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

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## 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 thiram. Although this active substance is no longer authorised within the European Union, MRLs based on the use of thiram were established by the Codex Alimentarius Commission (codex maximum residue limits; CXLs) and import tolerances were reported by Member States (including the supporting residues data). Based on the assessment of the available data, EFSA assessed the existing import tolerances, and a consumer risk assessment was carried out for thiram only. Although no apparent risk to consumers was identified, the import tolerances were not fully supported by data. Hence, the consumer risk assessment is considered indicative only and further consideration by risk managers is needed.



**Keywords:** dithiocarbamates, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, fungicide

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## Summary

Thiram was initially included in Annex I to Directive 91/414/EEC on 1 August 2004 by Commission Directive 2003/81/EC, and was deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved before 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(2) of the aforementioned regulation.

In the meantime, an application for renewal of the approval of thiram in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 was submitted by the Thiram Task Force (TTF). The peer review for the renewal of the first approval, with France designated as rapporteur Member State (RMS) has been completed by EFSA in 2017. In 2018, a decision of non-renewal of thiram was taken by Commission Implementing Regulation (EU) 2018/1500.

As the basis for the MRL review, on 15 October 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK were invited to submit by 18 November 2019 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, France, to identify the critical GAPs in the format of a specific GAP overview file. On the basis of all the data submitted by Member States and by the European Union Reference Laboratories for Pesticides Residues (EURL), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations and updated GAP overview file were provided by the RMS to EFSA on 27 May 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURL, and taking into account the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009 and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in October 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 27 November 2020 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of thiram in plant was investigated in primary crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as thiram (expressed as thiram). A specific residue definition for rotational crops is not deemed necessary considering that the crops under review are import tolerances. A residue definition for processed commodities could not be concluded on. Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water content commodities and high oil content commodities at the limit of quantification (LOQ) of 0.05 mg/kg. A data gap was, however, identified for the determination of the extraction efficiency of the thiram specific method in plants. According to the EURLs, a practical LOQ for thiram could not be proposed.

Available residue trials data were considered sufficient to derive tentative MRL proposals as well as risk assessment values for all commodities under evaluation according to the residue definition for enforcement of thiram (expressed as thiram), reflecting the residues from the use of thiram only.

Thiram is not authorised for use on crops that might be fed to livestock. Further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary.

The calculated exposure values were compared with the toxicological reference values for thiram, derived by EFSA (2017). The highest chronic exposure was calculated for Dutch toddlers, representing 0.6% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for avocados, representing 35% of the acute reference dose (ARfD). Although major uncertainties remain due to the data gaps identified, this indicative exposure calculation did not indicate a risk to consumers.

The derivation of the toxicological reference values of M1 is pending robust data addressing the toxicological profile of this metabolite. In addition, data on the level of the metabolite M1 in/on treated avocados and bananas are not available. Therefore, the consumer risk assessment for metabolite M1 could not be performed and the overall risk assessment for the uses under consideration should be considered on a tentative basis. It is underlined that the crops under consideration are consumed

peeled and according to the results of metabolism studies and residue trials, limited translocation of the residue from the peel to the pulp is expected. Therefore, it is expected that metabolite M1 will not be present at significant levels in the edible portion of the crops under assessment. Nevertheless, this conclusion should be confirmed by residue trials analysing for metabolite M1.

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## Background

Regulation (EC) No 396/2005[1] (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(2) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide by 1 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[2] before 2 September 2008.

Thiram was initially included in Annex I to Council Directive 91/414/EEC on 1 August 2004 by means of Commission Directive 2003/81/EC[2] which has been deemed to be approved under Regulation (EC) No 1107/2009[3], in accordance with Commission Implementing Regulation (EU) No 540/2011[4], as amended by Commission Implementing Regulation (EU) No 541/2011[5]. Therefore, EFSA initiated the review of all existing MRLs for that active substance.

An application for renewal of the approval of thiram in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 was submitted by the Thiram Task Force (TTF). The peer review for the renewal of the first approval, with France designated as rapporteur Member State (RMS) has been completed by EFSA in 2017. In 2008, a decision of non-renewal of thiram was taken by Commission Implementing Regulation (EU) 2018/1500[6].

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment reports prepared under Directive 91/414/EEC and Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, 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 Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

As the basis for the MRL review, on 15 October 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States and UK[7] were invited to submit by 18 November 2019 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 14 Member States and the UK provided feedback on their national authorisations of thiram. GAPs authorised in third countries were reported by the rapporteur Member State, France, after having consulted the main authorisation holders. At this moment grace periods for the disposal, storage and use of existing stocks of some of the plant protection products which contains thiram were applicable until 30 January 2020 (Regulation (EU) 2018/1500). Reported authorised uses in the EU were not considered/included in the GAP overview considering the EU uses withdrawal along the evaluation process. Subsequently, Member States and UK were requested to provide residue data supporting only the critical GAPs on import tolerances, within a period of 1 month, by 10 January 2020.

On the basis of all the data submitted by Member States, UK and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked France to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide

[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] Commission Directive 2003/81/EC of 5 September 2003 amending Council Directive 91/414/EEC to include molinate, thiram and ziram as active substances. OJ L 224, 6.9.2003, p. 29.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[4] Commission Implementing Regulation (EU) 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.

[6] Commission Implementing Regulation (EU) 2018/1500 of 9 October 2018 concerning the non-renewal of approval of the active substance thiram, and prohibiting the use and sale of seeds treated with plant protection products containing thiram, 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 Commission Implementing Regulation (EU) No 540/2011. OJ L 254, 10.10.2018, p. 1–3.

[7] The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the UK from the EU, and with the established transition period, the EU requirements on data reporting also apply to the UK data collected until 31 December 2020.

Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were submitted to EFSA on 27 May 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limit; CXLs), EFSA prepared in October 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 27 November 2020 were considered by EFSA during the finalisation of the reasoned opinion.

The **evaluation report** submitted by the RMS (France, 2020), taking into account also the information provided by Member States and UK during the collection of data, and the **EURL report on analytical methods** (EURL, 2020) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the **completeness check report** (EFSA, 2020a) and the **Member States consultation report** (EFSA, 2020b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (**PRIMo**) and the **PROFile** as well as the **GAP overview file** listing all import tolerances are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the 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:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- 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;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

## The active substance and its use pattern

Thiram is the ISO common name for tetramethylthiuram disulfide or bis (dimethylthiocarbamoyl)-disulfide (IUPAC).

The chemical structure of the active substance and its main metabolites are reported in Appendix F.

The EU MRLs for thiram are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) based on the uses of thiram were also established by the Codex Alimentarius Commission (CAC).

It is underlined that, although two lists of MRLs are currently set for thiram (one as thiram and specific for this active substance, and one as CS2, covering all dithiocarbamates), the present review is focussing only on the MRLs currently set as thiram.

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 (EC) No 2016/1 | Avocados (EFSA, 2015) |
| MRL Application | Regulation (EC) No 822/2009 | Bananas (EFSA, 2008) |

For the purpose of this MRL review, all the uses of thiram currently authorised in the third countries as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAP for thiram are given in Appendix A.

## Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (France, 2020);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Belgium, 1997, 2002);
- the renewal assessment report (RAR) and its revision prepared under Commission Implementing Regulation (EU) No 844/2012 (France, 2016a,b);
- the conclusion on the peer review of the pesticide risk assessment of the active substance thiram (EFSA, 2017);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 1996);
- the previous reasoned opinions on active substance thiram (EFSA, 2008, 2015).

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[8] 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

During the peer review for the renewal, the metabolism of thiram was investigated following foliar applications on fruits (apples and grapes) at application rates covering both import tolerances uses on avocados and bananas (France, 2016a; EFSA, 2017). Thiram was shown to be extensively degraded into polar compounds with further incorporation of the radioactive residues into natural constituents of the plant (EFSA, 2017). Most of the total radioactive residue (TRR) was detected in the surface of the fruits: less than 7% of the total initial radioactivity was found incorporated into the apple while in grapes in the surface wash of fruit and leaves more than 90% TRR was associated with thiram (France, 2016b). In the framework of the peer review, significant amounts of M1 compound (0.05–0.13 mg/kg) were observed in residue trial studies on apple, apricot and strawberry. This metabolite was not analysed for in the metabolism studies performed on fruits. The metabolism of thiram in fruits is sufficiently elucidated and the conclusions of the peer review on the metabolic pathway are applicable to the current review.

Metabolism studies following seed treatment on roots (sugar beet), cereals (wheat) and pulses/oilseeds (cotton, soya bean) are also available (Belgium, 1997) and were assessed in the framework of the peer review (EFSA, 2017). The metabolic patterns in the different crops following foliar and seed treatment were considered similar (EFSA, 2017).

### 1.1.2. Nature of residues in rotational crops

Studies investigating the nature of residues in rotational crops are not available. Since thiram is no longer approved in the European Union and the only uses under assessment are import tolerances, further consideration on rotational crops is not required.

### 1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed in the framework of the peer review (EFSA, 2017). Under standard hydrolysis conditions, thiram was shown to be degraded into numerous metabolites, i.e. M1, M2, M3, M7 and M8 that accounted for 0.2–5.1% of the applied radioactivity (AR) and M4 that was recovered as the predominant compound of total

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

residues with 14.4% AR under pasteurisation to 72.6% of AR under sterilisation (EFSA, 2017). During the peer review, significant residue levels of thiram (specific) were observed in the residue trials on fruit crops, and therefore, it could not be excluded that these metabolites may also occur at significant levels in processed commodities (EFSA, 2017). Furthermore, insufficient data were available to conclude on the toxicological profile of M1, M2, M4, M7 and M8 metabolites while M3 is a major rat metabolite and therefore considered as covered by the toxicological reference values set for the parent compound. Since the stability of M1 under processing could not be established based on the fruit processing residue trials analysing for M1 residues, a hydrolysis study simulating the standard processing conditions for M1 compound was requested to be provided. Considering the outstanding data on the fate of M1 compound under the standard hydrolysis conditions, the magnitude of residues of metabolites M2, M3, M4, M7 and M8 in fruit processed commodities and the unknown toxicity of M1, M2, M4, M7 and M8, the residue definition for processed commodities could not be concluded on in the framework of the peer review (EFSA, 2017).

Since no new information was provided in the framework of the current MRL review, a residue definition for processed commodities cannot be concluded on. Nevertheless, as the commodities under consideration are mainly consumed raw and peeled and according to the results of metabolism studies and residue trials limited translocation from the peel to the pulp is expected, the data gap identified in the peer review regarding the effect of processing on the nature of residues is not deemed relevant in the framework of this assessment.

#### 1.1.4. Methods of analysis in plants

Residues of thiram in food and feed of plant origin can be monitored by liquid chromatography with tandem mass spectrometry (LC–MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in dry commodities and an LOQ of 0.05 mg/kg in the other plant matrices (EFSA, 2017). A data gap was, however, identified for the determination of the extraction efficiency of the thiram specific method in plants (EFSA, 2017).

The EURLs reported that they are unable at the current stage to indicate any practical LOQs due to losses taking place during the analysis of thiram using procedures routinely employed by laboratories (EURL, 2020).

#### 1.1.5. Stability of residues in plants

The storage stability of thiram (specific), thiram as $CS_2$ and metabolite M1 were investigated in the framework of the peer review (EFSA, 2017) and in new studies submitted under this review (France, 2020).

The storage stability of thiram in primary crops was investigated in the framework of the peer review for the renewal (France, 2016b). Residues of thiram analysed as $CS_2$ were found to be stable at $< -20$°C for up to 78 weeks in high oil content matrices (cotton, soybean). No data were available regarding thiram (specific) or metabolite M1 for high oil content matrices. Furthermore, storage stability was demonstrated for thiram (specific) and metabolite M1 for up to 1 year at -18°C in high water content commodities (apricot, pear, cherry). However, a significant degradation of residues of thiram and its metabolites containing the $CS_2$ moiety ($CS_2$ moiety method) was observed in lettuce after ca. 2 months, suggesting that thiram (specific) might not be stable for 1 year for the whole high water content commodity crop group (EFSA, 2017).

New storage stability studies were performed on avocados and bananas and assessed by the RMS (France, 2020). In the first study with avocados, the results indicate no significant loss of thiram (specific) after a storage period of 4 months, but the study is considered as informative only since no control samples appear to have been analysed together with the supplemented samples (France, 2020). The second study demonstrated that residues of thiram analysed as $CS_2$ are stable for 3 months in whole avocados (France, 2020). In the storage stability study with bananas, thiram can be considered as stable upon deep frozen storage (–18°C) for about 3 months (96 days for thiram analysed as $CS_2$ and 97 days for thiram analysed as thiram). In addition, a storage stability trial performed in the framework of supervised residue trials showed that thiram analysed as $CS_2$ is expected to be stable upon deep frozen storage (–15°C) for 3 months (91 days) in whole bananas and 2.5 months (78 days) in banana pulp (France, 2020). An overview of all available stability studies is available in Appendix B.1.1.2.

### 1.1.6. Proposed residue definitions

The metabolism of thiram was similar in all crops assessed. There were no metabolism studies in rotational crops, and these are not necessary since further investigation on rotational crops is not required because thiram is no longer approved in the European Union and the only uses under assessment are import tolerances. For processed commodities, it is not possible to conclude on a residue definition, since information on the toxicological profile and magnitude of several metabolites is not available (see Section 1.1.3).

As the parent compound was found to be a sufficient marker in primary crops, the residue definition for enforcement is proposed as thiram only (expressed as thiram) (EFSA, 2017).

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.05 mg/kg in high water and high oil content matrices is available; however, there is a data gap on the extraction efficiency (EFSA, 2017). The EURLs reported that they are unable at the current stage to indicate any practical LOQs for thiram (EURL, 2020). During the member states consultation, the EURLs proposed the option of merging thiram and ziram into the same residue definition for monitoring (EFSA, 2020b). However, since the LC-MS/MS method used for the determination of thiram in the studies assessed in the peer review was considered acceptable and ziram was not observed in the metabolism studies, the proposed residue definition thiram (expressed as thiram) is considered the most appropriate for enforcement purposes. The analytical standard for thiram is commercially available (EURL, 2020).

The identified major metabolite M1 is not genotoxic, according to the assessment of the peer review, but available data were not sufficient to conclude on its toxicological profile (EFSA, 2017). Considering that metabolite M1 does not contain the common $CS_2$ moiety and the toxicological reference values of the parent compound cannot apply to this compound, EFSA proposed in the framework of the peer review two separate residue definitions for risk assessment (provisionally): (1) thiram and (2) M1 compound. It was noted that the way the residue definition for risk assessment would be expressed would depend upon further information on the toxicity profile of M1 (data gap).

Since no new information on the toxicity profile of M1 was received for this review (and therefore, the data gap was not addressed), the residue definition for risk assessment derived in the peer review is proposed on a tentative basis.

It is underlined that the crops under consideration are consumed peeled and according to the results of metabolism studies and residue trials limited translocation of the residue from the peel to the pulp is expected. Moreover, in the residue trials assessed during the peer review, metabolite M1 was always found at levels lower than the parent compound (the lowest ratio between parent and metabolite was 7.6:1, with parent compound present at 0.76 mg/kg and M1 at 0.10 mg/kg). It is therefore expected that metabolite M1 will not be present at significant levels in the edible portion of the crops under assessment. Nevertheless, this conclusion should be confirmed by residue trials analysing for metabolite M1 (data gap).

## 1.2. Magnitude of residues in plants

### 1.2.1. Magnitude of residues in primary crops

To assess the magnitude of thiram residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (France, 2020) and that were already submitted in the framework of previous MRL applications (EFSA, 2008, 2015).

Residue trial samples of bananas were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected in bananas. For avocados, considering that storage stability in high oil content commodities was only demonstrated for thiram analysed as $CS_2$ for ca. 3 months, information on the storage stability of thiram (specific) would be desirable to confirm the validity of the residue trials reported, since in three out of the six residue trials, the sample storage conditions were up to 130 days (France, 2020; see also Section 1.1.5).

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).

The number of residue trials obtained with the thiram specific method was not sufficient to derive an MRL for thiram (specific). Following the methodology proposed by EFSA in the framework of an import tolerance on bananas (EFSA, 2008) and avocados (EFSA, 2015), a 'correction' factor from trials where thiram was analysed as $CS_2$ to thiram analysed as itself has been estimated based on the samples analysed with both methods (France, 2020).

Metabolite M1 was not analysed for in any of the trials on avocados and bananas.

Therefore, only tentative MRLs and risk assessment could be derived for both crops under assessment and the following data gaps were identified:

- Avocados: four trials analysing for metabolite M1 are still required.
- Bananas: four trials analysing for metabolite M1 are still required.

### 1.2.2. Magnitude of residues in rotational crops

No studies investigating the magnitude of residues in rotational crops were available for this review, and these are not required, since thiram is no longer approved in the European Union and the only uses under assessment are import tolerances.

### 1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on apples, pears and strawberries in the framework of the peer review (EFSA, 2017). Studies on bananas were assessed in a previous MRL application (EFSA, 2008), and these studies were also reported by the RMS (France, 2020). Based on the residue trials reported by the RMS for whole fruit and pulp, a peeling factor was derived for avocados (France, 2020). An overview of all available processing studies in avocados and bananas (bagged and unbagged) is available in Appendix B.1.2.3. Results of the processing studies on apples, pears and strawberries can be found in the list of endpoints of the peer review (EFSA, 2017).

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment of the current review.

### 1.2.4. Proposed MRLs

The available data are considered sufficient to derive tentative MRL proposals as well as risk assessment values for all commodities under evaluation.

## 2. Residues in livestock

Thiram is not authorised for use on crops that might be fed to livestock. Further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary (European Commission, 1996).

Although not necessary for this current review, the metabolism of thiram was investigated in lactating goats and laying hens under the framework of the peer review. A residue definition for enforcement and risk assessment as thiram was proposed, and an LC–MS/MS method with LOQ of 0.01 mg/kg for the determination of thiram in food and feed of animal origin (meat, liver, kidney, fat, milk and egg) was reported. A data gap was, however, identified for the determination of the extraction efficiency of the thiram specific method in food of animal origin (EFSA, 2017).

## 3. Consumer risk assessment

In the framework of this review, only the uses of thiram reported by the RMS in Appendix A were considered. It is noted that the use of thiram was previously also assessed by the JMPR and thiram-MRLs correlated to CXLs were derived on pome fruits and strawberries, for which the critical dithiocarbamate use was thiram (FAO, 1996). Considering that all these CXLs were based on EU uses (FAO, 1996) and that thiram is no longer authorised in the EU and that no information is available on the levels of metabolite M1 and of the additional metabolites formed following hydrolysis, these CXLs should not be considered in the consumer risk assessment. However, EFSA performed an indicative calculation considering the CXLs for thiram (expressed as thiram) on pome fruits and strawberries in order to assist risk managers in the decision-making process. According to this indicative calculation, acute risks were identified for pears, apples, quinces, medlars and strawberries, while chronic risks were identified for the following diets: Dutch toddler, German child and Dutch child. In addition, risks were also identified for processed commodities: apple juice and pear juice. For loquats, in the absence of consumption data, it was not possible to calculate even an indicative exposure. Nevertheless, considering the results of all other pome fruits and the data gaps identified, it is also not possible to exclude a risk for consumers for this commodity.

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, 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). All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values for thiram, derived by EFSA (2017). The highest chronic exposure was calculated for Dutch toddlers, representing 0.6% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for avocados, representing 35% of the ARfD. Although major uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

The derivation of the toxicological reference values of M1 is pending robust data addressing the toxicological profile of this metabolite. In addition, data on the level of the metabolite M1 in/on treated avocados and bananas are not available. Therefore, the consumer risk assessment for metabolite M1 could not be performed and overall risk assessment for the uses under consideration should be considered on a tentative basis. It is underlined that the crops under consideration are consumed peeled and according to the results of metabolism studies and residue trials limited translocation of the residue from the peel to the pulp is expected. Therefore, it is expected that metabolite M1 will not be present at significant levels in the edible portion of the crops under assessment. Nevertheless, this conclusion should be confirmed by residue trials analysing for metabolite M1.

# Conclusions

The metabolism of thiram in plant was investigated in primary crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as thiram (expressed as thiram). A specific residue definition for rotational crops is not deemed necessary considering that he crops under review are import tolerances. A residue definition for processed commodities could not be concluded on. Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water content commodities and high oil content commodities at the LOQ of 0.05 mg/kg. A data gap was, however, identified for the determination of the extraction efficiency of the thiram specific method in plants. According to the EURLs, a practical LOQ for thiram could not be proposed.

Available residue trials data were considered sufficient to derive tentative MRL proposals as well as risk assessment values for all commodities under evaluation according to the residue definition for enforcement of thiram (expressed as thiram), reflecting the residues from the use of thiram only.

Thiram is not authorised for use on crops that might be fed to livestock. Further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary.

The calculated exposure values were compared with the toxicological reference values for thiram, derived by EFSA (2017). The highest chronic exposure was calculated for Dutch toddlers, representing 0.6% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for avocados, representing 35% of the ARfD. Although major uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

The derivation of the toxicological reference values of M1 is pending robust data addressing the toxicological profile of this metabolite. In addition, data on the level of the metabolite M1 in/on treated avocados and bananas are not available. Therefore, the consumer risk assessment for metabolite M1 could not be performed and the overall risk assessment for the uses under consideration should be considered on a tentative basis. It is underlined that the crops under consideration are consumed peeled and according to the results of metabolism studies and residue trials limited translocation of the residue from the peel to the pulp is expected. Therefore, it is expected that metabolite M1 will not be present at significant levels in the edible portion of the crops under assessment. Nevertheless, this conclusion should be confirmed by residue trials analysing for metabolite M1.

## Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). Due to the outstanding issues on the toxicological characterisation of metabolite M1, the consumer risk assessment could not be finalised. Consequently, none of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation, and the following data are required:

- Further toxicological information for metabolite M1 in order to better define the toxicological profile of this compound. This information is needed to conclude on the residue definition for risk assessment and to finalise the consumer risk assessment (data gap relevant for avocados and bananas);
- A representative study to assess the suitability of the extraction procedures applied in plant analytical method (data gap relevant for avocados and bananas);
- Four trials analysing for metabolite M1 (data gap relevant for avocados and bananas).

It is underlined that no analytical methods are currently available to the EURLs for the enforcement of the proposed residue definition as thiram (specific). This should be considered by risk managers when implementing the derived MRLs. EFSA also underlines that, according to the information provided by the EURLs, the analytical standard for thiram is commercially available (EURL, 2020).

Minor deficiencies were identified in the assessment, but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- A representative storage stability of thiram (specific) and metabolite M1 in high oil content commodities.

**Table 2:** Summary table

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|---|
| | | | | MRL (mg/kg) | Comment |
| **Enforcement residue definition:** thiram (expressed as thiram) | | | | | |
| 130010 | Apples | 5 | 8 | – | Further consideration needed[(a)] |
| 130020 | Pears | 5 | 8 | – | Further consideration needed[(a)] |
| 130030 | Quinces | 0.1 | 8 | – | Further consideration needed[(a)] |
| 130040 | Medlars | 0.1 | 8 | – | Further consideration needed[(a)] |
| 130050 | Loquats/Japanese medlars | 0.1 | 8 | – | Further consideration needed[(a)] |
| 152000 | Strawberries | 10 | 8 | – | Further consideration needed[(a)] |
| 163010 | Avocados | 0.2 | – | 0.2 | Further consideration needed[(b)] |
| 163020 | Bananas | 10 | – | 10 | Further consideration needed[(b)] |
| – | Other commodities of plant and/or animal origin | See Reg. 2016/1 | – | – | Further consideration needed[(c)] |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): There are no relevant authorisations or import tolerances reported at EU level; CXL is not sufficiently supported by data and a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-IV in Appendix E).
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E).
(c): 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).

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## 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 |
| CAC | Codex Alimentarius Commission |
| CAS | Chemical Abstract Service |
| CF | conversion factor for enforcement residue definition to risk assessment residue definition |
| CS | capsule suspension |
| CV | coefficient of variation (relative standard deviation) |
| CXL | codex maximum residue limit |
| DAR | draft assessment report |
| DAT | days after treatment |
| DB | dietary burden |
| DM | dry matter |
| DS | powder for dry seed treatment |
| EC | emulsifiable concentrate |
| EMS | evaluating Member State |
| EURLs | European Union Reference Laboratories for Pesticide Residues (former CRLs) |
| FAO | Food and Agriculture Organization of the United Nations |
| GAP | Good Agricultural Practice |
| GC | gas chromatography |
| GS | growth stage |
| HPLC-MS/MS | high performance liquid chromatography with tandem mass spectrometry |
| HR | highest residue |
| IEDI | international estimated daily intake |
| IESTI | international estimated short-term intake |
| ILV | independent laboratory validation |
| ISO | International Organisation for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| JMPR | Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| LC | liquid chromatography |
| LC–MS/MS | liquid chromatography with tandem mass spectrometry |
| LOQ | limit of quantification |
| Mo | monitoring |
| MRL | maximum residue level |
| MS | Member States |
| MS | mass spectrometry detector |
| MS/MS | tandem mass spectrometry detector |
| MW | molecular weight |
| NEDI | national estimated daily intake |
| NESTI | national estimated short-term intake |

| | |
|---|---|
| NTMDI | national theoretical maximum daily intake |
| OECD | Organisation for Economic Co-operation and Development |
| PBI | plant back interval |
| PF | processing factor |
| PHI | pre-harvest interval |
| PRIMo | (EFSA) Pesticide Residues Intake Model |
| PROFile | (EFSA) Pesticide Residues Overview File |
| RA | risk assessment |
| RD | residue definition |
| RAC | raw agricultural commodity |
| RD | residue definition |
| RMS | rapporteur Member State |
| SANCO | Directorate-General for Health and Consumers |
| SC | suspension concentrate |
| SEU | southern European Union |
| SMILES | simplified molecular-input line-entry system |
| SL | soluble concentrate |
| SP | water soluble powder |
| STMR | supervised trials median residue |
| TAR | total applied radioactivity |
| TMDI | theoretical maximum daily intake |
| TRR | total radioactive residue |
| UV | ultraviolet (detector) |
| WG | water dispersible granule |
| WHO | World Health Organization |
| WP | wettable powder |

# Appendix A – Summary of authorised uses considered for the review of MRLs

## A.1. Import tolerances

| Crop and/or situation | MS or country | F G or I[(a)] | 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) | a.s./hL min–max | Water L/ha min–max | Rate and unit | | |
| Avocados | Mexico | F | Funghi | WG | 800.0 g/kg | Foliar treatment – spraying | | 1–3 | | 2.40 | 1,000 | Kg a.s./ha | 0 | |
| Bananas | Brazil, Colombia, Costa Rica, Ecuador, Guatemala, Honduras, Mexico, Panama and Venezuela | F | Foliar funghi (*Mycosphaerella fijiensis*) | SC | 420.0 g/kg | Foliar treatment – spraying | | 1–10 | 5 | 1.26 | 15–30 | Kg a.s./ha | 0 | Aerial spraying From fruit emergence until harvest |

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

# Appendix B – List of end points

## B.1. Residues in plants

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

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

| **Primary crops** (available studies) | **Crop groups** | **Crop(s)** | **Application(s)** | **Sampling (DAT)** | **Comment/Source** |
|---|---|---|---|---|---|
| | Fruit crops | Apples | Foliar treatment: 1 × 29.5 kg a.s./ha | 0, 14, 28, 56, 101 | Radiolabelled active substance: $^{14}$C-thiram (France, 2016a,b; EFSA, 2017) |
| | | Grapes | Foliar treatment: 4 × 3.2 kg a.s./ha | 0, 14, 27 | Radiolabelled active substance: $^{14}$C-thiram (France, 2016a,b; EFSA, 2017) |
| | Root crops | Sugar beet | Seed treatment: 1 × 2.4 g a.s./kg seed or 1 × 120 g a.s./kg seed | 100 and at maturity (tops/leaves root) | Radiolabelled active substance: $^{14}$C-thiram (France, 2016a,b; EFSA, 2017) |
| | Cereals/grass | Wheat | Seed treatment: 1 × 0.334 g a.s./kg seed | 35 (leaves, stem) and at maturity (straw, chaff, grain) | Radiolabelled active substance: $^{14}$C-thiram (France, 2016a,b; EFSA, 2017) |
| | | | Seed treatment: 1 × 0.785 g a.s./kg seed or 1 × 4.19 g a.s./kg seed or 1 × 14 g a.s./kg seed | 32, 60 (Forage), 95 (straw, chaff, grain) | Radiolabelled active substance: $^{14}$C-thiram (France, 2016a,b; EFSA, 2017) |
| | | | Seed treatment: 1 × 1.28 g a.s./kg seed (1×) or 1 × 6.4 g a.s./kg seed | 30, 67 | Radiolabelled active substance: $^{14}$C-thiram (France, 2016a,b; EFSA, 2017) |
| | Pulses/oilseeds | Cotton | Seed treatment: 1 × 1.14 g a.s./kg seed (1×) or 1 × 7 g a.s./kg seed | 30, 67 | Radiolabelled active substance: $^{14}$C-thiram (France, 2016a,b; EFSA, 2017) |
| | | Soybean | Seed treatment: 1 × 1.03 g a.s./kg seed (1×) or 1 × 6.5 g a.s./kg seed | 30, 67 | Radiolabelled active substance: $^{14}$C-thiram (France, 2016a,b; EFSA, 2017) |
| | | | Seed treatment: 1 × 0.60 g a.s./kg seed (1×) 1 × 30 g a.s./kg seed | 29, 69 (forage) and at maturity (straw, pods, seeds) | Radiolabelled active substance: $^{14}$C-thiram (France, 2016a,b; EFSA, 2017) |
| **Rotational crops** (available studies) | **Crop groups** | **Crop(s)** | **Application(s)** | **PBI (DAT)** | **Comment/Source** |
| | Root/tuber crops | – | – | – | – |
| | Leafy crops | – | – | – | – |
| | Cereal (small grain) | – | – | – | – |

| **Processed commodities** (hydrolysis study) | **Conditions** | **Stable?** | **Comment/Source** |
|---|---|---|---|
| | Pasteurisation (20 min, 90°C, pH 4) | No | Thiram 80% TRR. Volatile compounds were negligible, less than 2% TAR (EFSA, 2017) |
| | Baking, brewing and boiling (60 min, 100°C, pH 5) | No | Thiram 20.8% TRR. Volatile radioactivity ranged between 16.7% and 21.0% TAR (EFSA, 2017) |
| | Sterilisation (20 min, 120°C, pH 6) | No | Thiram 0.6% TRR. Volatile radioactivity ranged between 16.7% and 21.6% TAR (EFSA, 2017) |
| | Other processing conditions | – | – |

| | | |
|---|---|---|
| Can a general residue definition be proposed for primary crops? | Yes | |
| Rotational crop and primary crop metabolism similar? | Not applicable. | Metabolism studies in rotational crops not available and not required since uses under assessment are import tolerances. |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Inconclusive | Pending outcome of the requested hydrolysis study on M1, the magnitude of M2, M3, M4, M7 and M8 residues in fruit processed commodities and toxicological information on compounds M1, M2, M4, M7, M8 in the framework of the peer-review (EFSA, 2017).<br>As the commodities under consideration are consumed mainly raw and peeled and according to the results of metabolism studies and residue trials limited translocation from the peel to the pulp is expected, the data gaps identified in the peer-review regarding the effect of processing on the nature of residues are not deemed relevant in the framework of this assessment. |
| Plant residue definition for monitoring (RD-Mo) | Thiram (expressed as thiram) | |
| Plant residue definition for risk assessment (RD-RA) | Primary crops: 1) thiram (expressed as thiram) and 2) metabolite M1 (tentative, pending upon the requested information on the toxicity profile of M1)<br><br>Processed commodities: Inconclusive, pending outcome of the requested hydrolysis study on M1, the magnitude of M2, M3, M4, M7 and M8 residues in fruit processed commodities and toxicological information on compounds M1, M2, M4, M7, M8. | |
| Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) | LC–MS/MS with a limit of quantification (LOQ) of 0.01 mg/kg in dry commodities and a LOQ of 0.05 mg/kg in the other plant matrices.<br>Confirmatory method available.<br>ILV available.<br>Extraction efficiency of thiram specific (data gap).<br>(EFSA, 2017)<br><br>The EURLs reported that they are unable at the current stage to indicate any practical LOQs due to losses taking place during the analysis of thiram using procedures routinely employed by laboratories (EURL, 2020). | |

a.i.: active ingredient; DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

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

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | | Compounds covered | Comment/ Source |
|---|---|---|---|---|---|---|---|
| | | | | Value | Unit | | |
| | High water content | Bananas | –18 | 3 | Months | Thiram (specific); thiram as $CS_2$ | France (2020) |
| | | Lettuce | –20 | 8 | Weeks | Thiram (specific) | EFSA (2017) |
| | | Plum | –20 | 71 | Weeks | Thiram (specific); thiram as $CS_2$ | EFSA (2017) |
| | | Apricot | –18 | 12 | Months | Thiram (specific); thiram as $CS_2$; M1 | EFSA (2017) |
| | | Pear | –18 | 12 | Months | Thiram (specific); M1 | EFSA (2017) |
| | | Pear | –18 | 13 | Weeks | ETU | EFSA (2017) |
| | | Cherry | –18 | 12 | Months | Thiram (specific); M1 | EFSA (2017) |
| | | Wheat forage | –20 | 8 | Weeks | Thiram as $CS_2$ | EFSA (2017) |
| | | Maize forage | –20 | 2 | Months | Thiram as $CS_2$ | EFSA (2017) |
| | | | | 5 | Months | M1 | EFSA (2017) |
| | | | | 0 | Weeks | Thiram (specific) | EFSA (2017) |
| | High oil content | Avocado | –18 | 3 | Months | Thiram as $CS_2$ | France (2020) |
| | | Cotton seed | –20 | 78 | Weeks | Thiram as $CS_2$ | EFSA (2017) |
| | | Soybean | –20 | 78 | Weeks | Thiram as $CS_2$ | EFSA (2017) |
| | High protein content | – | – | – | – | – | – |
| | High starch content | Wheat grain | –20 | 52 | Weeks | Thiram as $CS_2$ | EFSA (2017) |
| | | Barley grain | –20 | 4 | Months | Thiram as $CS_2$ | EFSA (2017) |
| | | | | 5 | Months | M1 | EFSA (2017) |
| | | Maize grain | –20 | 4 | Months | Thiram as $CS_2$ | EFSA (2017) |
| | | | | 0 | Weeks | Thiram (specific) | EFSA (2017) |
| | | | | 5 | Months | M1 | EFSA (2017) |
| | High acid content | Strawberry | –20 | 12 | Months | Thiram (specific); thiram as $CS_2$; M1 | EFSA (2017) |
| | | Grapes | –18 | 12 | Months | Thiram (specific); M1 | EFSA (2017) |
| | Processed products | Pear juice | –18 | 12 | Months | Thiram (specific); M1 | EFSA (2017) |
| | | | | 13 | Weeks | ETU | EFSA (2017) |
| | | Pear puree | –18 | 12 | Months | Thiram as $CS_2$; M1 | EFSA (2017) |
| | | | | 13 | Weeks | ETU | EFSA (2017) |
| | | Wine | –18 | 12 | Months | M1 | EFSA (2017) |
| | Others | Barley straw | –20 | 4 | Months | Thiram as $CS_2$ | EFSA (2017) |
| | | | | 5 | Months | M1 | EFSA (2017) |
| | | Maize straw | –20 | 1 | Month | Thiram as $CS_2$ | EFSA (2017) |
| | | | | 0 | Week | Thiram (specific) | EFSA (2017) |

### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials – Primary crops

| 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)] |
|---|---|---|---|---|---|---|---|
| **RD-Mo & RD-RA 1: thiram (expressed as thiram)<br>RD-RA 2: M1 (tentative)** | | | | | | | |
| Avocados | AU, MX | Mo & RA1: 2.28; 2.49; 2.56; 2.69; 4.30; 5.85<br>RA2: – | Residue trials on avocados compliant with GAP (EFSA, 2015; France, 2020)[(g)]. Residues in avocado pulp below the LOQ: 6 × < 0.08 (France, 2020)<br>$MRL_{OECD}$ = 10.09 | **10** (tentative)[(e)] | 5.85 | 2.63 | RA1: 1<br>RA 2: –[(f)] |
| Bananas | BR, CO, CR, EC, GT, HN, MX, PA, VZ | Mo & RA1: 5 × < 0.05; 0.061; 2 × 0.066; 0.071; 0.094; 0.110; 0.114<br>RA2: – | Residue trials on bananas compliant with GAP (EFSA, 2008; France, 2020)[(h)]. Residue levels for unbagged bananas, whole fruit. Residues in banana (unbagged) pulp varied between < 0.01 and 0.024 mg/kg (France, 2020)<br>$MRL_{OECD}$ = 0.16 | **0.2** (tentative)[(e)] | 0.11 | 0.06 | RA1: 1<br>RA 2: –[(f)] |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

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

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment (RA) 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.

(e): MRL is tentative since extraction efficiency of the analytical method of thiram (specific) and information on the levels and toxicity of metabolite M1 are missing.

(f): A conversion factor could not be derived since information on residue levels and toxicological profile of metabolite M1 are missing.

(g): Analysed as thiram: 2.28; 2.56; 4.30. Residues analysed as $CS_2$ and recalculated to thiram using a correction factor of 0.79: 2.49; 2.69; 5.85.

(h): Analysed as thiram: 0.061; 0.071; 0.114; 0.469. Residues analysed as $CS_2$ and recalculated to thiram by applying a correction factor of 0.24: 5 × < 0.05; 2 × 0.066; 0.094; 0.110.

#### B.1.2.2. Residues in rotational crops

**a) Overall summary**

| | | |
|---|---|---|
| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Not triggered | Since thiram is no longer approved in the European Union and the only uses under assessment are import tolerances, consideration on rotational crops is not required. |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered | Since thiram is no longer approved in the European Union and the only uses under assessment are import tolerances, consideration on rotational crops is not required. |

#### B.1.2.3. Processing factors

| Processed commodity | Number of valid studies[(a)] | Processing Factor (PF) | | Comment/ Source |
|---|---|---|---|---|
| | | Individual values | Median PF | |
| Bananas bagged, peeled | 3 | n.r. | 0.35 | France (2020) |
| Bananas unbagged, peeled | 11 | n.r | 0.19 | France (2020) |
| Bananas, peeled | 14 | n.r | 0.20 | France (2020) |
| Avocados, peeled | 6 | 0.01; 0.02; 0.03; 0.03; 0.03; 0.04 | < 0.03 | France (2020) |

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/ Residue level in raw commodity expressed according to RD-Mo); $CF_p$: Conversion factor for risk assessment in processed commodity (=Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo); n.r.: not reported.
Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

## B.3. Residues in livestock

Since crops under assessment are not fed to livestock, there is no need to derive a residue definition and/or MRLs for livestock.

## B.4. Consumer risk assessment

| | |
|---|---|
| ARfD | Thiram: 0.025 mg/kg bw (EFSA, 2017)<br>M1: open |
| Highest IESTI, according to EFSA PRIMo (rev.3.1) | Thiram: Avocados: 35% of ARfD<br>M1: not assessed |
| NESTI (% ARfD) | Not assessed in this review. |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities, to which the derived peeling factors were applied: avocados (PeF <0.03) and bananas (PeF = 0.19).<br><br>Metabolite M1 is not covered in the calculation as residue levels and toxicological information on this compound are not available. |

ARfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; IESTI: international estimated short-term intake.

| | |
|---|---|
| ADI | Thiram: 0.01 mg/kg bw per day (EFSA, 2017)<br>M1: open |
| TMDI according to EFSA PRIMo | Not assessed in this review. |
| NTMDI, according to (to be specified) | Not assessed in this review. |
| Highest IEDI, according to EFSA PRIMo (rev.3.1) | Thiram: 0.6% ADI (Dutch toddlers)<br>M1: not assessed |
| NEDI (% ADI) | Not assessed in this review. |
| Assumptions made for the calculations | The calculation is based on the median residue levels expected in raw agricultural commodities, to which the derived peeling factors were applied: avocados (PeF <0.03) and bananas (PeF = 0.19).<br><br>The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.<br><br>Metabolite M1 is not covered in the calculation as residue levels and toxicological information on this compound are not available. |

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake.

## B.5. Proposed MRLs

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|---|
| | | | | MRL (mg/kg) | Comment |
| **Enforcement residue definition:** thiram (expressed as thiram) | | | | | |
| 130010 | Apples | 5 | 8 | – | Further consideration needed[(a)] |
| 130020 | Pears | 5 | 8 | – | Further consideration needed[(a)] |
| 130030 | Quinces | 0.1 | 8 | – | Further consideration needed[(a)] |
| 130040 | Medlars | 0.1 | 8 | – | Further consideration needed[(a)] |
| 130050 | Loquats/Japanese medlars | 0.1 | 8 | – | Further consideration needed[(a)] |
| 152000 | Strawberries | 10 | 8 | – | Further consideration needed[(a)] |
| 163010 | Avocados | 0.2 | – | 0.2 | Further consideration needed[(b)] |
| 163020 | Bananas | 10 | – | 10 | Further consideration needed[(b)] |
| – | Other commodities of plant and/or animal origin | See Reg. 2016/1 | – | – | Further consideration needed[(c)] |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): There are no relevant authorisations or import tolerances reported at EU level; CXL is not sufficiently supported by data and a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-IV in Appendix E).
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E).
(c): 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).

# Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo(EU)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

## Thiram

| | | | |
|---|---|---|---|
| LOQs (mg/kg) range from: | | to: | |
| **Toxicological reference values** | | | |
| ADI (mg/kg bw per day): | **0.01** | ARfD (mg/kg bw): | **0.025** |
| Source of ADI: | **EFSA** | Source of ARfD: | **EFSA** |
| Year of evaluation: | **2017** | Year of evaluation: | **2017** |

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

**Normal mode**

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

No of diets exceeding the ADI : ---

**TMDI/NEDI/IEDI calculation (based on average food consumption)**

| Calculated exposure (% of ADI) | MS Diet | Expsoure (µg/kg bw per day) | 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 | Exposure resulting from MRLs set at the LOQ (in % of ADI) | Exposure resulting from commodities not under assessment (in % of ADI) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.6% | NL toddler | 0.06 | 0.6% | Bananas | | | | | | 0.6% |
| 0.2% | SE general | 0.02 | 0.2% | Bananas | 0.0% | Avocados | | | | 0.2% |
| 0.2% | IE adult | 0.02 | 0.1% | Avocados | 0.1% | Bananas | | | | 0.2% |
| 0.2% | NL child | 0.02 | 0.2% | Bananas | | Grapefruits | | | | 0.2% |
| 0.2% | DE child | 0.02 | 0.2% | Bananas | 0.0% | Avocados | | | | 0.2% |
| 0.2% | UK infant | 0.02 | 0.2% | Bananas | | Grapefruits | | | | 0.2% |
| 0.2% | FI 3 yr | 0.02 | 0.2% | Bananas | | Grapefruits | | | | 0.2% |
| 0.1% | DK child | 0.01 | 0.1% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | UK toddler | 0.01 | 0.1% | Bananas | | Grapefruits | | | | 0.1% |
| 0.1% | ES child | 0.01 | 0.1% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | FR child 3 15 yr | 0.01 | 0.1% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | FI 6 yr | 0.01 | 0.1% | Bananas | | Grapefruits | | | | 0.1% |
| 0.1% | GEMS/Food G07 | 0.01 | 0.1% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | FR toddler 2 3 yr | 0.01 | 0.1% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | DK adult | 0.01 | 0.1% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | GEMS/Food G10 | 0.01 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | IT toddler | 0.01 | 0.1% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | GEMS/Food G15 | 0.01 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | GEMS/Food G08 | 0.01 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | UK vegetarian | 0.01 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | GEMS/Food G11 | 0.01 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | UK adult | 0.01 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.1% | ES adult | 0.01 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.1% |
| 0.0% | DE women 14-50 yr | 0.00 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.0% |
| 0.0% | PT general | 0.00 | 0.0% | Bananas | | Grapefruits | | | | 0.0% |
| 0.0% | GEMS/Food G06 | 0.00 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.0% |
| 0.0% | DE general | 0.00 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.0% |
| 0.0% | FI adult | 0.00 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.0% |
| 0.0% | FR adult | 0.00 | 0.0% | Avocados | 0.0% | Bananas | | | | 0.0% |
| 0.0% | NL general | 0.00 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.0% |
| 0.0% | RO general | 0.00 | 0.0% | Bananas | | Grapefruits | | | | 0.0% |
| 0.0% | IT adult | 0.00 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.0% |
| 0.0% | FR infant | 0.00 | 0.0% | Bananas | | Grapefruits | | | | 0.0% |
| 0.0% | IE child | 0.00 | 0.0% | Bananas | 0.0% | Avocados | | | | 0.0% |
| 0.0% | PL general | 0.00 | 0.0% | Bananas | | Grapefruits | | | | 0.0% |
| 0.0% | LT adult | 0.00 | 0.0% | Bananas | | Grapefruits | | | | 0.0% |

**Conclusion:**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of thiram is unlikely to present a public health concern.

**Acute risk assessment/children** | **Acute risk assessment/adults/general population**

Details – acute risk assessment/children | Details – acute risk assessment/adults

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**

**Unprocessed commodities**

**Results for children**
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

**IESTI**

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|
| 35% | Avocados | 10/0.18 | 8.8 |
| 8% | Bananas | 0.2/0.02 | 2.1 |

**Results for adults**
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

**IESTI**

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|
| 11% | Avocados | 10/0.18 | 2.6 |
| 2% | Bananas | 0.2/0.02 | 0.46 |

Expand/collapse list

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

**Processed commodities**

**Results for children**
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

**IESTI**

| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|

**Results for adults**
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

**IESTI**

| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|

Expand/collapse list

**Conclusion:**
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of thiram is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

- PRIMo (CXL)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

| **Thiram** | | | |
|---|---|---|---|
| LOQs (mg/kg) range from: | | to: | |
| **Toxicological reference values** | | | |
| ADI (mg/kg bw per day): | **0.01** | ARfD (mg/kg bw): | **0.025** |
| Source of ADI: | | Source of ARfD: | |
| Year of evaluation: | | Year of evaluation: | |

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

**Normal mode**

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

No of diets exceeding the ADI : 3

TMDI/NEDI/IEDI calculation (based on average food consumption)

| Calculated exposure (% of ADI) | MS Diet | Exposure (µg/kg bw per day) | 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 | Exposure resulting from MRLs set at the LOQ (in % of ADI) | Exposure resulting from commodities not under assessment (in % of ADI) |
|---|---|---|---|---|---|---|---|---|---|---|
| 294% | NL toddler | 29.44 | 204% | Apples | 82% | Pears | 7% | Strawberries | | 294% |
| 260% | DE child | 25.96 | 237% | Apples | 12% | Pears | 10% | Strawberries | | 260% |
| 140% | NL child | 13.95 | 110% | Apples | 23% | Pears | 7% | Strawberries | | 140% |
| 70% | FR toddler 2 3 yr | 6.96 | 60% | Apples | 6% | Pears | 3% | Strawberries | | 70% |
| 60% | DK child | 6.00 | 44% | Apples | 13% | Pears | 3% | Strawberries | | 60% |
| 54% | DE women 14-50 yr | 5.41 | 49% | Apples | 3% | Pears | 2% | Strawberries | | 54% |
| 51% | DE general | 5.06 | 46% | Apples | 2% | Pears | 2% | Strawberries | | 51% |
| 44% | PL general | 4.45 | 39% | Apples | 5% | Pears | 0.4% | Strawberries | | 44% |
| 42% | FR child 3 15 yr | 4.18 | 32% | Apples | 5% | Pears | 5% | Strawberries | | 42% |
| 40% | UK toddler | 3.99 | 32% | Apples | 4% | Strawberries | 3% | Pears | | 40% |
| 39% | LT adult | 3.92 | 35% | Apples | 3% | Pears | 0.8% | Strawberries | | 39% |
| 39% | FR infant | 3.91 | 32% | Apples | 4% | Strawberries | 3% | Pears | | 39% |
| 39% | UK infant | 3.91 | 30% | Apples | 5% | Pears | 4% | Strawberries | | 39% |
| 35% | GEMS/Food G11 | 3.48 | 29% | Apples | 3% | Pears | 2% | Strawberries | | 35% |
| 33% | NL general | 3.29 | 28% | Apples | 4% | Pears | 2% | Strawberries | | 33% |
| 33% | ES child | 3.25 | 22% | Apples | 8% | Pears | 1% | Strawberries | | 33% |
| 31% | RO general | 3.08 | 27% | Apples | 2% | Pears | 1% | Strawberries | | 31% |
| 30% | SE general | 3.04 | 20% | Apples | 7% | Pears | 3% | Strawberries | | 30% |
| 29% | FI 3 yr | 2.88 | 18% | Apples | 7% | Strawberries | 3% | Pears | | 29% |
| 28% | GEMS/Food G08 | 2.77 | 23% | Apples | 3% | Pears | 2% | Strawberries | | 28% |
| 28% | PT general | 2.77 | 20% | Apples | 6% | Pears | 0.8% | Strawberries | | 28% |
| 27% | GEMS/Food G15 | 2.67 | 21% | Apples | 3% | Pears | 2% | Medlar | | 27% |
| 26% | IT toddler | 2.60 | 17% | Apples | 7% | Pears | 2% | Strawberries | | 26% |
| 26% | DK adult | 2.58 | 18% | Apples | 6% | Pears | 1% | Strawberries | | 26% |
| 26% | IE adult | 2.57 | 14% | Apples | 8% | Pears | 4% | Strawberries | | 26% |
| 24% | GEMS/Food G07 | 2.42 | 19% | Apples | 3% | Pears | 2% | Strawberries | | 24% |
| 22% | ES adult | 2.24 | 15% | Apples | 6% | Pears | 1% | Strawberries | | 22% |
| 21% | GEMS/Food G06 | 2.12 | 18% | Apples | 2% | Pears | 0.9% | Strawberries | | 21% |
| 21% | GEMS/Food G10 | 2.09 | 14% | Apples | 3% | Pears | 2% | Strawberries | | 21% |
| 21% | IT adult | 2.06 | 15% | Apples | 4% | Pears | 1% | Strawberries | | 21% |
| 20% | FI 6 yr | 2.04 | 11% | Apples | 6% | Strawberries | 3% | Pears | | 20% |
| 20% | FR adult | 1.99 | 15% | Apples | 3% | Pears | 3% | Strawberries | | 20% |
| 15% | FI adult | 1.49 | 11% | Apples | 3% | Strawberries | 1.0% | Pears | | 15% |
| 14% | UK vegetarian | 1.43 | 11% | Apples | 2% | Strawberries | 1% | Pears | | 14% |
| 10% | UK adult | 0.99 | 8% | Apples | 1% | Pears | 1.0% | Strawberries | | 10% |
| 7% | IE child | 0.72 | 6% | Apples | 0.6% | Pears | 0.5% | Strawberries | | 7% |

**Conclusion:**
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 294.4 % of the ADI.
For 3 diet(s) the ADI is exceeded.

| Acute risk assessment/children | Acute risk assessment/adults/general population |
|---|---|
| Details - acute risk assessment/children | Details - acute risk assessment/adults |

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**

**Unprocessed commodities**

**Results for children**
No. of commodities for which ARfD/ADI is exceeded (IESTI): 5

**Results for adults**
No. of commodities for which ARfD/ADI is exceeded (IESTI): 5

**IESTI**

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|---|---|---|---|
| 3501% | Pears | 7.9/6.32 | 875 | 772% | Pears | 7.9/6.32 | 193 |
| 2725% | Apples | 7.9/6.32 | 681 | 710% | Apples | 7.9/6.32 | 177 |
| 622% | Quinces | 7.9/6.32 | 155 | 385% | Quinces | 7.9/6.32 | 96 |
| 350% | Medlar | 7.9/6.32 | 87 | 173% | Medlar | 7.9/6.32 | 43 |
| 203% | Strawberries | 8/3.1 | 51 | 116% | Strawberries | 8/3.1 | 29 |
| 35% | Avocados | 10/0.18 | 8.8 | 11% | Avocados | 10/0.18 | 2.6 |
| 8% | Bananas | 0.2/0.02 | 2.1 | 2% | Bananas | 0.2/0.02 | 0.46 |

Expand/collapse list

**Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)** 5

**Processed commodities**

**Results for children**
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 2

**Results for adults**
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

**IESTI**

| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|---|---|---|---|
| 411% | Apples/juice | 7.9/1.9 | 103 | 253% | Apples/juice | 7.9/1.9 | 63 |
| 247% | Pears/juice | 7.9/1.9 | 62 | 9% | Quinces/jam | 7.9/1.9 | 2.4 |
| 23% | Quinces/jam | 7.9/1.9 | 5.7 | | | | |

Expand/collapse list

**Conclusion:**
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 5 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

# Appendix D – Input values for the exposure calculations

## D.1. Consumer risk assessment without consideration of the CXLs

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| **Risk assessment residue definition 1:** thiram (expressed as thiram) | | | | |
| Avocados | 0.08 | STMR × PeF (< 0.03) | 0.18 | HR × PeF (< 0.03) |
| Bananas | 0.01 | STMR × PeF (0.19) | 0.02 | HR × PeF (0.19) |
| **Risk assessment residue definition 2:** M1 (tentative) | | | | |
| Avocados | – | No data available regarding the levels of M1 in treated crops. Information on the toxicity of M1 not available | – | No data available regarding the levels of M1 in treated crops. Information on the toxicity of M1 not available |
| Bananas | – | | – | |

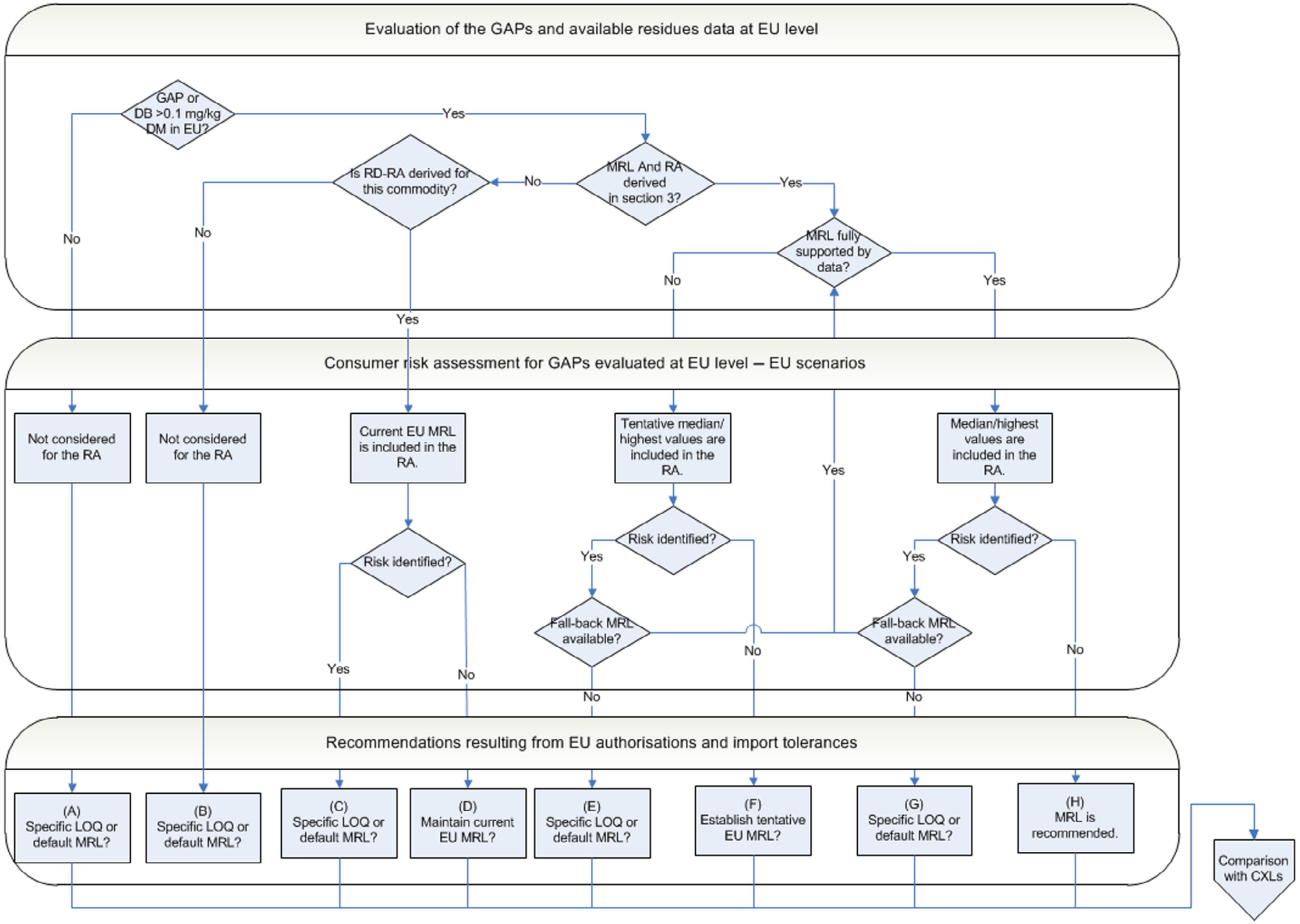
PeF: peeling factor.
*: Indicates that the input value is proposed at the limit of quantification.

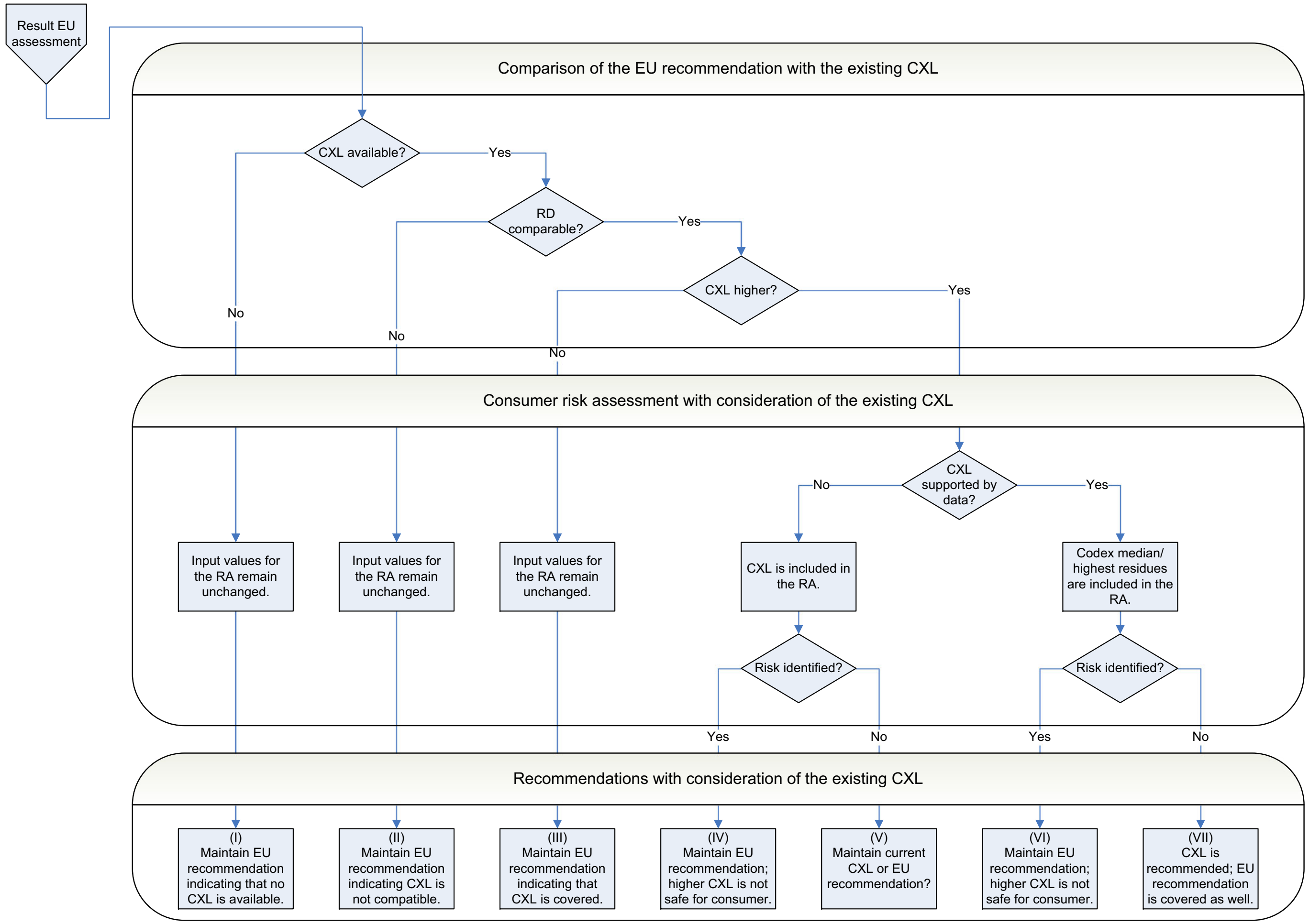
## D.2. Indicative consumer risk assessment with consideration of the CXLs

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| **Risk assessment residue definition 1:** thiram (expressed as thiram) | | | | |
| Pome fruits | 1.9 | STMR (CXL)[(a)] | 6.3 | HR (CXL)[(a)] |
| Strawberries | 2.1 | STMR (CXL) | 3.1 | HR (CXL) |
| Avocados | 0.08 | STMR × PeF (< 0.03) | 0.18 | HR × PeF (< 0.03) |
| Bananas | 0.01 | STMR × PeF (0.19) | 0.02 | HR × PeF (0.19) |
| **Risk assessment residue definition 2:** M1 (tentative) | | | | |
| Pome fruits | – | No data available regarding the levels of M1 in treated crops. Information on the toxicity of M1 not available | – | No data available regarding the levels of M1 in treated crops. Information on the toxicity of M1 not available |
| Strawberries | – | | – | |
| Avocados | – | | – | |
| Bananas | – | | – | |

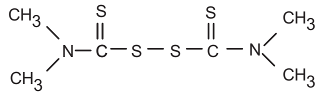
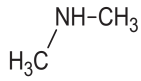
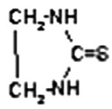
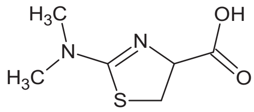
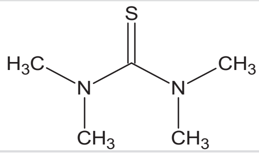
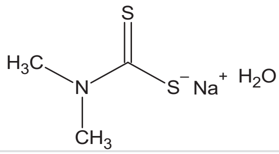
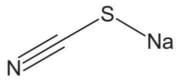
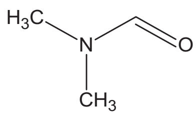
PeF: peeling factor.
*: Indicates that the input value is proposed at the limit of quantification.
(a): A conversion factor of 1.58 was used to convert the risk assessment values from $CS_2$ to thiram.

# Appendix E – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
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 EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain 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[(a)] | Chemical name/SMILES notation/In | Structural formula |
|---|---|---|
| **thiram** | Tetramethylthioperoxydicarbonic diamide<br>Tetramethylthiuram disulfide<br>Bis(dimethylthiocarbamoyl)disulfide<br>Bis(dimethylaminothiocarbonyl)-disulfide |  |
| **M4 (DMA)** | *N*-methylmethanamine<br><br>CNC<br><br>ROSDSFDQCJNGOL-UHFFFAOYSA-N |  |
| **ETU (Ethylenethiourea)** | 4,5-Dihydro-1H-imidazol-2-thione |  |
| **M1** | 2-(dimethylamino)-4,5-dihydro-1,3-thiazole-4-carboxylic acid<br><br>CN(C)C1=NC(CS1)C(O)=O<br><br>SUUMCDKAOZPOQX-UHFFFAOYSA-N |  |
| **M2** | 1,1,3,3-tetramethylthiourea<br><br>CN(C)C(=S)N(C)C<br><br>MNOILHPDHOHILI-UHFFFAOYSA-N |  |
| **M3** | sodium dimethylcarbamodithioate hydrate<br><br>[Na+].O.CN(C)C([S-])=S<br><br>RJCVAPZBRKHUSV-UHFFFAOYSA-M |  |
| **M7** | sodium thiocyanate<br><br>N#CS[Na]<br><br>VGTPCRGMBIAPIM-UHFFFAOYSA-M |  |
| **M8** | *N*,*N*-dimethylformamide<br><br>CN(C)C=O<br><br>ZMXDDKWLCZADIW-UHFFFAOYSA-N |  |

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).