Modification of the existing maximum residue levels for mancozeb in various crops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Indofil Industries Limited submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRLs) for the active substance mancozeb in garlic, broccoli, cauliflowers and leeks. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the crops under consideration. Based on the risk assessment results, EFSA derived recommendations for further consideration by the risk managers. Adequate analytical methods for enforcement are available to control the residues of mancozeb in the crops under consideration.

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Keywords: mancozeb, garlic, broccoli, cauliflower, leek, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Indoﬁl Industries Limited submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance mancozeb in garlic, broccoli, cauliflowers and leeks. Germany drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 1 June 2017. To accommodate for the intended uses of mancozeb, the EMS proposed to raise the existing MRLs:

- from 0.6 to 0.9 mg/kg in garlic,
- from 1 to 4 mg/kg in broccoli,
- from 1 to 4 mg/kg in cauliflowers and
- from 3 to 6 mg/kg in leeks.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identiﬁed data gaps, which were requested from the EMS. On 12 September 2019, the EMS submitted the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessment, the additional data provided by the EMS in the framework of this application, and also the recent conclusion on the peer review of the pesticide risk assessment of the active substance mancozeb in accordance with Regulation (EC) No 1107/2009, the following conclusions are derived.

The metabolism of mancozeb was investigated in primary crops belonging to the groups of fruit crops, root and tuber vegetables, cereals, pulses/oilseeds. EFSA concluded that for the crops assessed in this application, the metabolism of mancozeb has been suﬃciently addressed.

The crops under consideration can be grown in rotation with other plants and, therefore, residues of mancozeb may be expected to occur in succeeding crops as a result of the use of the product in primary crops. Data from soil degradation studies, however, suggest that mancozeb is rapidly biodegraded in soil and, therefore, investigation on the occurrence of residues of mancozeb and metabolites in rotational crops is not necessary.

Based on the studies assessed in the framework of Directive 91/414/EEC, the following residue definitions were derived.

The residue deﬁnition for enforcement was proposed as ‘dithiocarbamates (mancozeb) expressed as carbon disulfide (CS2)’. Since CS2 is the common moiety generated by analytical methods used for all dithiocarbamates, Regulation (EC) No 396/2005 establishes a screening residue deﬁnition for dithiocarbamates (maneb, mancozeb, metiram, propineb, thiram and ziram) expressed as CS2. For primary and rotational crops, the residue deﬁnition for risk assessment was proposed as ‘dithiocarbamates (mancozeb), expressed as mancozeb’. Since mancozeb was not stable in the hydrolysis studies simulating standard processing conditions, the residue deﬁnition for risk assessment in processed commodities was proposed as ‘mancozeb and ETU’.

Sufﬁciently validated analytical methods are available to quantify residues of mancozeb (expressed as CS2) in the crops assessed in this application according to the residue deﬁnition for enforcement.

It is highlighted that EFSA has recently published the conclusion on the peer review of the pesticide risk assessment of the active substance mancozeb under Regulation (EC) No 1107/2009. In the EFSA conclusion, the residue deﬁnition for enforcement was conﬁrmed, while for the raw agricultural commodities, a new residue deﬁnition for risk assessment, including also ETU, has been proposed.

However, this new residue deﬁnition for risk assessment was not considered in the current assessment.

The available residue trials in primary crops are suﬃcient to derive MRL proposals of 0.9 mg/kg for garlic, 4 mg/kg for broccoli and cauliflowers and 6 mg/kg for leeks.

Speciﬁc studies investigating the magnitude of mancozeb and ETU residues in processed commodities were submitted for the crops under assessment: garlic (studies on dry onions), broccoli (cleaned, cooked), cauliflowers (cleaned, cooked) and leeks (cleaned, cooked). Processing factors (PF) were derived for mancozeb from these studies in all processed commodities. For ETU, tentative PFS were derived for processed broccoli and leeks based on limited data sets.

Residues of mancozeb in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.
The toxicological profiles of mancozeb and ETU were first assessed in the framework of the European Union (EU) pesticides peer review under Directive 91/414/EEC where data were sufficient to derive an acute reference dose (ARfD) of 0.6 mg/kg body weight (bw) and an acceptable daily intake (ADI) of 0.05 mg/kg bw per day. An ARfD and an ADI for ethylenethiourea (ETU) were also derived at 0.05 mg/kg bw and 0.002 mg/kg bw per day, respectively. Nevertheless, lower toxicological reference values were recently derived in the framework of the renewal of the approval of mancozeb under Regulation (EC) No 1107/2009, noting that the values are not yet formally adopted. The data were sufficient to derive an ARfD for mancozeb of 0.05 mg/kg bw and an ADI of 0.002 mg/kg bw per day. The ADI for ethylenethiourea (ETU) was confirmed at 0.05 mg/kg bw per day while a new ARfD was derived at 0.002 mg/kg bw. Therefore, the consumer risk assessment was performed considering both the current toxicological reference values derived under the Directive 91/414/EEC (scenario 1) and the new toxicological reference values derived under Reg. (EC) No 1107/2009 (scenario 2). For both scenarios, the consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo).

When considering scenario 1, the short-term and the long-term exposures calculated in relation to the MRL proposals under assessment did not exceed the toxicological reference values. The highest acute consumer exposure in percentage of ARfD was calculated to be 57% for leeks, 47% for cauliflowers, 34% for broccoli and < 1% for garlic. The highest chronic intake was calculated to be 86% of the ADI (NL, toddler). The contribution of residues in garlic, broccoli, cauliflowers and leeks to the total consumer exposure accounted for less than 1% of the ADI each.

When considering, scenario 2, an acute consumer intake concern was identified in relation to the MRL proposal for leeks (7.3% of ARfD), cauliflowers (3.2% of ARfD) and broccoli (2.0% of ARfD). The highest acute consumer exposure in percentage of ARfD for garlic was 0.002 (DE child) and 0.001 (NL child) of the ADI. The contribution of residues in garlic, broccoli, cauliflowers and leeks to the total consumer exposure accounted for less than 0.001 of the ADI each.

Based on the above, further risk management considerations are required (see summary table below). Member states are recommended to be vigilant while monitoring residues of mancozeb in garlic, broccoli, cauliflowers and leeks as the crops under assessment have high natural background levels of CS2 and the available enforcement methods cannot distinguish between levels of naturally occurring CS2 and those arising from the use of dithiocarbamates.

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

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|------------|------------------------|-------------------------|-----------------------|
| 0220010 | Garlic     | 0.6                    | Further risk management considerations are required | The submitted data are sufficient to derive an MRL proposal of 0.9 mg/kg for the NEU use by extrapolation from results on onions. The short-term and the long-term exposures calculated in relation to the MRL proposal did not exceed the toxicological reference values currently applicable |

Considering the ADI recently derived in the framework of the process of renewal of mancozeb (EU peer review), Nevertheless, the contribution of residues in garlic to the consumer exposure is minor (0.05% of ARfD; less than 0.001% of the ADI). Further risk management considerations are required
| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-----------------|-----------|------------------------|-------------------------|-----------------------|
| 0241010 Broccoli | 1 | Further risk management considerations are required | The submitted data are sufficient to derive an MRL proposal of 4 mg/kg for the NEU use. Data from trials on broccoli and cauliflowers were combined. The short-term and the long-term exposures calculated in relation to the MRL proposal did not exceed the toxicological reference values currently applicable. Considering the ARfD and ADI derived recently in the framework of the process of renewal of mancozeb (EU peer review), further risk management considerations are required. |
| 0241020 Cauliflowers | 1 | Further risk management considerations are required | The submitted data are sufficient to derive an MRL proposal of 4 mg/kg for the NEU use. Data from trials on broccoli and cauliflowers were combined. The short-term and the long-term exposures calculated in relation to the MRL proposal did not exceed the toxicological reference values currently applicable. Considering the ARfD and ADI derived recently in the framework of the process of renewal of mancozeb (EU peer review), further risk management considerations are required. |
| 0270060 Leeks | 3 | Further risk management considerations are required | The submitted data are sufficient to derive an MRL proposal of 6 mg/kg for the NEU use. The short-term and the long-term exposures calculated in relation to the MRL proposal did not exceed the toxicological reference values currently applicable. Considering the ARfD and ADI derived recently in the framework of the process of renewal of mancozeb (EU peer review), further risk management considerations are required. |

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

Abstract ................................................................................................................................................... 1
Summary .................................................................................................................................................. 3
Assessment ............................................................................................................................................. 7
1. Residues in plants ........................................................................................................................ 8
   1.1. Nature of residues and methods of analysis in plants ............................................................... 8
   1.1.1. Nature of residues in primary crops ....................................................................................... 8
   1.1.2. Nature of residues in rotational crops .................................................................................... 8
   1.1.3. Nature of residues in processed commodities ....................................................................... 8
   1.1.4. Methods of analysis in plants .................................................................................................. 9
   1.1.5. Storage stability of residues in plants ..................................................................................... 9
   1.1.6. Proposed residue definitions .................................................................................................. 9
   1.2. Magnitude of residues in plants .................................................................................................. 9
   1.2.1. Magnitude of residues in primary crops .................................................................................. 9
   1.2.2. Magnitude of residues in rotational crops ............................................................................ 10
   1.2.3. Magnitude of residues in processed commodities ................................................................. 10
   1.2.4. Proposed MRLs ....................................................................................................................... 11
2. Residues in livestock ....................................................................................................................... 12
3. Consumer risk assessment ............................................................................................................. 12
4. Conclusion and Recommendations ............................................................................................... 12
References ............................................................................................................................................... 13
Abbreviations ........................................................................................................................................... 14
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs ............... 16
Appendix B – List of end points ............................................................................................................ 17
Appendix C – Pesticide Residue Intake Model (PRIMo) .................................................................... 25
Appendix D – Input values for the exposure calculations ................................................................. 28
Appendix E – Used compound codes .............................................................................................. 29

www.efsa.europa.eu/efsajournal 6 EFSA Journal 2020;18(8):6108
Assessment

Mancozeb is the ISO common name for manganese ethylenebis dithiocarbamate (polymeric) complex with zinc salt (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Mancozeb was evaluated in the framework of Directive 91/414/EEC1 with Italy designated as rapporteur Member State (RMS) for the representative uses as foliar applications on apples, grapes, tomatoes and potatoes. The draft assessment report (DAR) prepared by the RMS was not peer reviewed by European Food Safety Authority (EFSA). Therefore, no EFSA conclusion is available in the framework of the first approval of the active substance. Mancozeb was approved2 for the use as fungicide on 1 July 2006.

In the framework of Regulation (EC) No 1107/20093, mancozeb has been evaluated for the representative uses as a fungicide on wheat (winter/spring), grapevine, potatoes and tomatoes with the United Kingdom as new designated RMS. The EFSA conclusion on the peer review of the active substance in accordance with Regulation (EC) No 1107/2009 has been finalised and published in November 2019 (EFSA, 2019b). A decision on the renewal of the approval has not yet been taken.

The European Union (EU) maximum residue levels (MRLs) for the dithiocarbamates, including mancozeb, are set in Annex II and Annex III of the Regulation (EC) No 396/20054. Since the entry into force of this regulation, EFSA has issued several reasoned opinions on the modification of MRLs for dithiocarbamates. The proposals from these reasoned opinions have been considered in the preparation of EU legislation. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been performed.

In accordance with Article 6 of Regulation (EC) No 396/2005, Indofil Industries Limited submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing MRLs for the active substance mancozeb in garlic, broccoli, cauliflowers and leeks. Germany drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 1 June 2017. To accommodate for the intended uses of mancozeb, the EMS proposed to raise the existing MRLs, as following:

- from 0.6 to 0.9 mg/kg in garlic,
- from 1 to 4 mg/kg in broccoli,
- from 1 to 4 mg/kg in cauliflowers and
- from 3 to 6 mg/kg in leeks.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which were requested from the EMS. On 12 September 2019, the EMS submitted the requested information in a revised evaluation report (Germany, 2016), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2016), the draft assessment report (DAR) (Italy, 2000) prepared under Council Directive 91/414/EEC, the Commission review report on mancozeb (European Commission, 2009), the Joint Meetings on Pesticide Residues (JMPR) Evaluation reports (FAO, 2012, 2014) as well as the conclusions from previous EFSA outputs on dithiocarbamates (EFSA, 2009, 2010, 2011, 2015, 2016) and the conclusion on the peer of the pesticide risk assessment of the active substance mancozeb in accordance with Regulation (EC) No 1107/2009 (EFSA, 2019b).

For this application, the data requirements established in Regulation (EU) No 544/20115 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a-g, 2000, 2010a,b, 2017; OECD, 2011). The assessment is performed in

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb and metiram as active substances. OJ L 279, 22.10.2005, p. 63–69.
3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OJ L 309, 24.11.2009, p. 1–50.
4 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
5 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

As the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet initiated, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the MRL review.

The detailed description of the intended uses of mancozeb in garlic, broccoli, cauliflowers and leeks, which are the basis for the current MRL application, is reported in Appendix A.

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

The evaluation report submitted by the EMS (Germany, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo), version 3.1, are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of mancozeb in primary crops was evaluated by the RMS in the framework of the evaluation of the active substance under Directive 91/414/EEC (Italy, 2000) in fruit, root, cereals and pulses/oilseed crop groups. In the framework of the recent EFSA peer review conclusion, the same studies were re-evaluated and the metabolic pattern of the active substance was found to be similar in all crops (EFSA, 2019b). As metabolism studies on more than three representative crops indicated comparable metabolic pathways, the metabolic pattern identified in fruit, root, cereals and pulses/oilseed crops can be extrapolated to all types of crop groups. An overview of the available metabolism studies is presented in Appendix B.1.

1.1.2. Nature of residues in rotational crops

The crops under consideration can be grown in rotation with other plants and, therefore, residues of mancozeb may be expected to occur in succeeding crops as a result of the use of the product in primary crops. Data from soil degradation studies, however, suggest that mancozeb is rapidly biodegraded in soil (Italy, 2000) and, therefore, investigation on the occurrence of residues of mancozeb and metabolites in rotational crops is not necessary. This conclusion was also confirmed during the peer review for the renewal of the active substance (EFSA, 2019b).

1.1.3. Nature of residues in processed commodities

No study was available on the impact of processing on the nature of the residues in the context of this application. Some hydrolysis studies on the nature of residues under processing were submitted by the applicant and described by the RMS in the DAR (Italy, 2000). One of these studies conducted with the active substance metiram showed that ETU is formed during processing: up to 52% of applied radioactivity (AR) at pasteurisation, 88.4% at baking/brewing and boiling, up to 98.6% at sterilisation. Based on the structural similarities of the two active substances, the study on metiram was considered relevant for mancozeb too (Italy, 2000). This conclusion was also confirmed during the peer review for the renewal of the active substance where the same study was considered (EFSA, 2019b).

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6 Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine-disrupting properties.C/2018/2229. OJ L 101, 20.4.2018, p. 33–36.
1.1.4. Methods of analysis in plants

Analytical methods for the determination of mancozeb residues in plant commodities were submitted by the applicant and assessed by the RMS in the framework of Directive 91/414 (Italy, 2000). They are based on the conversion of dithiocarbamates to CS2 which is then measured by chromatography (HS-GS, GS-ECD, GC-FPD, HPLC-UVD, HPLC-MSD) or colorimetry.

During the EU renewal assessment process for mancozeb, an independently validated method was provided for monitoring purposes. The method allows the determination of mancozeb as CS2 by GC-MS and ETU by LC/MS/MS. The validated limit of quantification (LOQ) in high water matrices (apples) was 0.03 mg/kg (expressed as CS2) (Germany, 2016). Therefore, sufficient validation data are available to monitor residues of mancozeb (expressed as CS2) in garlic, broccoli, cauliflowers and leeks.

EFSA noted that the enforcement methods in place cannot distinguish between levels of naturally occurring CS2 and those arising from the use of dithiocarbamates. Additionally, the crops under assessment have a high natural CS2 background level which is expected to interfere with the levels of CS2 detected by an analytical method. In the context of pesticide monitoring, the levels of mancozeb in the crops under assessment would, therefore, be expected to be overestimated for some crops.

Analytical methods were also provided for both mancozeb and ETU in the context of the residue trials submitted within this application (Germany, 2016). For mancozeb, the LOQ in high water matrices was at the level of 0.05 mg/kg (expressed as mancozeb) and for ETU at the level of 0.01 mg/kg (Germany, 2016).

1.1.5. Storage stability of residues in plants

The stability of mancozeb residues in plant matrices under storage conditions prior to analysis was assessed in the framework of the evaluation of the active substance under Directive 91/414/EEC (Italy, 2000). Residues of mancozeb were found to be stable at frozen storage conditions up to 24 months in high water and acid content matrices. Residues of ETU were found to be stable at frozen storage conditions at least 2 months in high water content matrices. The commodities under assessment are high water content matrices and trial samples were stored under conditions ensuring stability of the analytes under assessment. Therefore, the data generated from the available residue trials were considered valid with regard to storage stability.

1.1.6. Proposed residue definitions

Based on the metabolism studies submitted in the framework of the evaluation of the active substance under Directive 91/414/EEC, the residue definition for enforcement in primary and rotational crops was proposed as ‘dithiocarbamates (mancozeb) determined and expressed as CS2’. The residue definition for risk assessment was proposed as ‘dithiocarbamates (mancozeb), expressed as mancozeb’ for all plant commodities (raw). In processed commodities, the proposed residue definition for risk assessment is ‘mancozeb and ETU’.

It is noted that for the raw agricultural commodities, a new residue definition for risk assessment, including also ETU, has been proposed in the recently published peer review on mancozeb, given that quantifiable residue levels of ETU were recovered in grapes and wheat grain and straw from the good agricultural practice (GAP) compliant residue trials and ETU is considered as toxicologically more potent compared to mancozeb (EFSA, 2019b). However, this new residue definition was not considered in the current assessment.

In Regulation (EC) No 396/2005, it was decided to establish a screening residue definition for dithiocarbamates, expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Samples taken in the context of the trials on primary crops were analysed in accordance with the residue definition for enforcement. Since the toxicological reference values are expressed as parent compound (mancozeb), a recalculation from CS2 to mancozeb using a conversion factor of 1.78 was performed to express the residues according to the risk assessment residue definition applicable at the time of submission of the application; samples were stored under conditions ensuring stability of the analytes under assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose.
The analytical method used to determine the CS$_2$ levels in the context of the residue trials and used, in a second step, to derive MRL proposals and risk assessment values for mancozeb, measures both naturally occurring CS$_2$ and the one generated from use of the active substance (see also section 1.1.4). Therefore, results based on this method would be expected to overestimate the levels of mancozeb in the crops under assessment and the exposure to mancozeb from consumption of the commodities issued from these crops.

**Garlic**

No residue trials on garlic were available; to support an MRL proposal in garlic, the applicant submitted 12 outdoor residue trials on onions, conducted in northern Europe (Germany, 2016). Extrapolation from onions to garlic is possible according to the European Commission Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Among non-independent but GAP-compliant pairs of trials, the higher residue seen in the replicates was chosen for the risk assessment. Due to the naturally occurring sulfur compounds in bulb vegetables, residues determined as CS$_2$ were also found in untreated control samples, partly at higher concentrations than the ones in the corresponding treated samples in all available trials in onions. The higher figures were preferred over those from samples originating from treated plots.

Nine out of the 12 trials were found to be independent and GAP compliant and therefore, were considered valid and sufficient for deriving an MRL proposal for mancozeb on garlic.

**Broccoli and cauliflowers**

In support of an MRL proposal in broccoli and cauliflowers, the applicant submitted 16 outdoor residue trials on broccoli and 14 outdoor residue trials on cauliflowers, conducted in the northern Europe (Germany, 2016).

Among non-independent but GAP-compliant pairs of trials, the higher residue seen in the replicates was chosen for the risk assessment. Due to the naturally occurring sulfur compounds in brassica vegetables, residues determined as CS$_2$ were also found in untreated control samples, partly at higher concentrations than the ones in the corresponding treated samples in all available trials in broccoli and cauliflowers. The higher figures were preferred over those from samples originating from treated plots.

Eight out of the 16 trials on broccoli and seven out of the 14 trials on cauliflowers were found to be independent and GAP compliant and, therefore, were considered valid and sufficient for deriving MRL proposals for mancozeb on these commodities. The results from these valid trials were pooled together, as GAPs for broccoli and cauliflowers were identical (European Commission, 2017).

**Leeks**

In support of an MRL proposal in leeks, the applicant submitted 14 outdoor residue trials on leeks, conducted in the northern Europe (Germany, 2016).

Among non-independent but GAP-compliant pair of trials, the higher residue seen in the replicates was chosen for the risk assessment. Due to the naturally occurring sulfur compounds in leeks, residues determined as CS$_2$ were also found in untreated control samples, partly at higher concentrations than that ones in the corresponding treated samples, in all available trials. The higher figures were preferred over those from samples originating from treated plots.

Eight out of the 14 trials on leeks were found to be independent and GAP compliant and, therefore, were considered valid and sufficient for deriving MRL proposals for mancozeb in this commodity.

1.2.2. Magnitude of residues in rotational crops

Not required (see also Section 1.1.2).

1.2.3. Magnitude of residues in processed commodities

Various processing studies on mancozeb in plant commodities were submitted in the first evaluation for the approval of the active substance (Italy, 2000).

Additional processing studies were submitted by the applicant for the crops under assessment: onions (representative for garlic), broccoli, cauliflowers and leeks. The samples taken were analysed for residues of mancozeb and ETU, in accordance with the residue definitions for risk assessment in processed commodities and stored under conditions ensuring stability of the analytes under assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Germany, 2016).

See also Appendix B.1.2.3.
Garlic

No processing studies on garlic were available. The applicant submitted two studies on processing onions (dried) instead, following four applications of mancozeb at an overall application rate of 2.0 kg a.i./ha, equal to the one reported in the GAP. Specimens of crop were taken 29 days after the final application (Germany, 2016).

Based on these studies and considering that the calculated processing factors did not deviate for more than 50%, a robust processing factor could be estimated for mancozeb in dry onions. These results suggest that no concentration of mancozeb (determined as CS$_2$) is expected during processing of onion (dry) and, therefore, during processing of garlic.

ETU was not formed during processing. Since the levels of ETU in raw and processed onion were below the LOQ, no processing factors could be estimated for this compound.

Broccoli

Two processing studies were conducted on processed broccoli (cleaned and cooked) following four and five applications of mancozeb, respectively, at an overall application rate of 4.8 kg a.i./ha i.e. three times higher than the one reported in the GAP. Specimens of crop were taken 31 days and 28 days, respectively, after the final application (Germany, 2016).

Based on these studies and considering the calculated processing factors did not deviate for more than 50%, robust processing factors could be estimated for mancozeb in cleaned and cooked broccoli. The results for cooked broccoli suggest that no concentration of mancozeb (determined as CS$_2$) is expected during cooking of broccoli inflorescences.

ETU was not present in the raw commodities but found at levels ≥ LOQ (0.01 mg/kg) in one of the two studies in cooked broccoli (0.05 mg/kg). In view of these results, the number of studies was not sufficient to derive a robust processing factor for ETU.

Cauliflowers

Two processing studies were conducted on cauliflowers (cleaned and cooked) following four applications of mancozeb at an application rate of 1.6 kg a.i./ha, equal to the one of the GAP for this commodity. Specimens of crop were taken 30 days and 31 days, respectively, after the final application (Germany, 2016).

Based on these studies and considering that the calculated processing factors did not deviate for more than 50%, robust processing factors could be estimated for mancozeb in cleaned and cooked cauliflowers. The results for cooked cauliflowers suggest that no concentration of mancozeb (determined as CS$_2$) is expected during cooking of cauliflower inflorescences.

ETU was not formed during processing. Since the levels of ETU in both raw and processed cauliflowers were below the LOQ, no processing factors could be estimated for this compound.

Leeks

Two processing studies were carried out on leeks (cleaned and cooked) following three applications of mancozeb at an application rate of 2.0 kg a.i./ha, equal to the one of the GAP for this commodity. Specimens of crop from the untreated and treated plots were taken 28 days after the final application (Germany, 2016).

Based on these studies, a robust processing factor could be estimated for mancozeb in cooked leeks, for which the calculated processing factors did not deviate for more than 50%. These results suggest that no concentration of mancozeb (determined as CS$_2$) is expected during processing of leeks.

ETU was found to be present in one of the two studies on raw leeks (0.05 mg/kg) and in both studies on cleaned leeks (0.02 and 0.05 mg/kg) but was not quantified in any of the studies on cooked leeks (< LOQ of 0.01 mg/kg). Based on the above, the number of studies on cleaned and cooked leeks was not sufficient to derive robust processing factors for ETU in these commodities.

1.2.4. Proposed MRLs

The number and quality of the residue trials were considered in line with the applicable data requirements and allow to calculate MRL proposals for mancozeb (expressed as CS$_2$) in garlic, broccoli, cauliflowers and leeks grown in NEU in accordance with the GAP table in Appendix A.
2. Residues in livestock

The assessment of residues in livestock is not relevant to the present application as garlic, broccoli, cauliflowers and leeks are not used for animal feed purposes.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016). As different toxicological reference values were derived for mancozeb and ETU, respectively, they were considered separately in the risk assessment.

ETU was found in some of the studies carried out on cooked broccoli and cleaned (washed) leeks but at low levels (up to 0.05 mg/kg; see Section 1.2.3). Based on these results, a risk assessment for ETU in the framework of the present application was not deemed necessary.

The short-term risk assessment was performed only for the commodities under assessment and for which new residue trials were available: garlic, broccoli, cauliflowers and leeks. The estimation of the exposure is based on the highest residue (HR) derived from the supervised field trials on the above-mentioned commodities.

To calculate the chronic exposure to mancozeb, EFSA used median residue values (STMR) derived from the residue trials conducted on crops under consideration multiplied by the molecular conversion factor 1.78 to express the residues as mancozeb equivalent, and the STMRs reported in a previous EFSA reasoned opinion (EFSA, 2016).

The input values used for the dietary exposure calculation are summarised in Appendix D.

The estimated exposures were then compared to the toxicological reference values derived for mancozeb in the framework of the first approval (European Commission, 2009) (scenario 1). EFSA also performed an additional calculation considering the toxicological reference values derived for mancozeb in the framework of the peer review for the renewal of the active substance (EFSA, 2019b), noting that the values are not yet formally adopted (scenario 2).

When considering scenario 1, the short-term and the long-term exposures calculated in relation to the MRL proposals under assessment did not exceed the toxicological reference values. The highest acute consumer exposure in percentage of ARfD was calculated to be 57% for leeks, 47% for cauliflowers, 34% for broccoli and < 1% for garlic.

A long-term consumer intake concern has not been identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be 86% of the ADI (NL, toddler). The contribution of residues in garlic, broccoli, cauliflowers and leeks to the total consumer exposure accounted for a less than 1% of the ADI each.

When considering scenario 2, an acute consumer intake concern was identified in relation to the MRL proposal for leeks (of ARfD), cauliflowers (of ARfD) and broccoli (of ARfD). The highest acute consumer exposure in percentage of ARfD for garlic was .

A long-term consumer intake concern has been identified. The highest chronic intakes were calculated to be (NL, toddler), (DE child) and (NL child) of the ADI. The contribution of residues in garlic, broccoli, cauliflowers and leeks to the total consumer exposure accounted for less than of the ADI each.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found sufficient to derive MRL proposals for garlic, broccoli, cauliflowers and leeks.

EFSA concluded that the short-term and the long-term exposures to mancozeb calculated in relation to the MRL proposals under assessment did not exceed the toxicological reference values derived during the first approval under Directive 91/414/EEC (European Commission, 2009). Considering, however, the ARfD and ADI derived recently in the framework of the process of renewal of mancozeb (EU peer review; EFSA, 2019b),
Based on the above, further risk management considerations are required before deciding on the revision of MRLs for mancozeb on garlic, broccoli, cauliflowers and leeks. Member states are recommended to be vigilant while monitoring residues of mancozeb in these commodities as the crops under assessment have high natural background levels of CS₂ and the available enforcement methods cannot distinguish between levels of naturally occurring CS₂ and those arising from the use of dithiocarbamates.

The MRL recommendations are summarised in Appendix B.4.

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**Abbreviations**

a.s.  active substance  
ADI  acceptable daily intake  
AR  applied radioactivity  
ARfD  acute reference dose  
BBCH  growth stages of mono- and dicotyledonous plants  
bw  body weight  
CF  conversion factor for enforcement to risk assessment residue definition  
CS  capsule suspension  
CXL  Codex maximum residue limit  
DALA  days after last application  
DAR  draft assessment report  
DAT  days after treatment  
DM  dry matter  
DP  dustable powder  
DS  powder for dry seed treatment  
EMS  evaluating Member State  
eq  residue expressed as a.s. equivalent  
FAO  Food and Agriculture Organization of the United Nations  
FPD  flame photometric detector  
GAP  Good Agricultural Practice  
GC  gas chromatography  
GC-FPD  gas chromatography with flame photometric detector  
GC-MS  gas chromatography with mass spectrometry  
GC-MS/MS  gas chromatography with tandem mass spectrometry  
GS  growth stage  
HPLC-UVD  high performance liquid chromatography with ultra-violet detector  
HR  highest residue  
IEDI  international estimated daily intake  
IESTI  international estimated short-term intake  
ILV  independent laboratory validation  
ISO  International Organisation for Standardisation  
IUPAC  International Union of Pure and Applied Chemistry  
JMPR  Joint FAO/WHO Meeting on Pesticide Residues  
K_{oc}  organic carbon adsorption coefficient
| Acronym | Definition |
|---------|------------|
| LC      | liquid chromatography |
| LOQ     | limit of quantification |
| MRL     | maximum residue level |
| MS      | Member States |
| MS      | mass spectrometry detector |
| MS/MS   | tandem mass spectrometry detector |
| NEU     | northern Europe |
| OECD    | Organisation for Economic Co-operation and Development |
| PBI     | plant back interval |
| PF      | processing factor |
| PHI     | preharvest interval |
| P<sub>ow</sub> | partition coefficient between n-octanol and water |
| PRIMo   | (EFSA) Pesticide Residues Intake Model |
| RA      | risk assessment |
| RAC     | raw agricultural commodity |
| RD      | residue definition |
| RMS     | rapporteur Member State |
| SANCO   | Directorate-General for Health and Consumers |
| SEU     | southern Europe |
| STMR    | supervised trials median residue |
| UV      | ultraviolet (detector) |
| WG      | water-dispersible granule |
| WHO     | World Health Organization |
| WP      | wettable powder |

Modifications of existing MRLs for mancozeb in various crops
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop name | Region/country | Outdoor/Indoor | Pests controlled | Active substance (a.s.) | Formulation type | a.s. conc. in formulation (g/kg or g/L) | Appl. method | Growth stage | No of appl. | Interval (days) Minim. | Water amount (L/ha) | Max. appl. Rate (g a.s./ha) | PHI (days) | Comments |
|-----------|----------------|----------------|------------------|-------------------------|-----------------|----------------------------------------|--------------|--------------|-------------|-------------------|-------------------|----------------------|----------|----------|
| Garlic    | NEU            | Outdoor        | Peronospora destructed Alternaria porri Puccinia allii | Mancozeb         | WG               | 750                                    | Foliar spraying | BBCH 12-49 | 4           | 7                 | 200-1,000        | 2,000                | 28        | –        |
| Broccoli Cauliflowers | NEU            | Outdoor        | Alternaria brassicicola Alternaria brassicae Pernospora parasitica | Mancozeb         | WG               | 750                                    | Foliar spraying | BBCH 12-49 | 4           | 14                | 200-1,000        | 1,600                | 30        | –        |
| Leeks     | NEU            | Outdoor        | Peronospora destructed Alternaria porri Puccinia allii | Mancozeb         | WG               | 750                                    | Foliar spraying | BBCH 12-49 | 3           | 7                 | 200-1,000        | 2,000                | 28        | –        |

NEU: northern European Union; SEU: southern European Union; MS: Member State.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI – minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DALA) | Comment/Source |
|----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                      | Tomatoes    | Foliar  | (9 × 2,700 g/ha) | 5              | $^{14}$C label at both of the two methanediyl carbons of the ethylenebis dithiocarbamate moiety (Italy 2000) |
| Root crops                       | Potatoes    | Foliar  | (1–3 × 4,000 g/ha, 4–6 × 1,700 g/ha) | 7 and 14 | $^{14}$C label at both of the two methanediyl carbons of the ethylenebis dithiocarbamate moiety (Italy 2000) |
|                                  | Sugar beets | Foliar  | (3 × 2,240 g/ha) | At harvest | $^{14}$C label at both of the two methanediyl carbons of the ethylenebis dithiocarbamate moiety (Italy 2000) |
| Cereals/grass                    | Wheat       | Foliar  | (3 × 2,240 g/ha) | 46           | $^{14}$C label not stated directly within the original report, but the same batch of mancozeb was used as for the sugar beet metabolisms study (Italy 2000) |
| Pulses/oilseeds                 | Soyabeans   | Foliar  | (2 × 3,360 g/ha) | 56 and 69    | $^{14}$C label at both of the two methanediyl carbons of the ethylenebis dithiocarbamate moiety (Italy 2000) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
|                                     |             |         |                |           | Not triggered  |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|-----------------------------------------|------------|---------|----------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4) | No | The hydrolysis study was conducted using metiram. In view of the similar structures of metiram and mancozeb, similar behaviour under hydrolysis conditions is expected. The only degradation product of toxicological concern was formed at elevated temperatures is ETU (Italy, 2000; EFSA, 2019b) |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5) | No |
|                                        | Sterilisation (20 min, 120°C, pH 6) | No |
Can a general residue definition be proposed for primary crops?

Yes  EFSA is aware that a new residue definition for risk assessment, including also ETU, has been proposed in the recently published peer review on mancozeb (EFSA, 2019b). However, this new residue definition was not considered in the current assessment.

Rotational crop and primary crop metabolism similar?

Not triggered

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

No  Hydrolysis studies on the nature of residues under processing described by the RMS in the DAR indicate that ETU is formed during cooking of vegetables at elevated temperatures (Italy, 2000). This conclusion was confirmed in the framework of the peer review for the renewal of the active substance (EFSA, 2019b)

Plant residue definition for monitoring (RD-Mo)

Dithiocarbamates (mancozeb) determined and expressed as CS$_2$ (same current and new RD)

Plant residue definition for risk assessment (RD-RA)

Current RD: – Dithiocarbamates (mancozeb), expressed as mancozeb for all plant commodities (raw) – Mancozeb and ETU, for processed commodities

New RD (not yet legally implemented): Mancozeb and ETU for all plant commodities (raw and processed) (EFSA, 2019b)

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

Analytical methods: conversion of mancozeb to CS$_2$ and determination with chromatography (HS-GS, GS-ECD, GC-FPD, HPLC-UVD, HPLC-MSD) or colorimetry. Methods cannot distinguish between levels of naturally occurring CS$_2$ and those arising from the use of dithiocarbamates (Italy, 2000) ILV in high water matrices (apples) available LOQ: 0.03 mg/kg (expressed as CS$_2$) in high water commodities (Germany, 2016)

DALA: days after last application; DAT: days after treatment; PBI: plant-back interval; GS-ECD: gas chromatography with electron capture detector; GC-FPD: gas chromatography with flame photometric detector; HPLC-UVD: high performance liquid chromatography with ultraviolet detector; HPLC-MSD: high-performance liquid chromatography with mass spectrometric detector; LOQ: limit of quantification; ILV: independent laboratory validation.
### B.1.1.2. Storage stability of residues in plants

| Plant products (available studies) | Category       | Commodity | T (°C) | Stability period Value | Stability period Unit | Compounds covered | Comment/ Source |
|-----------------------------------|----------------|-----------|--------|------------------------|-----------------------|--------------------|-----------------|
| High water content                | Apple          | –18       | 24.5   | Months                 | Mancozeb              | Italy (2000)       |
|                                  | Apple          | –18       | 2      | Months                 | ETU                   | Italy (2000)       |
|                                  | Tomato         | –18       | 24.5   | Months                 | Mancozeb              | Italy (2000)       |
|                                  | Tomato         | –18       | 12     | Months                 | ETU                   | Italy (2000)       |
|                                  | Lettuce        | –20       | 3      | Months                 | Mancozeb              | Italy (2000)       |
|                                  | Lettuce        | –20       | 2      | Months                 | ETU                   | Italy (2000)       |
|                                  | Cucumber       | –18       | 12     | Months                 | Mancozeb              | Italy (2000)       |
|                                  | Sweet corn     | –20       | 4      | Months                 | Mancozeb              | Italy (2000)       |
|                                  | Sweet corn     | –20       | 3.5    | Months                 | ETU                   | Italy (2000)       |
|                                  | Onion          | –18       | 6      | Months                 | ETU                   | Italy (2000)       |
| High acid content                | Orange         | –18       | 12     | Months                 | Mancozeb              | Italy (2000)       |
B.1.2. Magnitude of residues in plants

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

| Commodity       | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d)  |
|-----------------|------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|----------------|--------|
| Garlic          | NEU              | Mo: 0.04; 0.06; **0.12**; 0.13; **0.25**; 0.29; 0.29; 0.41; 0.45 RA: 0.07; 0.11; **0.21**, 0.23; **0.45**; 0.51; 0.52; 0.73; 0.80 | Residue trials on onions compliant with the GAP. Extrapolation to garlic possible. Numbers in bold are residues in untreated control samples which were higher than in the corresponding treated samples Unrounded MRLOECD 0.82/Rounded MRLOECD 0.9 | **0.9**              | Mo: 0.45 RA: 0.80 | Mo: 0.25 RA: 0.45 | 1.78   |
| Cauliflowes and Broccoli | NEU                  | Broccoli Mo: 0.1; 0.14; 0.16; 0.27; **0.38**; 0.52; 0.57; 2.8 RA: 0.18; 0.24; 0.29; **0.48**; 0.68; 0.93; 1.0; 4.9 Cauliflowers Mo: **0.11**, 0.12; 0.19; **0.24**, **0.62**; **0.73**; 1.4 RA: 0.20; 0.22; **0.34**, **0.43**, **1.1**, **1.3**; 2.5 | Residue trials on cauliflowers and broccoli compliant with the GAP. Cauliflowers and broccoli trials were combined (U test, 5%). Numbers in bold are residues in untreated control samples which were higher than in the corresponding treated samples Unrounded MRLOECD 3.4/Rounded MRLOECD 4 | **4**               | Mo: 2.8 RA: 4.9 | Mo: 0.27 RA: 0.48 | 1.78   |
| Leeks           | NEU              | Mo: 0.19; 0.21; 0.31; 0.52; 0.83; 1.7; 1.8; 3.3 RA: 0.34; 0.37; 0.54; 0.92; 1.5; 3.1; 3.3; 5.8 | Residue trials on leeks compliant with the GAP. Residues of CS2 were found in untreated control samples from all trials. Unrounded MRLOECD 5.47/Rounded MRLOECD 6 | **6**               | Mo: 3.3 RA: 5.8 | Mo: 0.675 RA: 1.21 | 1.78   |

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment considering the molecular weight of mancozeb.

Residue definition for enforcement: Dithiocarbamates (mancozeb) determined and expressed as CS₂

Residue definition for risk assessment: Dithiocarbamates (mancozeb), expressed as mancozeb.
B.1.2.2. Residues in rotational crops

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

| Commodity                  | Source       |
|----------------------------|--------------|
| Not triggered              | Italy (2000) |

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

| Commodity                  | Source       |
|----------------------------|--------------|
| Not triggered              | Italy (2000) |

B.1.2.3. Processing factors

| Processed commodity                        | Number of valid studies | Mancozeb equivalents | ETU     | Source          |
|--------------------------------------------|-------------------------|----------------------|---------|-----------------|
| Onion/dry                                  | 2                       | 0.14; 0.09           | 0.12    | (c)             |
| Broccoli, cleaned in fluorescence          | 2                       | 1.4; 1.01            | 1.2     | (c)             |
| Broccoli, cooked in fluorescence           | 2                       | 0.03; 0.04           | 0.04    | (c)             |
| Cauliflower, cooked in fluorescence        | 2                       | 0.92; 1.1            | 1.01    | (c)             |
| Leeks, cleaned                            | 2                       | 0.33; 0.14           | 0.23(d) | (c)             |
| Leeks, cooked                             | 2                       | < 0.06; 0.08         | 0.07    | (c)             |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): A conversion factor of 1.78 was used to recalculate the analytically determined CS₂ to mancozeb.
(c): A PF could not be calculated since ETU levels were < LOQ of 0.01 mg/kg in the RAC and the processed commodity.
(d): A tentative PF is derived based on a limited dataset.

B.2. Residues in livestock

Not relevant as none of the crops under assessment is expected to be fed to livestock.

B.3. Consumer risk assessment

Scenario 1: Based on the current toxicological reference values derived under Directive 91/414/EEC (European Commission, 2009).
### ARfD

| Commodity | Highest IESTI, according to EFSA PRIMo 3.1 | Assumptions made for the calculations |
|-----------|------------------------------------------|---------------------------------------|
| Leeks     | 57% of ARfD                              | The calculation was performed with revision 3.1 of the EFSA PRIMo. It is based on the highest residue levels expected in the raw agricultural commodities under assessment multiplied by the conversion factor for risk assessment (CF = 1.78), to convert the estimated levels of CS₂ to mancozeb equivalents. No risk assessment was performed on the metabolite ETU considering that studies carried out on the processed commodities under assessment showed no presence or low levels of residues of ETU (up to 0.05 mg/kg in cooked broccoli and cleaned leeks). |
| Cauliflowers | 47% of ARfD                       |                                       |
| Broccoli  | 34% of ARfD                              |                                       |
| Garlic    | < 1% of ARfD                             |                                       |

### ADI

| Commodity | Highest IEDI, according to EFSA PRIMo 3.1 | Assumptions made for the calculations |
|-----------|------------------------------------------|---------------------------------------|
| Leeks     | 86% ADI (NL toddler)                     | The calculation was performed with revision 3.1 of the EFSA PRIMo. It is based on the median residue levels (STMR) derived from the residue trials conducted on crops under consideration multiplied by the molecular conversion factor 1.78 to express the residues as mancozeb equivalent, and the STMRs reported in a previous EFSA reasoned opinion (EFSA, 2016). For citrus fruits and wine grapes, additional processing factors were applied. The exposure estimate was updated with (i) information on garlic, broccoli, cauliflowers and leeks based on new trials and (ii) information on the revised CXL for mancozeb in ginseng (FAO, 2014). No risk assessment was performed on the metabolite ETU considering that studies carried out on the processed commodities under assessment showed no presence or low levels of residues of ETU (up to 0.05 mg/kg in cooked broccoli and cleaned leeks). |
| Garlic    | < 1% of ADI                              |                                       |
| Broccoli  | < 1% of ADI                              |                                       |
| Cauliflowers | < 1% of ADI                      |                                       |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ETU: ethylenethiourea; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; HR: highest residue; GAP: Good Agricultural Practice.
**Scenario 2:** Based on the toxicological reference values derived under Reg. (EC) No 1107/2009 and not yet formally adopted (EFSA, 2019b).

| ARfD | Mancozeb: 0.15 mg/kg bw (EFSA, 2019b) |
|------|----------------------------------|
| Highest IESTI, according to EFSA PRIMo 3.1 | Leek: 228% of ARfD<br>Cauliflowers: 189% of ARfD<br>Broccoli: 136% of ARfD<br>Garlic: 2% of ARfD |
| Assumptions made for the calculations | The calculation was performed with revision 3.1 of the EFSA PRIMo. It is based on the highest residue levels expected in the raw agricultural commodities under assessment multiplied by the conversion factor for risk assessment (CF=1.78), to convert the estimated levels of CS2 to mancozeb equivalents. No risk assessment was performed on the metabolite ETU considering that studies carried out on the processed commodities under assessment showed no presence or low levels of residues of ETU (up to 0.05 mg/kg in cooked broccoli and cleaned leeks) |

| ADI | Mancozeb: 0.023 mg/kg bw per day (EFSA, 2019b) |
|-----|--------------------------------------------|
| Highest IEDI, according to EFSA PRIMo 3.1 | ADI (NL toddler)<br>Contribution of crops assessed:<br>Garlic: < 1% of ADI<br>Broccoli: 1.2% of ADI<br>Cauliflower: 1.3% of ADI<br>Leek: 1.4% of ADI |
| Assumptions made for the calculations | The calculation was performed with revision 3.1 of the EFSA PRIMo. It is based on the median residue levels (STMR) derived from the residue trials conducted on crops under consideration multiplied by the molecular conversion factor 1.78 to express the residues as mancozeb equivalent, and the STMRs reported in a previous EFSA reasoned opinion (EFSA, 2016). For citrus fruits and wine grapes, additional processing factors were applied. The exposure estimate was updated with (i) information on garlic, broccoli, cauliflowers and leeks based on new trials and (ii) information on the revised CXL for mancozeb in ginseng (FAO, 2014). No risk assessment was performed on the metabolite ETU considering that studies carried out on the processed commodities under assessment showed no presence or low levels of residues of ETU (up to 0.05 mg/kg in cooked broccoli and cleaned leeks) |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ETU: ethylenethiourea; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; HR: highest residue; GAP: Good Agricultural Practice
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|-----------|-------------------------|-------------------------|-----------------------|
| 0220010           | Garlic    | 0.6                     |                         | Further risk management considerations are required |
|                   |           |                         |                         | The submitted data are sufficient to derive an MRL proposal of 0.9 mg/kg for the NEU use by extrapolation from results on onions. The short-term and the long-term exposures calculated in relation to the MRL proposal did not exceed the toxicological reference values currently applicable. Considering the ADI recently derived in the framework of the process of renewal of mancozeb (EU peer review), ... Nevertheless, the contribution of residues in garlic to the consumer exposure is minor (<sup>[1]</sup> of ARFD; less than <sup>[1]</sup> of the ADI). Further risk management considerations are required. |
| 0241010           | Broccoli  | 1                       |                         | Further risk management considerations are required |
|                   |           |                         |                         | The submitted data are sufficient to derive an MRL proposal of 4 mg/kg for the NEU use. Data from trials on broccoli and cauliflowers were combined. The short-term and the long-term exposures calculated in relation to the MRL proposal did not exceed the toxicological reference values currently applicable. Considering the ARFD and ADI derived recently in the framework of the process of renewal of mancozeb (EU peer review), ... Further risk management considerations are required. |
| 0241020           | Cauliflowers | 1                     |                         | Further risk management considerations are required |
|                   |           |                         |                         | The submitted data are sufficient to derive an MRL proposal of 4 mg/kg for the NEU use. Data from trials on broccoli and cauliflowers were combined. The short-term and the long-term exposures calculated in relation to the MRL proposal did not exceed the toxicological reference values currently applicable. Considering the ARFD and ADI derived recently in the framework of the process of renewal of mancozeb (EU peer review), ... Further risk management considerations are required. |
| 0270060           | Leeks     | 3                       |                         | Further risk management considerations are required |
|                   |           |                         |                         | The submitted data are sufficient to derive an MRL proposal of 6 mg/kg for the NEU use. The short-term and the long-term exposures calculated in relation to the MRL proposal did not exceed the toxicological reference values currently applicable. Considering the ARFD and ADI derived recently in the framework of the process of renewal of mancozeb (EU peer review), ... Further risk management considerations are required. |

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<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.
**Appendix C – Pesticide Residue Intake Model (PRIMo)**

**Scenario 1:** Based on the toxicological reference values set in the EU peer review under Directive 91/414/EEC (European Commission, 2009)

**Toxicological reference values**

| Commodity | ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|-----------|------------------------|-----------------|
| Mancozeb  | 0.6                    | 20              |

**Input values**

**Mancozeb**

- **LOQs (mg/kg)** range from: 0.05 to 25.0
- **Year of evaluation:** 2005
- **Source of ADI:** EC
- **Source of ARfD:** EC

**Supplementary results – chronic risk assessment**

- **No of diets exceeding the ADI:** --
- **Details:**
  - Refined calculation mode
    - Chronic risk assessment: JMPR methodology (IEDI/TMDI)
    - No acute risk assessment
    - No of commodities not under assessment
    - MRLs set at the LOQ
    - Exposure
      - Highest contributor to diet: Table grapes (86% 42.88)
      - 2nd contributor to MS: Pears (26% 16.35)
      - 3rd contributor to MS: Tomatoes (25% 16.35)

**Conclusion:**

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

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7 Despite no new uses for mancozeb in pears are proposed in the current application, the ARfD for mancozeb is exceeded for this commodity (121% of ARfD for pears). This is due to the difference in consumption statistics available in the two versions of PRIMo (version 2 vs. 3.1). Additionally, the values used in the present assessment need to be refined/confirmed in the framework of an MRL review which, in the case of mancozeb, is still pending. Finally, it is important to point out that the estimation of the exposure considers mancozeb as the only source of CS₂ despite other EU-approved dithiocarbamates, such as metiram and ziram, are also authorised for use in pears. This assumption would be expected to result in an overestimation of the exposure to mancozeb from pears.
### Acute risk assessment/children

The acute risk assessment is based on the ARfD.

The calculation is based on the large portion of the most critical consumer group.

#### Show results for all crops

| Commodity                  | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity                  | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|----------------------------|---------------------------|---------------------|-----------------------|----------------------------|---------------------------|---------------------|-----------------------|
| Pears                      | 5.25                      | 467                 | 42%                   | Table grapes               | 5.37                      | 262                 | 26%                   |
| Apples                     | 5.25                      | 566                 | 31%                   | Head cabbages              | 5.45                      | 187                 | 17%                   |
| Wheat berries              | 5.45                      | 473                 | 27%                   | Pears                      | 5.25                      | 160                 | 16%                   |
| Papayas                    | 7.46                      | 316                 | 19%                   | Broccoli                   | 4.49                      | 117                 | 17%                   |
| Cauliflowers               | 4.92                      | 284                 | 19%                   | Green beans                | 4.99                      | 117                 | 17%                   |
| Escarole/rode-leaved       | 5.94                      | 279                 | 19%                   | Cauliflowers               | 4.99                      | 117                 | 17%                   |
| Bananas                    | 2.79                      | 271                 | 17%                   | Papayas                    | 7.14                      | 104                 | 17%                   |
| Lettuce                    | 5.94                      | 264                 | 15%                   | Apple                      | 5.25                      | 160                 | 15%                   |
| Broccoli                   | 4.49                      | 204                 | 14%                   | Leeks                      | 5.45                      | 187                 | 14%                   |
| Shoot cabbages             | 3.14                      | 137                 | 14%                   | Blueberries                | 5.06                      | 83                  | 13%                   |
| Melons                     | 1.91                      | 192                 | 13%                   | Quinces                    | 5.52                      | 80                  | 13%                   |
| Tomatoes                   | 3.22                      | 187                 | 13%                   | Leafy green                  | 5.86                      | 104                 | 13%                   |
| Oranges                    | 5.31                      | 174                 | 11%                   | Cucumbers                  | 5.25                      | 160                 | 11%                   |
| Cucumbers                  | 2.26                      | 161                 | 10%                   | Currants (red, black and   | 5.96                      | 160                 | 10%                   |
| Watermelon                 | 1.97                      | 155                 | 10%                   | Bananas                    | 2.79                      | 94                  | 10%                   |
| Peaches                    | 2.14                      | 140                 | 10%                   | Courgettes                 | 2.46                      | 77                  | 10%                   |
| Quinces                    | 5.55                      | 139                 | 9%                    | Watermelons                | 1.57                      | 51                  | 9%                    |
| Mangos                     | 2.15                      | 125                 | 9%                    | Tomatoes                   | 3.32                      | 51                  | 9%                    |
| Currants                   | 2.46                      | 114                 | 8%                    | Melons                     | 1.51                      | 50                  | 8%                    |
| Grapefruits                | 5.31                      | 103                 | 7%                    | Mangoes                    | 2.15                      | 41                  | 7%                    |
| Mandarins                  | 5.65                      | 98                  | 7%                    | Gooseberries (green, red    | 5.96                      | 41                  | 7%                    |
| Plums                      | 2.05                      | 86                  | 7%                    | Orange                     | 5.12                      | 40                  | 7%                    |
| Aubergines/egg plants      | 3.32                      | 81                  | 6%                    | Red mustard                | 5.84                      | 37                  | 6%                    |
| Medlar                     | 5.25                      | 73                  | 6%                    | Plums                      | 2.05                      | 36                  | 6%                    |
| Currants (red, black and   | 5.96                      | 71                  | 6%                    | Medlar                      | 5.65                      | 37                  | 6%                    |
| Radishes                   | 2.49                      | 61                  | 5%                    | Mandarins                  | 5.65                      | 37                  | 5%                    |
| Blueberries                | 5.06                      | 54                  | 5%                    | Peaches                    | 2.14                      | 28                  | 5%                    |
| Gooseberries (green, red   | 5.06                      | 53                  | 4%                    | Radishes                   | 2.49                      | 26                  | 4%                    |
| Apricots                   | 2.14                      | 52                  | 4%                    | Grapefruits                | 5.31                      | 24                  | 4%                    |
| Kohlrabies                 | 1.09                      | 46                  | 4%                    | Cherries (sweet)           | 2.24                      | 21                  | 4%                    |
| Lemons                     | 5.12                      | 45                  | 3%                    | Pumpkins                   | 1.51                      | 19                  | 3%                    |
| Potatoes                   | 0.30                      | 41                  | 3%                    | Wine grapes                | 0.50                      | 17                  | 3%                    |
| Cranberries                | 5.06                      | 41                  | 3%                    | Apricots                   | 2.14                      | 16                  | 3%                    |
| Pumpkins                   | 1.51                      | 34                  | 3%                    | Bears (with pods)          | 1.16                      | 15                  | 3%                    |
| Beetroots                  | 0.50                      | 30                  | 2%                    | Gherkins                   | 2.24                      | 15                  | 2%                    |
| Limes                      | 5.12                      | 26                  | 2%                    | Chinese cabbages/pe-tsai    | 0.50                      | 14                  | 2%                    |
| Cherries (sweet)           | 2.24                      | 26                  | 2%                    | Oranges                    | 1.09                      | 13                  | 2%                    |
| Kaleas                     | 0.50                      | 24                  | 2%                    | Lamb's lettuce/corn salads | 5.94                      | 13                  | 2%                    |
| Beets (with pods)          | 1.16                      | 22                  | 2%                    | Kohlrabies                 | 1.09                      | 13                  | 2%                    |
| Carrots                    | 0.20                      | 21                  | 2%                    | Beetroot                   | 0.50                      | 12                  | 2%                    |
| Wildflowers/Belgian endives| 0.50                      | 21                  | 2%                    | Lemons                     | 5.12                      | 12                  | 2%                    |
| Onions                     | 10.91                     | 21                  | 2%                    | Brussels sprouts           | 2.11                      | 11                  | 2%                    |
| Lamb's lettuce/corn salads | 5.94                      | 20                  | 2%                    | Parsley                    | 5.65                      | 11                  | 2%                    |
| Celeriac/kum Rooted         | 0.30                      | 19                  | 2%                    | Kales                      | 1.09                      | 13                  | 2%                    |
| Roman rocket/rucula        | 5.46                      | 19                  | 2%                    | Cranberries                | 5.94                      | 10                  | 2%                    |
| Table olives               | 5.46                      | 18                  | 2%                    | Wildflowers/Belgian endives| 0.50                      | 9.8                 | 2%                    |
| Chinese cabbages/pe-tsai   | 0.50                      | 18                  | 2%                    | Limes                      | 5.12                      | 9.3                 | 2%                    |
| Brussels sprouts           | 2.11                      | 15                  | 1%                    | Roman rocket/rucula        | 5.94                      | 8.2                 | 1%                    |
| Parnips                    | 0.20                      | 12                  | 1%                    | Potatoes                   | 0.30                      | 8.0                 | 1%                    |
| Cherol                     | 5.89                      | 12                  | 1%                    | Barley                     | 2.11                      | 7.4                 | 1%                    |
| Rhubarbus                  | 0.50                      | 11                  | 1%                    | Cranberries                | 0.20                      | 6.7                 | 1%                    |
| Salaries                   | 0.20                      | 10                  | 0.9%                  | Table olives               | 0.55                      | 5.4                 | 0.9%                  |
| Parsley                    | 0.58                      | 9.7                 | 0.9%                  | Buckeye and other pseudo   | 0.05                      | 5.3                 | 0.9%                  |
| Spring onions/green onions | 1.01                      | 9.5                 | 0.8%                  | Parnips                    | 0.20                      | 4.8                 | 0.8%                  |
| Barley                     | 2.15                      | 8.5                 | 0.7%                  | Celeriac/kum Rooted         | 0.30                      | 4.0                 | 0.7%                  |
| Blackcurr and other        | 0.05                      | 7.6                 | 0.6%                  | Salaries                   | 0.20                      | 3.6                 | 0.6%                  |

**Modifications of existing MRLs for Mancozeb in various crops**

www.efsa.europa.eu/efsajournal 26 EFSA Journal 2020;18(8):6108
| %  | Crop Description                             | Value 1 | Value 2 | Value 3 | Value 4 | Value 5 | Value 6 | Value 7 | Value 8 | Value 9 | Value 10 |
|----|---------------------------------------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| 1% | Chives                                       | 5/8.9   | 7.3     | 0.6%    | Pancreas root/Hamang root | 0.20.34 | 3.5    |         |         |         |         |
| 1% | Peas (with pods)                             | 1/0.67  | 7.1     | 0.5%    | Peas (with pods) | 1/0.6/7 | 3.0    |         |         |         |         |
| 1% | Ginger                                      | 2/2.46  | 6.9     | 0.5%    | Celery leaves | 5/8.9  | 2.9    |         |         |         |         |
| 1% | Asparagus                                   | 0.5/0.36| 6.9     | 0.5%    | Kaki/Japanese Persimmon | 0.2/0.12 | 2.7    |         |         |         |         |
| 1% | Wine grapes                                 | 5/0.74  | 6.8     | 0.5%    | Asparagus     | 0.5/0.36 | 2.7    |         |         |         |         |
| 1% | Sage                                        | 5/8.9   | 6.7     | 0.5%    | Spring onion/Green onion | 10.61  | 2.7    |         |         |         |         |
| 1% | Basil and edible flowers                    | 5/8.9   | 6.5     | 0.4%    | Rhabditis    | 0.5/0.28 | 2.6    |         |         |         |         |
| 1.0%| Kaki/Japanese Persimmon                     | 0.2/0.12| 5.8     | 0.4%    | Chives and other sprouts | 5/8.94  | 2.6    |         |         |         |         |
| 0.7%| Celery leaves                               | 5/8.9   | 4.3     | 0.4%    | Olives for oil production | 53.24 | 2.5    |         |         |         |         |
| 1% | Olives for oil production                   | 5/3.24  | 4.1     | 0.4%    | Horseradish  | 0.25.34 | 2.5    |         |         |         |         |
| 0.5%| Beans (with pods)                           | 1.0/1.6 | 3.3     | 0.4%    | Shallots     | 1/0.91  | 1.2    |         |         |         |         |
| 0.5%| Peas (without pods)                         | 1/0.21  | 3.0     | 0.3%    | Sage         | 5/8.9   | 1.8    |         |         |         |         |
| 0.5%| Garlic                                     | 0.9/0.8 | 2.8     | 0.3%    | Wheat        | 10.21/1 | 1.6    |         |         |         |         |
| 0.3%| Cress and other sprouts and cultivated fungi| 5/6.94  | 2.0     | 0.3%    | Chives       | 5/8.9   | 1.5    |         |         |         |         |
| 0.3%| Chives/pickled                              | 1.0/1.2 | 1.5     | 0.2%    | Beans        | 0.18/1  | 1.2    |         |         |         |         |
| 0.3%| Peas (with pods)                            | 0.2/2.46| 1.5     | 0.2%    | Basil and edible flowers | 5/8.9 | 1.1    |         |         |         |         |
| 0.3%| Peas (without pods)                         | 0.2/2.46| 1.5     | 0.2%    | Peas (without pods) | 0.2/0.2 | 1.0    |         |         |         |         |
| 0.2%| Rye                                         | 1/0.21  | 1.2     | 0.2%    | Rye          | 0.21/1  | 1.0    |         |         |         |         |
| 0.2%| Garlic                                      | 0.9/0.8 | 1.2     | 0.1%    | Rosemary     | 5/8.9   | 0.89   |         |         |         |         |
| 0.09%| Thyme                                      | 5/8.9   | 0.53    | 0.1%    | Rosemary     | 5/8.9   | 0.89   |         |         |         |         |
| 0.09%| Ginseng root                                | 1.6/2.65| 0.53    | 0.1%    | Rosemary     | 5/8.9   | 0.89   |         |         |         |         |
| 0.06%| Walnuts                                     | 0.10/1 | 0.36    | 0.1%    | Rosemary     | 5/8.9   | 0.89   |         |         |         |         |
| 0.06%| Chives/pickled                              | 1/0.91  | 0.28    | 0.1%    | Beans (without pods) | 0.10/2 | 0.77   |         |         |         |         |
| 0.046%| Rosemary                                    | 5/8.9   | 0.27    | 0.1%    | Chives       | 5/8.9   | 0.72   |         |         |         |         |
| 0.046%| Repaid seed/cana seeds                      | 0.5/0.16| 0.22    | 0.1%    | Peas         | 0.118/0 | 0.60   |         |         |         |         |
| 0.03%| Watermelon                                  | 0.3/0.41| 0.19    | 0.09%   | Garlic       | 0.9/8.9 | 0.52   |         |         |         |         |
| 0.03%| Wild funi                                   | 0.5/0.09| 0.16    | 0.08%   | Watermelon   | 0.3/0.41| 0.48   |         |         |         |         |
| 0.02%| Horseradish                                 | 2/2.04  | 0.14    | 0.07%   | Cultivated funi | 0.5/0.09 | 0.46   |         |         |         |         |
| 0.01%| Laurel leaves                               | 5/8.9   | 0.09    | 0.04%   | Walnuts      | 0.10/1 | 0.23   |         |         |         |         |
| 0.02%| Wild funi                                   | 0.5/0.09| 0.14    | 0.01%   | Repaid seed/cana seeds | 0.5/0.16 | 0.08   |         |         |         |         |

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation): 1

### Results for children

For processed commodities for which ARfD/ADI is exceeded (IESTI):

| Highest % of ARfD/ADI | Processed commodities | MRL/uid for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-----------------------|------------------------|---------------------|
| 77%                   | Escaroles/broad-leaved endive | 5/5.94 | 342 |
| 64%                   | Broccoli/broiled | 4/4.9 | 386 |
| 57%                   | Cauliflower/broiled | 4/4.9 | 341 |
| 55%                   | Leek/broiled | 6/5.8 | 332 |
| 19%                   | Currants (red, black and white) | 5/4.09 | 117 |
| 15%                   | Courgettes/broiled | 2/2.46 | 287 |
| 14%                   | Apple/sauce | 5/1.54 | 83 |
| 9%                    | Ginger/sauce | 2/2.46 | 37 |
| 8%                    | Pear/sauce | 5/1.54 | 50 |
| 7%                    | Orange/sauce | 5/1.54 | 47 |
| 6%                    | Peach/sauce | 5/1.54 | 47 |
| 5%                    | Tomato/sauce | 5/1.54 | 47 |

### Results for adults

For processed commodities for which ARfD/ADI is exceeded (IESTI):

| Highest % of ARfD/ADI | Processed commodities | MRL/uid for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-----------------------|------------------------|---------------------|
| 77%                   | Escaroles/broad-leaved endive | 5/5.94 | 342 |
| 64%                   | Broccoli/broiled | 4/4.9 | 386 |
| 57%                   | Cauliflower/broiled | 4/4.9 | 341 |
| 55%                   | Leek/broiled | 6/5.8 | 332 |
| 19%                   | Currants (red, black and white) | 5/4.09 | 117 |
| 15%                   | Courgettes/broiled | 2/2.46 | 287 |
| 14%                   | Apple/sauce | 5/1.54 | 83 |
| 9%                    | Ginger/sauce | 2/2.46 | 37 |
| 8%                    | Pear/sauce | 5/1.54 | 50 |
| 7%                    | Orange/sauce | 5/1.54 | 47 |
| 6%                    | Peach/sauce | 5/1.54 | 47 |
| 5%                    | Tomato/sauce | 5/1.54 | 47 |

### Conclusions

The estimated short-term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

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

D.1. Consumer risk assessment

| Commodity   | Chronic risk assessment | Acute risk assessment |
|-------------|-------------------------|-----------------------|
|             | **Input value (mg/kg)** | **Comment**           | **Input value (mg/kg)** | **Comment**           |
| Garlic      | 0.45 STMR × CF (1.78)   | 0.8 HR × CF (1.78)    |
| Cauliflowers| 0.48 STMR × CF (1.78)   | 4.9 HR × CF (1.78)    |
| Broccoli    | 0.48 STMR × CF (1.78)   | 4.9 HR × CF (1.78)    |
| Leeks       | 1.21 STMR × CF (1.78)   | 5.8 HR × CF (1.78)    |
| Further uses| See FAO (2014) and EFSA (2009, 2010, 2011, 2016) | Acute risk assessment was undertaken with regard to the intended uses only |
Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChIKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| mancozeb             | manganese ethylenbis (dithiocarbamate) (polymeric) complex with zinc salt | ![Structural formula](image) |
| ETU                  | 2-imidazolidinethione S=C1NCCN1 PDQAZBW-RQCBVE-UHFFFAOYSA-N | ![Structural formula](image) |

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 06 Sep 2017).
(c): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 Feb 2018).