0.01*               | HR (metam)            |
| Cherries (sweet)                 | 0.01*                   | STMR (metam)          | 0.01*               | HR (metam)            |
| Plums                            | 0.01*                   | STMR (metam)          | 0.01*               | HR (metam)            |
| Table grapes                     | 0.01*                   | STMR (metam)          | 0.01*               | HR (metam)            |
| Wine grapes                      | 0.01*                   | STMR (metam)          | 0.01*               | HR (metam)            |

### Notes

- **STMR**: supervised trials median residue; **HR**: highest residue; **MRL**: maximum residue level.
- *: Indicates that the input value is proposed at the limit of quantification.
- EU MRL (dazomet): The GAP on dazomet is not supported by data (EFSA, 2019). The current MRL is used for an indicative assessment. There is no GAP on metam.
- EU MRL (metam): The GAP on metam is not supported by data (see Section 1). The current MRL is used for an indicative assessment. There is no GAP on dazomet or the GAP on dazomet leads to a lower MRL (EFSA, 2019).
- STMR/HR (dazomet): The risk assessment values are derived from a dazomet use (EFSA, 2019). The GAP on metam is either not supported by data, either less critical or there is no GAP authorised on metam.
- STMR/HR (metam): The risk assessment values are derived from a metam use. The GAP on dazomet is less critical or there is no GAP authorised on dazomet (EFSA, 2019).
- STMR/HR (metam/dazomet): Same risk assessment values are derived from a metam or dazomet use.
| Commodity                          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Strawberries                      | 0.01*                   | STMR (metam, tentative)| 0.03               | HR (metam, tentative) |
| Blackberries                      | 0.01*                   | STMR (metam)          | 0.01*              | HR (metam)            |
| Raspberries (red and yellow)      | 0.01*                   | STMR (metam)          | 0.01*              | HR (metam)            |
| Blueberries                       | 0.01*                   | STMR (metam)          | 0.01*              | HR (metam)            |
| Cranberries                       | 0.01*                   | STMR (metam)          | 0.01*              | HR (metam)            |
| Currants (black, red and white)   | 0.01*                   | STMR (metam)          | 0.01*              | HR (metam)            |
| Gooseberries (green, red and yellow) | 0.01*               | STMR (metam)          | 0.01*              | HR (metam)            |
| Potatoes                          | –                       | No data available     | –                  | No data available     |
| Sweet potatoes                    | –                       | No data available     | –                  | No data available     |
| Yams                              | –                       | No data available     | –                  | No data available     |
| Beetroots                         | –                       | No data available     | –                  | No data available     |
| Carrots                           | 0.09                    | STMR (metam, tentative)| 0.23               | HR (metam, tentative) |
| Celeriacs/turnip rooted celeries  | –                       | No data available     | –                  | No data available     |
| Horseradishes                     | –                       | No data available     | –                  | No data available     |
| Jerusalem artichokes              | 0.09                    | STMR (metam, tentative)| 0.23               | HR (metam, tentative) |
| Parsnips                          | 0.09                    | STMR (metam, tentative)| 0.23               | HR (metam, tentative) |
| Parsley roots/Hamburg roots parsley | 0.09               | STMR (metam, tentative)| 0.23               | HR (metam, tentative) |
| Radishes                          | 0.09                    | STMR (metam, tentative)| 0.23               | HR (metam, tentative) |
| Salsifies                         | –                       | No data available     | –                  | No data available     |
| Swedes/rutabagas                  | –                       | No data available     | –                  | No data available     |
| Turnips                           | –                       | No data available     | –                  | No data available     |
| Onions                            | 0.01                    | STMR (metam, tentative)| 0.35               | HR (metam, tentative) |
| Shallots                          | –                       | No data available     | –                  | No data available     |
| Tomatoes                          | 0.01*                   | STMR (metam, tentative)| 0.01*              | HR (metam, tentative) |
| Sweet peppers/bell peppers        | –                       | No data available     | –                  | No data available     |
| Aubergines/eggplants              | 0.01*                   | STMR (metam, tentative)| 0.01*              | HR (metam, tentative) |
| Okra/lady’s fingers               | –                       | No data available     | –                  | No data available     |
| Cucumbers                         | 0.01*                   | STMR (metam)          | 0.07               | HR (metam)            |
| Gherkins                          | 0.01*                   | STMR (metam)          | 0.07               | HR (metam)            |
| Courgettes                        | 0.01*                   | STMR (metam)          | 0.07               | HR (metam)            |
| Melons                            | –                       | No data available     | –                  | No data available     |
| Pumpkins                          | –                       | No data available     | –                  | No data available     |
| Watermelons                       | –                       | No data available     | –                  | No data available     |
| Lamb’s lettuces/com salads         | 0.01                    | STMR (metam, tentative)| 0.14               | HR (metam, tentative) |
| Lettuces                          | 0.01                    | STMR (metam, tentative)| 0.14               | HR (metam, tentative) |
| Escaroles/broad-leaved endives     | 0.01                    | STMR (metam, tentative)| 0.14               | HR (metam, tentative) |
| Cresses and other sprouts and shoots | 0.01                | STMR (metam, tentative)| 0.14               | HR (metam, tentative) |
| Land cresses                       | 0.01                    | STMR (metam, tentative)| 0.14               | HR (metam, tentative) |
| Roman rocket/rucola               | 0.01                    | STMR (metam, tentative)| 0.14               | HR (metam, tentative) |
| Commodity                              | Chronic risk assessment |          | Acute risk assessment |          |
|----------------------------------------|-------------------------|----------|-----------------------|----------|
|                                        | Input value (mg/kg)     | Comment  | Input value (mg/kg)   | Comment  |
| Red mustards                           | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Baby leaf crops (including brassica species) | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Spinaches                              | 0.01*                   | STMR (metam, tentative) | 0.01*    | HR (metam, tentative) |
| Purslanes                              | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Chards/beet leaves                     | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Watercresses                           | –                       | No data available | –         | No data available |
| Witloofs/Belgian endives               | –                       | No data available | –         | No data available |
| Chervil                                | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Chives                                 | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Celery leaves                          | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Parsley                                | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Sage                                   | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Rosemary                               | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Thyme                                  | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Basil and edible flowers               | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Laurel/bay leave                       | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Tarragon                               | 0.01                    | STMR (metam, tentative) | 0.14     | HR (metam, tentative) |
| Herbal infusions from roots            | –                       | No data available | –         | No data available |
| Sugar beet roots                       | –                       | No data available | –         | No data available |

STMR: supervised trials median residue; HR: highest residue.

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

(a): The input values for DMTU are derived from metam uses only (limited data). There is no data on DMTU for supporting the GAPs on dazomet (EFSA, 2019).
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg DM in EU?
  - Yes
  - MRL derived in Section 3?
    - Yes
      - MRL fully supported by data?
        - Yes
          - MRL is recommended.
        - No
          - Risk identified?
            - Yes
              - Fall-back MRL available?
                - Yes
                  - MRL is recommended.
                - No
                  - Not considered for the RA.
            - No
              - Tentative median/highest values are included in the RA.
  - No
    - MRL fully supported by data?
      - Yes
        - MRL is recommended.
      - No
        - Risk identified?
          - Yes
            - Fall-back MRL available?
              - Yes
                - MRL is recommended.
              - No
                - Not considered for the RA.
          - No
            - Tentative median/highest values are included in the RA.

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

- Not considered for the RA.
- Current EU MRL is included in the RA.
- Tentative median/highest values are included in the RA.
- Median/highest values are included in the RA.
- Risk identified?
  - Yes
    - Fall-back MRL available?
      - Yes
        - MRL is recommended.
      - No
        - Not considered for the RA.
  - No
    - Risk identified?
      - Yes
        - Fall-back MRL available?
          - Yes
            - MRL is recommended.
          - No
            - Not considered for the RA.
      - No
        - Tentative median/highest values are included in the RA.

Recommendations resulting from EU authorisations and import tolerances

- (A) Specific LOQ or default MRL?
- (B) Specific LOQ or default MRL?
- (C) Maintain current EU MRL?
- (D) Specific LOQ or default MRL?
- (E) Establish tentative EU MRL?
- (F) Specific LOQ or default MRL?
- (G) MRL is recommended.

Comparison with CXLs
Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes: RD comparable?
    - Yes: CXL higher?
      - Yes: Maintain EU recommendation; higher CXL is not safe for consumer.
      - No: Input values for the RA remain unchanged.
    - No: CXL supported by data?
      - Yes: Codex median/highest residues are included in the RA.
      - No: Risk identified?
        - Yes: Recommendations with consideration of the existing CXL.
        - No: Consumers' risk assessment with consideration of the existing CXL.
  - No: RD comparable?
    - Yes: CXL supported by data?
      - Yes: Codex median/highest residues are included in the RA.
      - No: Risk identified?
        - Yes: Recommendations with consideration of the existing CXL.
        - No: Consumers' risk assessment with consideration of the existing CXL.
    - No: Risk identified?
      - Yes: Recommendations with consideration of the existing CXL.
      - No: Consumers' risk assessment with consideration of the existing CXL.

Consumer risk assessment with consideration of the existing CXL

- CXL supported by data?
  - Yes: Codex median/highest residues are included in the RA.
  - No: Risk identified?
    - Yes: Recommendations with consideration of the existing CXL.
    - No: Consumers' risk assessment with consideration of the existing CXL.

Recommendations with consideration of the existing CXL

- (I) Maintain EU recommendation indicating that no CXL is available.
- (II) Maintain EU recommendation indicating CXL is not compatible.
- (III) Maintain EU recommendation indicating that CXL is covered.
- (IV) Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
- (V) Maintain EU recommendation; higher CXL is not safe for consumer.
- (VI) Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
- (VII) CXL is recommended; EU recommendation is covered as well.
## Appendix F – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChIKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-----------------------------------------------|---------------------------------|
| **Dazomet**                     | 3,5-dimethyl-1,3,5-thiadiazinane-2-thione      | ![Structural formula for Dazomet](image) |
|                                 | S=C1SCN(C)CN1C                                 |                                 |
|                                 | QAYICIQNSGETAS-UHFFFAOYSA-N                   |                                 |
| **Metam**                       | methylthiocarbamic acid                        | ![Structural formula for Metam](image) |
|                                 | SC(NC)=S                                       |                                 |
|                                 | HYVVIDQGFXBRZ-UHFFFAOYSA-N                    |                                 |
| **methylisothiocyanate (MITC)** | methylisothiocyanate                           | ![Structural formula for methylisothiocyanate](image) |
|                                 | or isothiocyanatomethane                      |                                 |
|                                 | C\N=C=S                                        |                                 |
|                                 | LGDSHYSYDSCRFAB-UHFFFAOYSA-N                  |                                 |
| **N,N'-dimethylthiourea (DMTU)** | N,N'-dimethylthiourea                         | ![Structural formula for N,N'-dimethylthiourea](image) |
|                                 | or 1,3-dimethylthiourea                       |                                 |
|                                 | S=C(NC)NC                                      |                                 |
|                                 | VLCDOUXFNUCKK-UHFFFAOYSA-N                    |                                 |
| **methylamine**                 | methanamine                                    | ![Structural formula for methylamine](image) |
|                                 | CN                                             |                                 |
|                                 | BAVYZALUXFZLV-UHFFFAOYSA-N                    |                                 |
| **1,1,3-trimethylthiourea (TMTU)** | 1,1,3-trimethylthiourea                       | ![Structural formula for 1,1,3-trimethylthiourea](image) |
|                                 | CN(C)C(-S)NC                                   |                                 |
|                                 | JAEZSIYWDWMMN-UHFFFAOYSA-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).