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

European Food Safety Authority (EFSA), Alba Brancato, Daniela Brocca, Luis Carrasco Cabrera, Chloe De Lentdecker, Zoltan Erdos, Lucien Ferreira, Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Alfonso Lostia, Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Ragnor Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Jose Tarazona, Anne Theobald, Benedicte Vagenende and Laura Villamar-Bouza

Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance tembotrione. To assess the occurrence of tembotrione residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011 as well as the import tolerances and European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

© 2018 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: tembotrione, MRL review, regulation (EC) No 396/2005, consumer risk assessment, triketone, herbicide

Requestor: European Commission
Question number: EFSA-Q-2013-00967
Correspondence: pesticides.mrl@efs.europa.eu
Acknowledgement: EFSA wishes to thank the rapporteur Member State Austria for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B and Villamar-Bouza L, 2018. Reasoned opinion on the review of the existing maximum residue levels for tembotrione according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(9):5417, 38 pp. https://doi.org/10.2903/j.efsa.2018.5417

ISSN: 1831-4732

© 2018 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

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

Tembotrione was approved on 1 May 2014 by means of Commission Implementing Regulation 1192/2013 under Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Austria, the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 22 September 2017 and finalised on 24 November 2017. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 23 January 2018.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, and the additional information provided by the RMS and Member States, EFSA prepared in June 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 18 July 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of tembotrione was studied in maize grain, stover and forage (cereal crops) during the peer review. In the framework of this review, an additional metabolism study on poppy seeds (pulses/oilseed) was submitted and assessed. The parent tembotrione was rapidly metabolised and metabolites M5 (dihydroxy-tembotrione) and subsequently M6 (benzoic acid) were mainly formed. A metabolism study in fruiting vegetables or another third crop group is not available and still required in relation to a reported authorised Good Agricultural Practice (GAP) on fruit spices.

During the peer review, it was concluded that the metabolism of tembotrione in rotational crops is similar to the pathway observed in primary crops. The occurrence of significant tembotrione residues in rotational crops was considered unlikely and available studies were considered sufficient during the peer review. These conclusions are supported during this review.

Monitoring methods are available for tembotrione and its metabolite M5 with a limit of quantification (LOQ) of 0.01 mg/kg, respectively, for high water, high acid, high oil and dry commodities. A validated high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) method, independent laboratory validation (ILV) and a confirmatory liquid chromatography with tandem mass spectrometry (LC-MS/MS) method with a LOQ of 0.01 mg/kg for tembotrione and M5, respectively, are available. For spices a method for enforcement is still required.

The same residue definitions (tembotrione and its metabolite M5, expressed as tembotrione) as proposed during the peer review are still supported in this review limited to cereals, pulses and oilseeds. It is applicable to rotational crops and processed commodities. Nevertheless, no residue definitions could be proposed for fruit spices. According to the information provided by the EURLs an analytical standard is commercially available for tembotrione and metabolite M5.

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for sweet corn for which tentative MRLs are derived and for fruit spices where no MRL could be derived.

A metabolism study in dairy cattle dosed with radio-labelled M5 was performed and showed that unchanged M5 was the only significant radioactive component seen in liver and kidney. During the peer review, it was concluded that only the metabolite M5 should be defined as the residue of concern in food of animal origin based on the intake of maize silage and grain where M5 residues and exposure are expected. This conclusion is supported during this review. A HPLC-MS/MS method for enforcement of metabolite M5 with a LOQ of 0.01 mg/kg in muscle, liver, kidney, liver and eggs and with a LOQ of 0.002 mg/kg in milk for M5 is available. An ILV and a confirmatory LC-MS/MS method are available.

Based on the results of the livestock feeding study and considering the calculated dietary burden, significant residues in kidney and liver of cattle and swine are expected and MRLs for these commodities can be proposed. For milk and for all other cattle and swine tissues, MRLs can be established at the LOQ. According to the information provided by the EURLs an analytical standard is commercially available for metabolite M5.

Chronic and acute consumer exposures resulting from the authorised uses reported in the framework of this review were calculated using revision 2 of the EFSA Pesticide Residues Intake Model.
(PRIMo). For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for UK, toddler, representing 25% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for sweet corn, representing 3.2% of the acute reference dose (ARfD). It has to be noted that metabolite M5 is less toxic than the parent (ADI = 0.013 mg/kg body weight (bw) per day). During the peer review, a toxicity equivalence factor (TEF) of 0.0308 was derived. During this review, the risk assessment was carried out with the ADI of the parent without consideration of the TEF. Since no consumer concern was identified, a refined assessment considering the TEF was not carried out and is not considered necessary.

In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of tembotrione and that further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.
# Table of contents

Abstract................................................................................................................................................... 1  
Summary................................................................................................................................................. 3  
Background ............................................................................................................................................. 6  
Terms of Reference .................................................................................................................................. 7  
The active substance and its use pattern ................................................................................................. 7  
Assessment.............................................................................................................................................. 8  
1. Residues in plants ................................................................................................................................ 8  
   1.1. Nature of residues and methods of analysis in plants .................................................................... 8  
   1.1.1. Nature of residues in primary crops ............................................................................................ 8  
   1.1.2. Nature of residues in rotational crops .......................................................................................... 9  
   1.1.3. Nature of residues in processed commodities ........................................................................... 9  
   1.1.4. Methods of analysis in plants ...................................................................................................... 9  
   1.1.5. Stability of residues in plants ..................................................................................................... 9  
   1.1.6. Proposed residue definitions....................................................................................................... 9  
   1.2. Magnitude of residues in plants ..................................................................................................... 10  
   1.2.1. Magnitude of residues in primary crops .................................................................................... 10  
   1.2.2. Magnitude of residues in processed commodities ...................................................................... 11  
   1.2.3. Proposed MRLs .......................................................................................................................... 11  
2. Residues in livestock ............................................................................................................................ 11  
   2.1. Nature of residues and methods of analysis in livestock ................................................................. 11  
   2.2. Magnitude of residues in livestock ................................................................................................ 12  
3. Consumer risk assessment .................................................................................................................... 12  
Conclusions.............................................................................................................................................. 13  
Recommendations.................................................................................................................................... 14  
References............................................................................................................................................... 15  
Abbreviations ........................................................................................................................................... 16  
Appendix A – Summary of authorised uses considered for the review of MRLs ...................................... 18  
Appendix B – List of end points ............................................................................................................... 24  
Appendix C – Pesticide Residue Intake Model (PRIMo) ......................................................................... 32  
Appendix D – Input values for the exposure calculations ......................................................................... 34  
Appendix E – Decision tree for deriving MRL recommendations ........................................................... 36  
Appendix F – Used compound codes .................................................................................................... 38
Background

Regulation (EC) No 396/20051 (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC2 a reasoned opinion on the review of the existing MRLs for that active substance. As tembotrione was included in Annex I to Council Directive 91/414/EEC on 1 May 2014 by means of Commission Implementing Regulation 1192/20133, and has been deemed to be approved under Regulation (EC) No 1107/20094, in accordance with Commission Implementing Regulation (EU) No 540/20115, as amended by Commission Implementing Regulation (EU) No 541/20116, EFSA initiated the review of all existing MRLs for that active substance.

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

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

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

Austria, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for tembotrione and to prepare a supporting evaluation report (Austria, 2014). The PROFile and the supporting evaluation report were submitted to EFSA on 25 February 2014 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 22 September 2017 and finalised on 24 November 2017. Additional evaluation reports were submitted by Austria, the Czech Republic, France, Greece, the Netherlands, Portugal, Spain, the United Kingdom and the European Union Reference Laboratories for Pesticide Residues (Austria, 2017; Czech Republic, 2017; EURL, 2017; France, 2017; Netherlands, 2017; Portugal, 2017, 2018; Spain, 2017; United Kingdom, 2017; Greece, 2018) and, after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 23 January 2018. Further clarifications were sought from Member States via a written procedure in January–February 2018.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, and the additional information provided by the Member States, EFSA prepared in June 2018 a draft reasoned opinion on the review of the existing MRLs for tembotrione.

1 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.
2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.
3 Commission Implementing Regulation (EU) No 1192/2013 of 22 November 2013 approving the active substance tembotrione, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 314, 23.11.2013, p. 6-10.
4 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.
5 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.
6 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.
opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 18 July 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Austria, 2014, 2017) and the evaluation reports submitted by Member States Austria, the Czech Republic, France, Greece, the Netherlands, Portugal, Spain, the United Kingdom and the EURL (Czech Republic, 2017; EURL, 2017; France, 2017; Netherlands, 2017; Portugal, 2017, 2018; Spain, 2017; United Kingdom, 2017; Greece, 2018) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

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

Tembotrione is the ISO common name for 2-{2-chloro-4-mesyl-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl}cyclohexane-1,3-dione (IUPAC).

Tembotrione belongs to the group of triketone compounds which are used as a post-emergence herbicide for use in maize, for grain and silage production and sweet corn. After foliar application, tembotrione is rapidly taken up into the leaves and transported to the growing parts of the plant with associated necrosis of foliar tissues.

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

Tembotrione was evaluated in the framework of Commission Regulation (EU) No 188/2011 with Austria designated as RMS. The representative uses supported for the peer review process were field broadcast application on maize and sweet corn for the control of grasses and broad leaved weeds. Following the peer review, which was carried out by EFSA (2013), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Implementing Regulation 1192/2013, which entered into force on 1 May 2014. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, tembotrione is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to use as a herbicide only.

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

| Procedure                  | Legal implementation        | Remarks                                                                 |
|----------------------------|-----------------------------|-------------------------------------------------------------------------|
| MRL application            | Regulation (EU) No 251/2013 | Reasoned opinion on the setting of new MRLs for tembotrione in kidney and liver of bovine and swine (EFSA, 2012) |

MRL: maximum residue level.
For the purpose of this MRL review, the critical uses of tembotrione currently authorised within the EU, as well as uses authorised in third countries that might have a significant impact on international trade, have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAPs for tembotrione are given in Appendix A.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Austria, 2014), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Austria, 2007, 2012), the conclusion on the peer review of the pesticide risk assessment of the active substance tembotrione (EFSA, 2013), the previous reasoned opinion on tembotrione (EFSA, 2012) as well as the evaluation reports submitted during the completeness check (Czech Republic, 2017; EUR, 2017; France, 2017; Netherlands, 2017; Portugal, 2017; Spain, 2017; United Kingdom, 2017). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of tembotrione following foliar application was studied in maize grain, stover and forage (cereal crops) during the peer review with the test substance labelled either on the phenyl- or cyclohexyl-moiety in each crop study (Austria, 2007). In the framework of this review, an additional metabolism study on poppy seeds (pulses/oilseed) with both labels was submitted and assessed (France, 2017).

In maize, the parent tembotrione was rapidly metabolised and metabolites M5 (dihydroxy-tembotrione) and subsequently M6 (benzoic acid) were mainly formed. As a minor route, cleavage of the ether bond in M6 was observed resulting in the substituted benzyl alcohol metabolite M2 (Austria, 2007).

In maize at maturity, metabolite M6 represented the major residue (up to 59.5% total radioactive residue (TRR) (0.017 mg eq/kg) in grain and up to 39.6% TRR (0.049 mg eq/kg) in stover). Other metabolites in grain were less than 10% TRR (M5 represented 0.9% TRR; < 0.001 mg eq/kg) and in stover only metabolite M2 was above 10% TRR (11.6-% TRR; 0.014 mg eq/kg). In corn forage, metabolite M6 represented 40.9% TRR (0.027 mg eq/kg), metabolite M2 10.2% TRR (0.007 mg eq/kg) and metabolite M5 9.8% TRR (0.006 mg eq/kg) (Austria, 2007).

In poppy seeds, tembotrione was extensively metabolised and only detected in poppy straw at very low amounts (0.8% TRR; 0.11 mg eq/kg). In seeds, metabolite M6 (benzoic acid) represented the main residue augmenting to 69.7% TRR (0.093 mg eq/kg). In poppy seed balls, this metabolite represented 41.7% TRR (2.084 mg eq/kg) and in poppy straw 43.5% TRR (10.168 mg eq/kg). Some other metabolites were identified at low amounts (France, 2017).

It has to be noted that a metabolism study in fruiting vegetables or another third crop group is not available and is still required to support the northern outdoor authorised GAP on fruit spices.

1.1.2. Nature of residues in rotational crops

Tembotrione is authorised for use on cereals which may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, periods required for 90% dissipation (DT₉₀ values) of tembotrione and its main soil metabolite M6 were up to 262 and 242 days.
respectively, which is higher than the trigger value of 100 days (EFSA, 2013). Therefore, further investigation of residues in rotational crops was performed and evaluated.

During the peer review, the metabolism of tembotrione in rotational crops was studied in three rotational crop studies covering cereals, root and tuber vegetables and leafy crops grown after soil application of U-14C-phenyl labelled tembotrione at 212 g a.s./ha which represents approximately twice the most critical GAP rate for all crops in this review.

During the peer review, it was concluded that the metabolism of tembotrione in rotational crops is similar to the pathway observed in primary crops (EFSA, 2013). This conclusion is supported in this review.

1.1.3. Nature of residues in processed commodities

The effect of processing under standard hydrolyses conditions on the nature of residues of tembotrione and its metabolite M5 was investigated in studies performed at three test conditions simulating pasteurisation (20 min at 90°C, pH 4), baking/brewing/boiling (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) in the framework of the peer review (Austria, 2007).

From these studies, it can be concluded that tembotrione is stable under conditions simulating processing by pasteurisation, baking/brewing/boiling. Minor (less than 10% applied radioactivity (AR)) degradation of phenyl- and cyclohexyl-labelled tembotrione was reported under sterilisation conditions. Metabolite M5 was stable under all three processing conditions and degradation products were not formed (Austria, 2007).

Additional information was not received during this review and it is concluded that tembotrione and its metabolite M5 are stable.

1.1.4. Methods of analysis in plants

Monitoring methods are available for tembotrione and its metabolite M5 with a limit of quantification (LOQ) of 0.01 mg/kg, respectively, for high water, high acid, high oil and dry commodities. A high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) method is validated in tomato, orange, oil seed rape and maize grain. An independent laboratory validation (ILV) and a confirmatory liquid chromatography (LC–MS/MS) method with a LOQ of 0.01 mg/kg for tembotrione and M5, respectively, are available (Austria, 2007).

Furthermore, the EURLs provided a LC–MS/MS method for high water, high acid and dry plant commodities with a LOQ of 0.01 mg/kg for tembotrione and M5 however not for animal commodities, respectively (EURLs, 2017). The EURLs reported validation data for high water commodities for M5 during the Member State consultation (EFSA, 2018b).

It is concluded that tembotrione and its metabolite M5 can be enforced in high water, high acid, high oil and dry commodities with a LOQ of 0.01 mg/kg, respectively.

It has to be noted that no method for spices is available and is still required to support the authorised GAP on fruit spices.

1.1.5. Stability of residues in plants

The storage stability of tembotrione and its metabolites M6, M5 and M2 was investigated in the framework of the peer review (Austria, 2007, 2009, 2011). Additional storage stability studies were also assessed in the framework of this review (France, 2017).

Storage stability of tembotrione and its metabolites M6, M5 and M2 were further investigated in sunflower seeds. While the parent, M6 and M2 were stable -18 °C for 33 months, M5 was reported to be stable for 26 months (Austria, 2014; France, 2017).

In high water content and in dry commodities (corn grain, forage and fodder) stored at −18°C, tembotrione, M2 and M6 are stable for at least 28 months while M5 is stable for at least 30 months. In high oil content matrices (sunflower seeds) stored at −18°C, tembotrione, M2 and M6 are stable for at least 33 months and M5 for at least 26 months.

1.1.6. Proposed residue definitions

In the plant metabolism studies, the main residues were the parent and its metabolites M6 (tembotrione-benzoic acid), M5 (dihydroxy-tembotrione) and M2 (tembotrione carboxy benzyl alcohol). These metabolites were therefore included in the analysis of supervised field trials. However, the data from the supervised field trials showed that the residues of the metabolites M6 and M2 were either
very low or found at very early time points not reflecting the currently authorised GAP conditions. The only substance that was found in animal feed items was metabolite M5. Therefore, this metabolite even though found only in small amounts was included in the residue definitions for monitoring and risk assessment during the peer review (EFSA, 2013).

Following the review of the available metabolism studies and supervised residue trial data, including a new metabolism study and residue trials on poppy seeds, the residue definitions (tembotrione and its metabolite M5) as proposed during the peer review are still supported in this review. The same residue definition as for raw commodities is applicable to rotational crops and processed commodities.

It is noted that the proposed residue definitions are limited to cereals, pulses and oilseeds and that an additional metabolism study is still required to support the authorised GAP on fruit spices. Therefore, no residue definitions could be proposed for fruit spices.

A fully validated method is available for the enforcement of tembotrione and its metabolite M5 with a combined LOQ of 0.02 mg/kg for high water, high acid, high oil and dry commodities noting that a method for fruit spices is still required. According to the information provided by the EURLs an analytical standard is commercially available for tembotrione and metabolite M5 (EFSA, 2018b).

In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of tembotrione and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of tembotrione residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Austria, 2014), including residue trials evaluated in the framework of the peer review (EFSA, 2013; Austria, 2014) or in the framework of a previous MRL application (EFSA, 2012) and additional data submitted during the completeness check (Austria, 2017; Czech Republic, 2017; France, 2017; Netherlands, 2017; Portugal, 2017, 2018; Spain, 2017; United Kingdom, 2017; Greece, 2018). All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions.

Residue trials are not available to support the northern outdoor GAP on fruit spices and the Czech Republic proposed to waive a need for residue trials because the crop is harvested 1 year after treatment and a no residue situation was to be anticipated (Czech Republic, 2017). However, considering that this crop group is not covered by a metabolism study, this proposed waiver is not considered acceptable. Therefore, MRLs and risk assessment values could not be derived for this crop and a full data set supporting the northern outdoor GAP on fruit spices is still required.

For sweet corn, only tentative MRL and risk assessment values could be derived by EFSA and the following data gap was identified:

- All available residue trials supporting the import tolerance were performed with two instead of one application and residues were analysed using a method with a higher LOQ of 0.02 mg/kg for each compound. Although residues were found above the LOQ in one trial only (M5: 0.024 mg/kg), the derived MRL and risk assessment values are expected to be overestimated. Therefore, eight additional trials on sweet corn compliant with the US import tolerance and analysed with an analytical method validated at a lower combined LOQ of 0.02 mg/kg are still required.

For all other crops, available residue trials were sufficient to derive MRL and risk assessment values taking note of the following considerations:

- Poppy seeds: only two residue trials are available to support the southern outdoor GAP and five to support the northern outdoor GAP. Additional trials would be in principle still required. However, the reduced number of trials is considered acceptable for a minor crop. In addition, the southern European Union (SEU) and the northern European Union (NEU) GAPs are the same and all available trials were below the LOQ. Further residue trials are therefore not required. Magnitude of residues in rotational crops.
Confin ed rotational crop studies were investigated during the peer review (EFSA, 2013). Tembotrione was applied on bare sandy loam soil with approximately twice the critical GAP rate (212 g a.s./ha). Swiss chard, turnips and spring wheat were planted 90 DAT. The TRR for swiss chard, turnip tops and roots was 0.134, 0.050 and 0.013 mg eq/kg. The TRR for wheat forage, wheat hay and wheat straw and wheat grain was 0.031, 0.246, 0.188 and 0.178 mg eq/kg, respectively. The principal residues were identified as metabolites M6 and M2 (Austria, 2007).

For a realistic prediction of possible soil degradation in succeeding crops, field tests have been performed. Tembotrione residues including its metabolites M2, M5 and M6 after two applications (2 × 92 g a.s./ha) to corn were investigated to determine a plant-back interval (PBI) for leafy vegetables, root crops and cucurbits. It was reported during the peer review that tembotrione and its metabolites in the raw agricultural commodity (RAC) of mustard green, turnips and summer squash grown at a PBI of 90–120 days were below the LOQ.

In addition the magnitude of tembotrione and metabolites M2, M5 and M6 in or on winter wheat raw agricultural commodities when used as a rotational crop after two applications of tembotrione (actual application rates ranged from 0.091 to 0.099 g a.s./ha) was determined. Winter wheat was planted at PBIs of 83 and 158 days after the last application to corn. Residues for M2, M5 and M6 were reported in mg tembotrione eq/kg however total residue levels were below LOQ in forage, hay, grain and straw for both PBIs (Austria, 2009).

The occurrence of significant tembotrione residues at shorter PBIs was considered unlikely and available studies were considered sufficient during the peer review (EFSA, 2013). This conclusion is supported during this review.

Therefore, these studies are considered sufficient by EFSA to demonstrate the absence of residues in rotational crops, provided that tembotrione is applied in compliance with the GAPs reported in Appendix A.

1.2.2. Magnitude of residues in processed commodities

Studies investigating the magnitude of residues in whole grain milling grits (large), meal, flour, refined oil (following wet and dry milling), starch and silage production were evaluated during the peer review (EFSA, 2013). An overview of these studies is given in Appendix B.1.2.3.

Robust processing factors could not be derived since for each processed commodity only one study was available. Considering that corn silage was the main contributor to the dietary burden of cattle and swine (see Section B.1.2.3), additional processing studies are still desirable to refine the dietary burden. Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be required.

1.2.3. Proposed MRLs

Consequently, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for sweet corn for which tentative MRLs are derived and for fruit spices where no MRL could be derived. Tentative MRLs were also derived for feed crops (cereal straw and forage) in view of the future need to set MRLs in feed items.

2. Residues in livestock

Tembotrione is authorised for use on common millet, maize, sorghum forage which might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for cattle (all), dairy cattle and swine, were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in these groups of livestock.

2.1. Nature of residues and methods of analysis in livestock

Studies on laying hen and lactating cows were performed with phenyl-U-14C- and cyclohexyl-U-14C-labelled tembotrione at dosing levels of 0.08 and 0.85 mg/kg body weight (bw) per day and of 0.03 and 0.3 mg/kg bw per day and metabolite M5 at a dosing level of 0.26 mg/kg bw per day. Tembotrione was not extensively metabolised and remained the major compound in all tissues. In the hen study, the parent ranged in tissues between 25% and 97.1% TRR (7–2,037 mg eq/kg) and in
the lactating cow study 21–96% TRR (3–2,046 mg eq/kg) with highest concentrations in the liver and kidney. Hydroxylation was observed in the hen study (4% TRR (61 mg eq/kg)) in the liver only and in the lactating cow unidentified metabolites in liver and kidney were reported below 3.5% TRR (106 mg eq/kg). A metabolism study in dairy cattle dosed with radiolabelled M5 was performed and showed that unchanged M5 was the only significant radioactive component seen in liver and kidney (69.9% TRR (427 mg eq/kg); 85.5% TRR (133 mg eq/kg)) (Austria, 2007).

During the peer review, it was concluded that only the metabolite M5 should be defined as the residue of concern in food of animal origin since on the intake of maize silage and grain where residues of M5; however, no significant residues of tembotrione were reported. Therefore, only exposure to M5 is to be expected. Hence, in view of the livestock dietary burden, the residue definition for monitoring and risk assessment in ruminants was set as metabolite M5 only (Austria, 2007; EFSA, 2013). This conclusion is still supported during this review. Since the general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to swine.

A HPLC–MS/MS method for enforcement of metabolite M5 with a LOQ of 0.01 mg/kg in muscle, liver, kidney, liver and eggs and with a LOQ of 0.002 mg/kg in milk for M5 is available. An ILV and a confirmatory LC–MS/MS method were provided (Austria, 2007). According to the information provided by the EURLs, an analytical standard is commercially available for metabolite M5 (EFSA, 2018b).

Storage stability studies in all animal tissues are not available for tembotrione or any of the metabolites and are not required because the samples of the animal feeding studies were stored frozen and were analysed within 30 days (Austria, 2007).

2.2. Magnitude of residues in livestock

MRL and risk assessment values for animal products were derived according to the OECD guidance which was agreed upon at the European level (OECD, 2013). The overview of the study results used to derive risk assessment values and MRL proposals are summarised in Appendix B.2.2.

During the peer review, one livestock feeding study performed on dairy cattle was evaluated by the RMS in the DAR (Austria, 2007; EFSA, 2013). Four dose levels were tested (0.002, 0.018, 0.055 and 0.182 mg/kg bw per day) for 28–30 days, whereby the second lowest dietary burden is closest to the calculated dietary burden for cattle (all) and dairy cattle (1.1N) and the lowest to swine (0.6N). Samples of milk, fat, kidney, liver and muscle were analysed for metabolite M5 with the validated LOQ of 0.002 mg/kg for milk and 0.01 mg/kg for tissues.

Residues of M5 were below the LOQ in milk, muscle and fat at all dose levels and in liver and kidney at the lowest dose level. However at the three higher dose levels in kidney mean residue levels of 0.015 mg/kg, 0.042 mg/kg and of 0.142 mg/kg and in kidney and 0.032 mg/kg, 0.132 mg/kg and 0.341 mg/kg in liver were reported.

Based on the results of the livestock feeding study and considering the calculated dietary burden, significant residues in kidney and liver of cattle and swine are expected and MRLs for these commodities are proposed. For milk and for all other cattle and swine tissues MRLs can be established at the LOQ.

MRLs for poultry and sheep products are not required because they are not expected to be exposed to significant levels of M5 residues.

3. Consumer risk assessment

In the framework of this review, only the uses of active substance reported by the RMS in Appendix A were considered.

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). 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). For fruit spices where residue data were waved because no residues are expected, EFSA considered the existing EU MRL at the LOQ for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D.

The exposures calculated were compared with the toxicological reference values for tembotrione, derived by EFSA (2013) under Directive 91/414/EEC. The highest chronic exposure was calculated for
UK, toddler, representing 25% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for sweet corn, representing 3.2% of the acute reference dose (ARfD).

It has to be noted that metabolite M5 is less toxic than the parent (ADI = 0.013 mg/kg bw per day). During the peer review, a toxicity equivalence factor (TEF) of 0.0308 was derived (EFSA, 2013). In a previous MRL application, this factor was considered for dietary risk assessment of bovine and swine liver and kidney where the metabolite M5 is the relevant residue (EFSA, 2012). During this review, the risk assessment was carried out with the ADI of the parent without consideration of the TEF. Since no consumer concern was identified, a refined assessment considering the TEF was not carried out and is not considered necessary.

It can be concluded that although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

Conclusions

The metabolism of tembotrione was studied in maize grain, stover and forage (cereal crops) during the peer review. In the framework of this review, an additional metabolism study on poppy seeds (pulses/oilseed) was submitted and assessed. The parent tembotrione was rapidly metabolised and metabolites M5 (dihydroxy-tembotrione) and subsequently M6 (benzoic acid) were mainly formed. A metabolism study in fruiting vegetables or another third crop group is not available and still required in relation to a reported authorised GAP on fruit spices.

During the peer review, it was concluded that the metabolism of tembotrione in rotational crops is similar to the pathway observed in primary crops. The occurrence of significant tembotrione residues in rotational crops was considered unlikely and available studies were considered sufficient during the peer review. These conclusions are supported during this review.

Monitoring methods are available for tembotrione and its metabolite M5 with an LOQ of 0.01 mg/kg, respectively, for high water, high acid, high oil and dry commodities. A validated HPLC-MS/MS method, an ILV and a confirmatory LC-MS/MS method with an LOQ of 0.01 mg/kg for tembotrione and M5, respectively, are available. For spices, a method for enforcement is still required.

The same residue definitions (tembotrione and its metabolite M5, expressed as tembotrione) as proposed during the peer review are still supported in this review limited to cereals, pulses and oilseeds. It is applicable to rotational crops and processed commodities. Nevertheless, no residue definitions could be proposed for fruit spices. According to the information provided by the EURLs, an analytical standard is commercially available for tembotrione and metabolite M5.

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for sweet corn for which tentative MRLs are derived and for fruit spices where no MRL could be derived. A metabolism study in dairy cattle dosed with radioactive component seen in liver and kidney. During the peer review, it was concluded that only the metabolite M5 should be defined as the residue of concern in food of animal origin based on the intake of maize silage and grain where M5 residues and exposure are expected. This conclusion is supported during this review. A HPLC-MS/MS method for enforcement of metabolite M5 with an LOQ of 0.01 mg/kg in muscle, liver, kidney, liver and eggs and with an LOQ of 0.002 mg/kg in milk for M5 is available. An ILV and a confirmatory LC-MS/MS method are available.

Based on the results of the livestock feeding study and considering the calculated dietary burden, significant residues in kidney and liver of cattle and swine are expected and MRLs for these commodities can be proposed. For milk and for all other cattle and swine tissues, MRLs can be established at the LOQ. According to the information provided by the EURLs, an analytical standard is commercially available for metabolite M5.

Chronic and acute consumer exposures resulting from the authorised uses reported in the framework of this review were calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for UK, toddler, representing 25% of the ADI, and the highest acute exposure was calculated for sweet corn, representing 3.2% of the ARfD. It has to be noted that metabolite M5 is less toxic than the parent (ADI = 0.013 mg/kg bw per day). During the peer review, a TEF of 0.0308 was derived. During this review, the risk assessment was carried out with the ADI of the parent without consideration of the TEF. Since no consumer concern was identified, a refined assessment considering the TEF was not carried out and is not considered necessary.
In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of tembotrione and that further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for further details). In particular, some tentative MRLs need to be confirmed by the following data:

- additional residue trials for sweet corn;
- a representative study investigating metabolism in fruit crops;
- an analytical method for enforcement for fruit spices;
- additional residue trials on fruit spices.

Minor deficiencies were also 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:

- additional processing studies to refine the dietary burden.

**Table 2: Summary table**

| Code number(a) | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | Comment |
|----------------|-----------|-------------------------|-----------------------|---------|
|                |           | MRL (mg/kg)             |                       |         |
| Enforcement residue definition 1 (plant commodities): Sum of parent tembotrione (AE 0172747) and metabolite M5 (4,6-dihydroxy tembotrione), expressed as tembotrione |
| 234000         | Sweet corn | 0.05                    | 0.05                  | Further consideration needed(b) |
| 401030         | Poppy seeds | 0.02*                   | 0.02*                 | Recommended(c) |
| 500030         | Maize grains | 0.02*                   | 0.02*                 | Recommended(c) |
| 500040         | Common millet | 0.02*                  | 0.02*                 | Recommended(c) |
| 500080         | Sorghum grains | 0.02*              | 0.02*                 | Recommended(c) |
| 820000         | Fruit spices | 0.05*                   | 0.05*                 | Further consideration needed(d) |
| Enforcement residue definition 2 (animal commodities): M5 (4,6-dihydroxy tembotrione), only |
| 1011010        | Swine muscle | 0.01*                  | 0.01*                | Recommended(c) |
| 1011020        | Swine fat tissue | 0.01*               | 0.01*                | Recommended(c) |
| 1011030        | Swine liver | 0.02                    | 0.015                | Recommended(c) |
| 1011040        | Swine kidney | 0.02                    | 0.015                | Recommended(c) |
| 1012010        | Bovine muscle | 0.01*                 | 0.01*                | Recommended(c) |
| 1012020        | Bovine fat tissue | 0.01*               | 0.01*                | Recommended(c) |
| 1012030        | Bovine liver | 0.15                     | 0.05                 | Recommended(c) |
| 1012040        | Bovine kidney | 0.04                    | 0.02                 | Recommended(c) |
| 1015010        | Equine muscle | 0.01*                  | 0.01*                | Recommended(c) |
| 1015020        | Equine fat tissue | 0.01*               | 0.01*                | Recommended(c) |
| 1015030        | Equine liver | 0.15                     | 0.05                 | Recommended(c) |
| 1015040        | Equine kidney | 0.04                     | 0.02                 | Recommended(c) |
| 1020010        | Cattle milk | 0.01*                     | 0.01*                | Recommended(c) |
| 1020040        | Horse milk | 0.01*                     | 0.01*                | Recommended(c) |
| –              | Other commodities of plant and animal origin | Regulation (EC) No 251/2013 | Further consideration needed(e) |
MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set/proposed at the limit of quantification. (F): Residue is fat soluble.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(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 E-I in Appendix E).
(c): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(d): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(e): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

References

Austria, 2007. Draft Assessment Report (DAR) on the active substance tembotrione prepared by the rapporteur Member State Austria in the framework of Directive 91/414/EEC, February 2007. Available online: www.efsa.europa.eu

Austria, 2009. Addenda to the DAR on the active substance tembotrione prepared by the rapporteur Member State Austria in the framework of Directive 91/414/EEC, April to December 2009. Available online: www.efsa.europa.eu

Austria, 2011. Evaluation Report prepared under Article 8 of Regulation (EC) No 396/2005 ‘modification of MRLs for tembotrione in bovine kidney and liver, and in swine liver. November 2011. Available online: www.efsa.europa.eu

Austria, 2012. Final Addendum to Draft Assessment Report on tembotrione, compiled by EFSA, December 2012. Available online: www.efsa.europa.eu

Austria, 2014. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for tembotrione, February 2014. Available online: www.efsa.europa.eu

Austria, 2017. Revised evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for tembotrione. September 2017. Available online: www.efsa.europa.eu

Czech Republic, 2017. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for tembotrione, November 2017. Available online: www.efsa.europa.eu

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

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the setting of new MRLs for tembotrione in kidney and liver of bovine and swine. EFSA Journal 2012;10(10):2932, 39 pp. https://doi.org/10.2903/j.efsa.2012.2932

EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance tembotrione. EFSA Journal 2013;11(3):3131, 81 pp. https://doi.org/10.2903/j.efsa.2013.3131

EFSA (European Food Safety Authority), 2018a. Completeness check report on the review of the existing MRLs of active substance prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 27 June 2018. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2018b. Member States consultation report on the review of the existing MRLs of active substance prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 6 August 2018. Available online: www.efsa.europa.eu

EURL (European Union Reference Laboratories for Pesticide Residues), 2017. Data pool on method validation for pesticide residues. Status on 24 November 2017. Available online: www.eurl-pesticides-datapool.eu

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

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

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

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

www.efsa.europa.eu/efsajournal 15 EFSA Journal 2018;16(9):5417
European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.
European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.3, June 2017.
FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Edition. FAO Plant Production and Protection Paper 197, 264 pp.
France, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for tembotrione, November 2017. Available online: www.efsa.europa.eu
Greece, 2018. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for tembotrione, February 2018. Available online: www.efsa.europa.eu
Netherlands, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for tembotrione, October 2017. Available online: www.efsa.europa.eu
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org
OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.
Portugal, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for tembotrione, November 2017. Available online: www.efsa.europa.eu
Portugal, 2018. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for tembotrione, February 2018. Available online: www.efsa.europa.eu
Spain, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for tembotrione, November 2017. Available online: www.efsa.europa.eu
United Kingdom, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for tembotrione, November 2017. Available online: www.efsa.europa.eu

Abbreviations
a.i. active ingredient
a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement residue definition to risk assessment residue definition
CXL codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DB dietary burden
DM dry matter
DT_{90} period required for 90% dissipation (define method of estimation)
eq residue expressed as a.s. equivalent
EURLs European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HPLC–MS/MS high performance liquid chromatography with tandem mass spectrometry
HR highest residue
| Abbreviation | Description |
|--------------|-------------|
| 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 |
| LC-MS/MS     | liquid chromatography with tandem mass spectrometry |
| LOQ          | limit of quantification |
| Mo           | monitoring |
| MRL          | maximum residue level |
| MS/MS        | tandem mass spectrometry detector |
| NEU          | northern European Union |
| OD           | oil dispersion |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant-back interval |
| PF           | processing factor |
| PHI          | preharvest interval |
| PRIMO        | (EFSA) Pesticide Residues Intake Model |
| PROFile      | (EFSA) Pesticide Residues Overview File |
| QqQ          | triple-quadrupole |
| R_{ber}      | statistical calculation of the MRL by using a non-parametric method |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SC           | suspension concentrate |
| SEU          | southern European Union |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TAR          | total applied radioactivity |
| TRR          | total radioactive residue |
| WG           | water-dispersible granule |
| WHO          | World Health Organization |
### Appendix A – Summary of authorised uses considered for the review of MRLs

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

| Crop and/or situation | MS or country | F or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|--------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| **Sweet corn**        | AT, CZ, HU, NL | F      | Weeds, grass and broadleaf weed control, *Echinochloa crus-galli*, *Chenopodium album* agg., annual dicotyledonous and monocotyledonous weeds | OD 44 g/L | Foliar treatment – spraying | 12–18 1 | – – | 0.1 kg a.i./ha | 49 | The same critical GAP applies to formulation Laudis WG (200 g a.i./kg). All uses are covered by the critical GAP outlined in the DAR |
| **Poppy seeds**       | AT, CZ, HU    | F      | *Echinochloa crus-galli*, *Chenopodium album* agg., annual dicotyledonous weeds | OD 44 g/L | Foliar treatment – spraying | 14–18 1 | – – | 0.1 kg a.i./ha | n.a. | The PHI is covered by the normal vegetation period between last application and harvest |
| **Maize**             | AT, BE, CZ, FR, HU, NL | F | Weeds, grass and broadleaf weed control, *Echinochloa crus-galli*, *Chenopodium album* agg., annual dicotyledonous and monocotyledonous weeds | OD 44 g/L | Foliar treatment – spraying | 12–18 1 | – – | 0.1 kg a.i./ha | 90 | The same critical GAP applies to formulation Laudis WG (200 g a.i./kg). All uses are covered by the critical GAP outlined in the DAR |
| Crop and/or situation | MS or country | F or G | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|----------------------|--------------|--------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Common millet        | FR           | F      | Weeds, grass and broadleaf weed control, *Echinochloa crus-galli*, *Chenopodium album* agg., annual dicotyledonous and monocotyledonous weeds | SC          | 345 g/L    | Foliar treatment – spraying   | 12–16      | 0.1 kg a.i./ha | n.a.    |
| Fruit spices         | CZ           | F      | Annual weeds                      | OD          | 44 g/L     | Foliar treatment – spraying   | 13–19      | 0.099 kg a.i./ha | BBCH 13-19 in the first year of the growing season |
| Common millet (for forage) | FR    | F | Weeds, Grass and broadleaf weed control, *Echinochloa crus-galli*, *Chenopodium album* agg., Annual dicotyledonous and monocotyledonous weeds | OD          | 44 g/L     | Foliar treatment – spraying   | 12–18      | 0.1 kg a.i./ha | 90      |
| Crop and/or situation | MS or country | Pest or group of pests controlled | Preparation | Method | Interval between application (min) | Number min–max | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|----------------------------------|-------------|--------|-----------------------------------|---------------|------------------------------|------------|---------|
| Maize (for forage)    | UK            | Weeds, Grass and broadleaf weed control, *Echinochloa crus-galli*, *Chenopodium album* agg., Annual dicotyledonous and monocotyledonous weeds | OD          | 44 g/L | Foliar treatment – spraying       | 12–18         | 0.099 kg a.i./ha               | 80         | Number of applications 1–2 (split). The total application per season must not exceed 100 g a.s./ha |

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

| 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 |
|-----------------------|---------------|-------------|-----------------------------------|-------------|------------|---------------------------------|---------------|---------|
| Sweet corn            | BG, EL, ES, IT, PT | F       | Weeds, grass and broadleaf weed control, *Echinochloa crus-galli*, *Chenopodium album* agg., annual dicotyledonous and monocotyledonous weeds | OD 44 g/L | Foliar treatment – spraying 12–18 1 | – | – | 0.1 kg a.i./ha 49 | The same critical GAP applies to formulation Laudis WG (200 g a.i./kg). All uses are covered by the critical GAP outlined in the DAR |
| Poppy seeds           | PT, HU        | F       | Weeds, grass and broadleaf weed control, *Echinochloa crus-galli*, *Chenopodium album* agg., annual dicotyledonous and monocotyledonous weeds | OD 44 g/L | Foliar treatment – spraying 12–18 1 | – | – | 0.1 kg a.i./ha n.a. | |
| Maize                 | BG, EL, ES, FR, IT, PT | F       | Weeds, grass and broadleaf weed control, *Echinochloa crus-galli*, *Chenopodium album* agg., annual dicotyledonous and monocotyledonous weeds | OD 44 g/L | Foliar treatment – spraying 12–18 1 | – | – | 0.1 kg a.i./ha 90 | The same critical GAP applies to formulation Laudis WG (200 g a.i./kg). All uses are covered by the critical GAP outlined in the DAR |
| Crop and/or situation | MS or country | F or 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                      | a.s./hL min–max | Water L/ha min–max | Rate and unit |         |
| Sorghum               | FR            | F               | Weeds, grass and broadleaf weed control, Echinochloa crus-galli, Chenopodium album agg., annual dicotyledonous and monocotyledonous weeds | SC          | 345 g/L   | Foliar treatment – spraying       | –               | –                  | 0.1 kg a.i./ha | n.a.    |
| Maize (for forage)   | EL            | F               | Weeds, grass and broadleaf weed control, Echinochloa crus-galli, Chenopodium album agg., annual dicotyledonous and monocotyledonous weeds | OD          | 44 g/L    | Foliar treatment – spraying       | 12–16           | 1                  | –             | 0.1 kg a.i./ha | 90     |
| Sorghum (for forage) | FR            | F               | Weeds, grass and broadleaf weed control, Echinochloa crus-galli, Chenopodium album agg., annual dicotyledonous and monocotyledonous weeds | OD          | 44 g/L    | Foliar treatment – spraying       | 12–18           | 1                  | –             | 0.1 kg a.i./ha | 90     |

NEU: northern European Union; SEU: southern European Union; MS: Member State; MRL: maximum residue level; a.s.: active substance; a.i.: active ingredient; OD: oil dispersion; SC: suspension concentrate; GAP: Good Agricultural Practice; WG: water-dispersible granule.

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

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-------------|-----------------------------------|-------------|-------------|-------------------------------|--------------|---------|
| Sweet corn            | USA                     | F           | Weeds                             | SC          | Foliar treatment – spraying   | 16–59          | −            | −       | 0.095 kg a.i./ha | 49 AT provided the registered US label for the GAP (1 × 0.095 g a.s./ha, PHI = 45 days) during the completeness check |

NEU: northern European Union; SEU: southern European Union; MS: Member State; MRL: maximum residue level; a.s.: active substance; a.i.: active ingredient; SC: suspension concentrate; GAP: Good Agricultural Practice.

(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) |
|-----------------------------------|-------------|----------------------------------|-----------------------------------------------------|----------------|
| Cereals/grass crops               | Maize grain and stover | Foliar, BBCH 12-14, 1 × 100 g a.s./ha | 0; 14; 49; 84; 124                                  |
|                                   | Maize grain whole plant, forage and stover | Foliar, BBCH 14-15, 1 × 200 g a.s./ha | 0; 14; 29; 49; 89; 113                               |
|                                   | Pulses/oilseeds | Poppy seeds, seed bolls, upper stem and straw | Foliar, BBCH 34, 1 × 182.5 g a.s./ha | 54; 60         |
|                                   |              |                                  | Foliar, BBCH 34, 1 × 200 g a.s./ha | 60             |

Source: Austria (2007, 2014), France (2017)

| Rotational crops (available studies) | Crop groups | Crop(s)                          | Application(s)                                      | PBI (DAT) |
|--------------------------------------|-------------|----------------------------------|-----------------------------------------------------|-----------|
| Root/tuber crops                     | Turnips     | Bare soil, 212 g a.s./ha         |                                                     | 90        |
| Leafy crops                          | Swiss chard | Bare soil, 212 g a.s./ha         |                                                     | 90        |
| Cereal (small grain)                 | Spring wheat| Bare soil, 212 g a.s./ha         |                                                     | 90        |

Source: Austria (2007)

| Processed commodities (hydrolysis study) | Conditions                                      | Investigated? |
|-----------------------------------------|-------------------------------------------------|---------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4)              | Yes           |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5)| Yes           |
|                                        | Sterilisation (20 min, 120°C, pH 6)              | Yes           |

Source: Austria (2007)

Can a general residue definition be proposed for primary crops? No

Rotational crop and primary crop metabolism similar? Yes

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

Plant residue definition for monitoring (RD-Mo) For cereal, pulses and oilseeds: Sum of parent tembotrione (AE 0172747) and metabolite M5 (4,6-dihydroxy tembotrione), expressed as tembotrione

Plant residue definition for risk assessment (RD-RA) For cereal, pulses and oilseeds: Sum of parent tembotrione (AE 0172747) and metabolite M5 (4,6-dihydroxy tembotrione), expressed as tembotrione

Conversion factor (monitoring to risk assessment) Not applicable
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

High water, high acid, high oil and dry commodities:
- Primary method: HPLC-MS/MS; LOQ = 0.01 mg/kg for tembotrione and M5, respectively; tomato, orange, oilseed rape and maize; ILV available; confirmatory method LC-MS/MS, LOQ = 0.01 mg/kg (Austria, 2007).
- Provided by EURLs: LC-MS/MS; LOQ = 0.01 mg/kg for tembotrione; validation data for cucumber, orange juice and almonds; LC-MS/MS; LOQ = 0.01 mg/kg for M5 in high water and acid and dry commodities (cucumber, orange juice, wheat); for high oil commodities a second fortification level is missing (validation data for cashews at 0.01 mg/kg) (EURL, 2017; EFSA, 2018b).
- LC-QqQ-MS/MS; LOQ = 0.01 mg/kg for tembotrione; validation data for wheat (EURLs, 2017), additional data were reported during the Member State consultation with an LOQ of 0.005 mg/kg on wheat, rye, oats and rice (EFSA, 2018b).

a.s.: active substance; 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; QqQ: triple-quadrupole.

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

| Plant products (available studies) | Category | Commodity          | T (°C) | Stability (months) | Comments                  |
|-----------------------------------|----------|--------------------|--------|-------------------|--------------------------|
| High water content                | Turnip roots | –10                | 12     | Tembotrione, M6, M5, M2 |
|                                  | Yellow squash | –10               | 12     | Tembotrione, M6, M5, M2 |
|                                  | Mustard green | –10               | 12     | Tembotrione, M6, M5, M2 |
|                                  | Maize forage  | –10               | 28     | Tembotrione, M2, M6 |
|                                  |            | –10               | < 3    | M5                |
|                                  |            | –18               | 30     | M5                |
| High oil content                 | Sunflower seeds | –18               | 33     | Tembotrione, M6 and M2 |
|                                  |            | –18               | 26     | M5                |
| Dry/high starch                   | Maize corn  | –10               | 28     | Tembotrione, M2, M6 |
|                                  |            | –10               | < 3    | M5                |
|                                  |            | –18               | 30     | M5                |
|                                  | Maize stover | –10               | 28     | Tembotrione, M2, M6 |
|                                  |            | –10               | < 3    | M5                |

Source: Austria (2007, 2009, 2011), France (2017)
### B.1.2. Magnitude of residues in plants

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

| Crop               | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)                                                                 | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR (mg/kg) | STMR (mg/kg) |
|--------------------|---------------|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|-----------------------|------------|--------------|
| Sweet corn         | NEU           | < 0.02; < 0.02; < 0.02; < 0.02                                                                                                   | GAP-compliant trials on sweet corn (Austria, 2009, 2014) MRL\textsubscript{OECD} = 0.02                  | 0.02*                 | 0.02       | 0.02         |
|                    | SEU           | < 0.02; < 0.02; < 0.02; < 0.02                                                                                                   | GAP-compliant trials on sweet corn (Austria, 2009, 2014) MRL\textsubscript{OECD} = 0.02                  | 0.02*                 | 0.02       | 0.02         |
| Import (USA)       |               | < 0.04; < 0.04; < 0.04; < 0.04                                                                                                   | Trials on sweet corn with 2 instead of 1 application (Austria, 2009, 2014) MRL\textsubscript{OECD} = 0.05 | 0.05\textsuperscript{(d)} (tentative) | 0.04       | 0.04         |
| Poppy seeds        | NEU           | < 0.02; < 0.02; < 0.02; < 0.02                                                                                                   | GAP-compliant trials on poppy seeds (Austria, 2014; France, 2017) MRL\textsubscript{OECD} = 0.02         | 0.02*                 | 0.02       | 0.02         |
|                    | SEU           | < 0.02; < 0.02                                                                                                                   | GAP-compliant trials on poppy seeds (France, 2017; Portugal, 2018)                                       | 0.02*                 | 0.02       | 0.02         |
| Maize grain        | NEU           | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; < 0.02                                                                 | GAP-compliant trials on maize corn (Austria, 2007; France, Netherlands, 2017) MRL\textsubscript{OECD} = 0.02 | 0.02*                 | 0.02       | 0.02         |
|                    | SEU           | < 0.02; < 0.02; < 0.02; < 0.02                                                                                                   | GAP-compliant trials on maize corn (Austria, 2007) MRL\textsubscript{OECD} = 0.02                           | 0.02*                 | 0.02       | 0.02         |
| Common millet grains | NEU         | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; < 0.02                                                                 | GAP-compliant trials on maize corn (Austria, 2007; France, Netherlands, 2017). Extrapolated to common millet grains MRL\textsubscript{OECD} = 0.02 | 0.02*                 | 0.02       | 0.02         |
| Sorghum grains     | SEU           | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02                                                                                           | GAP-compliant trials on maize corn (Austria, 2007). Extrapolated to sorghum grains MRL\textsubscript{OECD} = 0.02 | 0.02*                 | 0.02       | 0.02         |
| Fruit spices       | NEU           | –                                                                                                                                | No trials available. Harvest more than a year after application and residues are not expected however no metabolism study available | –                    | –          | –            |

\textsuperscript{a) Regions in outdoor trials: NEU=Northeastern USA, SEU=Southeastern USA, WEU=Western Europe, SEU=Southern Europe, WEU=Western Europe, S=South, N=North, A=Arctic.  
\textsuperscript{b) HR (mg/kg) is the Harmonised Reference value as per EU legislation.  
\textsuperscript{c) STMR (mg/kg) is the Scientifically Derived Maximum Residue Level (STMR) as per EU legislation.  
\textsuperscript{d) (tentative)
| Crop             | Region/ indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR (mg/kg)\(^{(b)}\) | STMR (mg/kg)\(^{(c)}\) |
|------------------|--------------------------|---------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-----------------------|-------------------|--------------------|
| Maize forage     | NEU                      | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; 0.02; 0.03; 0.03; 0.07; 0.07; 0.27          | GAP-compliant trials (Austria, 2007, 2009; France, Netherlands, 2017). Extrapolated to common millet forage MRL\(_{OECD}\) = 0.3 | 0.3\(^{(f)}\) (tentative) | 0.27              | 0.02               |
|                  | SEU                      | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; 0.02; 0.03; 0.03; 0.07; 0.07; 0.27          | GAP-compliant trials on maize corn forage (Austria, 2007, 2009) R\(_{ber}\) = 0.04                               | 0.04\(^{(f)}\) (tentative) | 0.03              | 0.02               |
| Common millet forage | NEU                       | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; 0.02; 0.03; 0.03; 0.07; 0.07; 0.27          | GAP-compliant trials on maize green material (Austria, 2007, 2009; France, Netherlands, 2017). Extrapolated to common millet forage MRL\(_{OECD}\) = 0.3 | 0.3\(^{(f)}\) (tentative) | 0.27              | 0.02               |
| Sorghum forage   | SEU                      | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; 0.02; 0.03; 0.03; 0.07; 0.07; 0.27          | GAP-compliant trials on maize corn forage (Austria, 2007, 2009). Extrapolated to sorghum forage R\(_{ber}\) = 0.04                               | 0.04\(^{(f)}\) (tentative) | 0.03              | 0.02               |
| Maize stover     | NEU                      | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; 0.02; 0.03; 0.03; 0.06; 0.1               | GAP-compliant trials on maize plants and rest of plants (Austria, 2007; France, Netherlands, 2017) MRL\(_{OECD}\) = 0.12 | 0.15\(^{(f)}\) (tentative) | 0.10              | 0.02               |
|                  | SEU                      | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; 0.02; 0.03; 0.03; 0.02; 0.03             | GAP-compliant trials on maize plants (Austria, 2007) R\(_{ber}\) = 0.04                                               | 0.04\(^{(f)}\) (tentative) | 0.03              | 0.02               |
| Common millet stover | NEU                      | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; 0.02; 0.03; 0.03; 0.06; 0.1               | GAP-compliant trials on maize plants and rest of plants (Austria, 2007; France, Netherlands, 2017). Extrapolated to common millet straw MRL\(_{OECD}\) = 0.12 | 0.15\(^{(f)}\) (tentative) | 0.10              | 0.02               |
| Sorghum stover   | SEU                      | < 0.02; < 0.02; < 0.02; < 0.02; < 0.02; 0.02; 0.03; 0.03; 0.06; 0.1               | GAP-compliant trials on maize plants (Austria, 2007). Extrapolated to sorghum stover R\(_{ber}\) = 0.04                            | 0.04\(^{(f)}\) (tentative) | 0.03              | 0.02               |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; R\(_{ber}\): statistical calculation of the MRL by using a non-parametric method.

\(*\): Indicates that the MRL is proposed at the limit of quantification.
\(\text{(a)}\): 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.
\(\text{(b)}\): Highest residue.
\(\text{(c)}\): Supervised trials median residue.
\(\text{(d)}\): Tentative MRL derived from overdosed trials.
\(\text{(e)}\): Tentative MRL derived from samples stored longer than demonstrated storage conditions.
\(\text{(f)}\): Tentative MRL derived in view of future setting MRLs for feed items.
B.1.2.2. Residues in succeeding crops

| Confined rotational crop study (quantitative aspect) | In the confined rotational crop studies evaluated during the peer review (see Section 1.2.2), total radioactive residue (TRR) recovered in crops grown in rotation was between 0.013 and 0.247 mg eq/kg. Metabolite M6 represented the main residue in swiss chard, turnip tops and roots, wheat forage, hay, straw and grain (15.5–90.6% TRR). Considering that 1.8 N rate of the critical GAP (1 × 100 g a.s./ha) rate was applied, tembotrione residues in edible crops are to be expected. |
| Field rotational crop study | Three rotational field trials with twice the critical GAP rate (1 × 100 g a.s./ha) were performed covering two PBIs (90 and 120 DAT) for each crop (turnips, mustard green, summer squash) and for winter wheat. Residues were below LOQ for all PBIs. During the peer review, it was concluded that residues in rotational crops are not expected, that occurrence of significant residues at shorter PBIs is unlikely and that available studies were sufficient (EFSA, 2013). |

GAP: Good Agricultural Practice; a.s.: active substance; PBI: plant-back interval; DAT: days after treatment; LOQ: limit of quantification.

B.1.2.3. Processing factors

| Processed commodity | Number of studies(a) | Processing factor (PF) |
|---------------------|----------------------|------------------------|
|                     |                      | Individual values      | Median PF |
| Whole corn grain milling: large grits | 1 | 0.98 | – |
| Whole corn grain milling: meal | 1 | 1.12 | – |
| Whole corn grain milling: flour | 1 | 0.087 | – |
| Whole corn grain milling: starch | 1 | 0.05 | – |
| Whole corn grain dry milling: refined oil | 1 | 0.01 | – |
| Whole corn grain wet milling: refined oil | 1 | 0.01 | – |
| Green plant material: silage processing | 1 | 0.85 | – |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

B.2. Residues in livestock

| Relevant groups | Dietary burden expressed in mg/kg bw per day Med. Max. | Most critical diet(a) | Most critical commodity(a) | Trigger exceeded (Y/N) |
|-----------------|---------------------------------|------------------------|---------------------------|------------------------|
| Cattle (all diets) | 0.0018 0.0162 0.05 0.55 | Cattle (dairy) | Corn, forage/silage | Yes |
| Cattle (dairy only) | 0.0018 0.0162 0.05 0.42 | Cattle (dairy) | Corn, forage/silage | Yes |
| Sheep (ewe only) | 0.0012 0.0014 0.04 0.04 | Sheep (ram/ewe) | Sorghum, forage | No |
| Swine (all diets) | 0.0008 0.0036 0.03 0.16 | Swine (breeding) | Corn, forage/silage | Yes |
| Poultry (all diets) | 0.0018 0.0061 0.03 0.09 | Poultry (layer) | Corn, forage/silage | No |
| Poultry (layer only) | 0.0018 0.0061 0.03 0.09 | Poultry (layer) | Corn, forage/silage | No |

bw: body weight; DM: dry matter.
(a): Calculated for the maximum dietary burden.
B.2.1. Nature of residues and methods of analysis in livestock

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

| Livestock (available studies) | Animal     | Dose (mg/kg bw per day) | Duration (days) | N rate/comment                                                                 |
|-------------------------------|------------|-------------------------|-----------------|--------------------------------------------------------------------------------|
|                               | Dairy cattle | 0.03, 0.3               | 7               | Tembotrione                                                                     |
|                               | Dairy cattle | 0.26                    | 5               | Metabolite M5/7.22 N rate based on maximum dietary burden of metabolite M5 for cattle |
|                               | Laying hen  | 0.08, 0.85              | 14              | Tembotrione                                                                     |
| Source: Austria (2007)       |             |                         |                 |                                                                                  |

- Time needed to reach a plateau concentration in milk and eggs (days)
  - Milk: 2
  - Egg: 7

- Metabolism in rat and ruminant similar (Yes/No)
  - Yes

- Animal residue definition for monitoring (RD-Mo)
  - M5 (4,6-dihydroxy tembotrione), only

- Animal residue definition for risk assessment (RD-RA)
  - M5 (4,6-dihydroxy tembotrione), only

- Conversion factor (monitoring to risk assessment)
  - Not applicable

- Fat soluble residues (Yes/No)
  - No

- Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
  - Animal commodities:
    - HPLC-MS/MS; LOQ = 0.01 mg/kg (meat, liver, kidney, liver and eggs) and of 0.002 mg/kg (milk) for tembotrione and M5, respectively.
    - ILV available; confirmatory method LC-MS/MS, LOQ = 0.01 mg/kg (Austria, 2007)

bw: body weight; 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.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (months/years) |
|-------------------------------------|--------|-----------|--------|--------------------------|
|                                     |        |           |        | Stability studies in animal tissues from livestock feeding study were not carried out and are not required since all samples from the livestock feeding study were immediately frozen and analysed within 30 days (Austria, 2007) |

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|-----------------------|----------------------|
|                  | Mean | Highest | STMR<sup>a</sup> (mg/kg) | HR<sup>b</sup> (mg/kg) |                         |
| Cattle (all diets) |     |         |                          |                      |                         |
| Closest feeding level (0.018 mg/kg bw; 1.1 × N rate)<sup>c</sup> |     |         |                          |                      |                         |
| Muscle            | < 0.01 | < 0.01 | 0.01                     | 0.01                 | 0.01*                   |
| Fat               | < 0.01 | < 0.01 | 0.01                     | 0.01                 | 0.01*                   |
| Liver             | 0.032  | 0.04    | 0.01                     | 0.04                 | 0.05                    |
| Kidney            | 0.015  | 0.02    | 0.01                     | 0.02                 | 0.02                    |
| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N (mg/kg) | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|------------------------------|---------------------|
|                  | Mean | Highest | STMR<sup>(a)</sup> | HR<sup>(b)</sup> |
| Cattle (dairy only) | Milk | 0.002 | 0.002 | 0.002 | 0.01* |
| Sheep (all diets) | MRLs are not required since dietary burden was below the trigger value. |
| Sheep (dairy only) | MRLs are not required since dietary burden was below the trigger value. |
| Swine<sup>(e)</sup> | Closest feeding level (0.018 mg/kg bw; 5 × N rate)<sup>(c)</sup> | Muscle | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* |
|                  | Fat | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01 | 0.01* |
|                  | Liver | 0.032 | 0.04 | 0.01 | 0.01 | 0.015 |
|                  | Kidney | 0.015 | 0.02 | 0.01 | 0.01 | 0.015 |
| Poultry (all diets) | MRLs are not required since dietary burden was below the trigger value. |
| Poultry (layer only) | MRLs are not required since dietary burden was below the trigger value. |

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; bw: body weight.

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

(a): As the mean residue levels were not reported for tissues and eggs (minor deficiency), the mean residue level for milk and the highest residue levels for eggs and tissues were recalculated at the 1N rate for the median dietary burden.

(b): The mean residue level in milk and the highest residue levels in eggs and tissues, were recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.

(d): Highest residue level from day 1 to day 28 (daily mean of 3 cows).

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

### B.3. Consumer risk assessment

#### B.3.1. Consumer risk assessment without consideration of the existing CXLs

| ADI | 0.0004 mg/kg bw per day derived for tembotrione (EFSA, 2013) |
| --- | --- |
| Highest IEDI, according to EFSA PRIMO | 25% ADI (UK, toddler) |
| Assumptions made for the calculations | The calculation is based on the median residue levels in the raw agricultural commodities. For fruit spices where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. In animal commodities MS (ADI = 0.013 mg/kg bw/day) is relevant however was considered at the ADI of the parent. The contributions of commodities where no GAP was reported in the framework of this review, were not included in the calculation |
## B.4. Proposed MRLs

| Code number(s) | Commodity | Existing EU MRL (mg/kg) | MRL (mg/kg) | Outcome of the review | Comment |
|----------------|-----------|------------------------|-------------|-----------------------|---------|
| **Enforcement residue definition 1 (plant commodities):** Sum of parent tembotrione (AE 0172747) and metabolite M5 (4,6-dihydroxy tembotrione), expressed as tembotrione | | | | | |
| 234000 | Sweet corn | 0.05 | 0.05 | Further consideration needed(b) | |
| 401030 | Poppy seeds | 0.02* | 0.02* | Recommended(c) | |
| 500030 | Maize grains | 0.02* | 0.02* | Recommended(c) | |
| 500040 | Common millet | 0.02* | 0.02* | Recommended(c) | |
| 500080 | Sorghum grains | 0.02* | 0.02* | Recommended(c) | |
| 820000 | Fruit spices | 0.05* | 0.05* | Further consideration needed(d) | |
| **Enforcement residue definition 2 (animal commodities):** M5 (4,6-dihydroxy tembotrione), only | | | | | |
| 1011010 | Swine muscle | 0.01* | 0.01* | Recommended(c) | |
| 1011020 | Swine fat tissue | 0.01* | 0.01* | Recommended(c) | |
| 1011030 | Swine liver | 0.02 | 0.015 | Recommended(c) | |
| 1011040 | Swine kidney | 0.02 | 0.015 | Recommended(c) | |
| 1012010 | Bovine muscle | 0.01* | 0.01* | Recommended(c) | |
| 1012020 | Bovine fat tissue | 0.01* | 0.01* | Recommended(c) | |
| 1012030 | Bovine liver | 0.15 | 0.05 | Recommended(c) | |
| 1012040 | Bovine kidney | 0.04 | 0.02 | Recommended(c) | |
| 1013000 | Equine muscle | 0.01* | 0.01* | Recommended(c) | |
| 1013020 | Equine fat tissue | 0.01* | 0.01* | Recommended(c) | |
| 1013030 | Equine liver | 0.15 | 0.05 | Recommended(c) | |
| 1013040 | Equine kidney | 0.04 | 0.02 | Recommended(c) | |
| 1020010 | Cattle milk | 0.01* | 0.01* | Recommended(c) | |
| 1020040 | Horse milk | 0.01* | 0.01* | Recommended(c) | |
| Other commodities of plant and animal origin | Regulation (EC) No 251/2013 | | | Further consideration needed(e) | |

MRL: maximum residue level; CXL: codex maximum residue limit.
**: Indicates that the MRL is set/proposed at the limit of quantification. (F): Residue is fat soluble.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(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 E-I in Appendix E).
(c): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(d): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(e): 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)

### Tembotrione

| Status of the active substance: | Included |
|--------------------------------|----------|
| LOQ (μg/kg tissue): | 0.02 |

**Toxicological end points**

| ADI (μg/kg bw): | 0.004 |
| ARfD (μg/kg bw): | 0.1 |
| Source of ADI: | EFSA |
| Source of ARfD: | EFSA |
| Year of evaluation: | 2013 |

**Summary of the active substance**

- **Code no.**
- **LOQ (μg/kg bw):** 0.02
- **Proposed LOQ:**
  - ADI (μg/kg bw/day): 0.0004
  - ARfD (μg/kg bw): 0.1

**Year of evaluation:** 2013

**Source of ADI:** EFSA
**Source of ARfD:** EFSA

### Chronic risk assessment – refined calculations

#### TMDI (mg/kg bw/day) Minimum – Maximum

| Commodity/group of commodities | 25.0 | 24.9 |
|--------------------------------|------|------|
| 25.6 UK Infant | 0.8 | 0.7 |
| 24.6 FR toddler | 0.8 | 0.7 |
| 23.5 NL child | 0.8 | 0.7 |
| 21.4 WHO Cluster diet B | 0.8 | 0.7 |
| 20.1 UK Toddler | 0.8 | 0.7 |
| 19.0 NL general | 0.8 | 0.7 |
| 18.0 WHO regional European diet | 0.8 | 0.7 |
| 17.0 SE general population 90th percentile | 0.8 | 0.7 |
| 16.0 ES child | 0.8 | 0.7 |
| 15.0 FR infant | 0.8 | 0.7 |
| 14.7 US child | 0.8 | 0.7 |
| 14.2 FR toddler | 0.8 | 0.7 |
| 13.0 NL child | 0.8 | 0.7 |
| 12.8 WHO Cluster diet E | 0.8 | 0.7 |
| 11.8 FR child | 0.8 | 0.7 |
| 11.0 UK Toddler | 0.8 | 0.7 |
| 10.6 WHO cluster diet D | 0.8 | 0.7 |
| 10.0 UK child | 0.8 | 0.7 |
| 9.4 WHO Cluster diet F | 0.8 | 0.7 |
| 9.2 UK Cluster diet D | 0.8 | 0.7 |
| 8.1 WHO cluster diet D | 0.8 | 0.7 |
| 8.0 NL general | 0.8 | 0.7 |
| 7.2 DK child | 0.8 | 0.7 |
| 7.2 DK general population 90th percentile | 0.8 | 0.7 |
| 6.8 ES adult | 0.8 | 0.7 |
| 6.5 LT adult | 0.8 | 0.7 |
| 6.4 DK adult | 0.8 | 0.7 |
| 3.0 FI adult | 0.8 | 0.7 |
| 3.0 FI general population | 0.8 | 0.7 |
| 2.3 UK vegetarian | 0.8 | 0.7 |
| 2.1 UK adult | 0.8 | 0.7 |
| 0.4 IT child/toddler | 0.8 | 0.7 |
| 0.2 IT adult | 0.8 | 0.7 |
| 0.0 NL general population | 0.8 | 0.7 |

**Conclusion:**
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs, were below the ADI.
A long-term intake of residues of tembotrione is unlikely to present a public health concern.

---

**Review of the existing MRLs for tembotrione**

See www.efsa.europa.eu/efsajournal 32 EFSA Journal 2018;16(9):5417
The acute risk assessment is based on the ARfD.
For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

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

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

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

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

The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**pTMRL: provisional temporary MRL.
***) pTMRL: provisional temporary MRL for unprocessed commodity.

### Acute risk assessment/children – refined calculations

| Commodity         | Threshold MRL (mg/kg) | pTMRL (mg/kg) |
|-------------------|-----------------------|---------------|
| Sweet corn        | 0.044                 | 2.3           |
| Bovine: Liver     | 0.044                 | 0.4           |
| Milk and milk products | 0.002             | 0.2           |
| Maize             | 0.02                  | 0.1           |
| Bovine: Meat      | 0.01                  | 0.1           |

### Acute risk assessment/adults/general population – refined calculations

| Commodity         | Threshold MRL (mg/kg) | pTMRL (mg/kg) |
|-------------------|-----------------------|---------------|
| Maize flour       | 0.02                  | 0.0           |
| Maize             | 0.01                  | 0.0           |

| No of commodities for which ARfD/ADI is exceeded | No of commodities for which ARfD/ADI is exceeded |
|--------------------------------------------------|--------------------------------------------------|
| IESTI 1                                           | IESTI 2                                           |
| Highest % of ARfD/ADI | threshold MRL | Highest % of ARfD/ADI | threshold MRL |
| Sweet corn | 0.044 | 2.3 | Sweet corn | 0.044 |
| Bovine: Liver | 0.044 | 0.4 | Bovine: Liver | 0.044 |
| Milk and milk products | 0.002 | 0.2 | Milk and milk products | 0.002 |
| Maize | 0.02 | 0.1 | Maize | 0.02 |
| Bovine: Meat | 0.01 | 0.1 | Bovine: Meat | 0.01 |

### No of critical MRLs (IESTI 1)

| No of commodities for which ARfD/ADI is exceeded |
|--------------------------------------------------|
| IESTI 1                                           |
| IESTI 2                                           |

### No of critical MRLs (IESTI 2)

| No of commodities for which ARfD/ADI is exceeded |
|--------------------------------------------------|
| IESTI 1                                           |
| IESTI 2                                           |

**Conclusion:**

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

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

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

### D.1. Livestock dietary burden calculations

| Feed commodity            | Median dietary burden | Maximum dietary burden |
|---------------------------|-----------------------|------------------------|
|                           | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment                |
| **Risk assessment residue definition:** Sum of parent tembotrione (AE 0172747) and metabolite M5 (4,6-dihydroxy tembotrione), expressed as tembotrione |                       |                        |                        |
| Maize, grain              | 0.02* STMR            |                        | 0.02* STMR          |                        |
| Corn, pop, grain          | 0.02* STMR            |                        | 0.02* STMR          |                        |
| Corn, field, milled by-pdts | 0.02* STMR(a)        |                        | 0.02* STMR(a)       |                        |
| Corn, field, hominy meal  | 0.02* STMR(a)         |                        | 0.02* STMR(a)       |                        |
| Corn, field, distiller’s grain (dry) | 0.02* STMR(a) |                        | 0.02* STMR(a)       |                        |
| Corn, field, gluten feed  | 0.02* STMR(a)         |                        | 0.02* STMR(a)       |                        |
| Corn, field, gluten, meal | 0.02* STMR(a)         |                        | 0.02* STMR(a)       |                        |
| Millet, grain             | 0.02* STMR(a)         |                        | 0.02* STMR(a)       |                        |
| Sorghum, grain            | 0.02* STMR(a)         |                        | 0.02* STMR(a)       |                        |
| Millet, forage            | 0.02 STMR             |                        | 0.27 HR             |                        |
| Corn, forage              | 0.02 STMR             |                        | 0.27 HR             |                        |
| Sorghum, forage           | 0.02 STMR             |                        | 0.03 HR             |                        |
| Sorghum, silage           | 0.01 STMR x 0.6(b)    | 0.02 HR x 0.6(b)       |                        |                        |
| Millet, straw (fodder, dry) | 0.02 STMR           |                        | 0.10 HR             |                        |
| Corn, field, stover (fodder) | 0.02 STMR            |                        | 0.10 HR             |                        |
| Corn, pop, stover         | 0.02 STMR             |                        | 0.10 HR             |                        |
| Sorghum, stover           | 0.02 STMR             |                        | 0.03 HR             |                        |

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

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

(a): For corn field milled by-products, hominy meal, dry distillers grain, gluten feed, gluten meal, millet and sorghum grain no default processing factor was applied because tembotrione is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

(b): For sorghum silage, in the absence of processing factors supported by data, default processing factors of 0.6 was included in the calculation to consider the potential concentration of residues in these commodities.

### D.2. Consumer risk assessment

| Commodity            | Chronic risk assessment | Acute risk assessment |
|----------------------|-------------------------|-----------------------|
|                      | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| **Risk assessment residue definition 1 (plant commodities):** Sum of parent tembotrione (AE 0172747) and metabolite M5 (4,6-dihydroxy tembotrione), expressed as tembotrione |                       |                        |                       |
| Sweet corn           | 0.04                    | STMR (tentative)(b)   | 0.044                  | HR (tentative)(b)     |
| Poppy seeds          | 0.02*                   | STMR(a)               | 0.02*                  | HR(a)                 |
| Maize grains         | 0.02*                   | STMR(a)               | 0.02*                  | HR(a)                 |
| Common millet grains | 0.02*                   | STMR(a)               | 0.02*                  | HR(a)                 |
| Sorghum grains       | 0.02*                   | STMR(a)               | 0.02*                  | HR(a)                 |
| Fruit spices         | 0.05*                   | EU MRL(c)             | 0.05*                  | EU MRL(c)             |

**Risk assessment residue definition 2 (animal commodities):** M5 (4,6-dihydroxy tembotrione), only

| Commodity            | Chronic risk assessment | Acute risk assessment |
|----------------------|-------------------------|-----------------------|
|                      | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Swine meat           | 0.01*                   | 0.8 × STMR muscle + 0.2 × STMR fat(d) | 0.01* | 0.8 × HR muscle + 0.2 × HR fat(d) |
| Swine fat tissue     | 0.01*                   | STMR(a)               | 0.01*                  | HR(a)                 |
| Swine liver          | 0.01                    | STMR(a)               | 0.013                  | HR(a)                 |
| Swine kidney         | 0.01                    | STMR(a)               | 0.011                  | HR(a)                 |
### Commodity

| Commodity            | Chronic risk assessment   | Acute risk assessment        |
|----------------------|---------------------------|------------------------------|
|                      | Input value (mg/kg)       | Comment                      | Input value (mg/kg)   | Comment                      |
| Bovine meat          | 0.01*                     | $0.8 \times \text{STMR muscle} + 0.2 \times \text{STMR fat}^{(d)}$ | 0.01*              | $0.8 \times \text{HR muscle} + 0.2 \times \text{HR fat}^{(d)}$ |
| Bovine fat tissue    | 0.01*                     | STMR^{(a)}                  | 0.01*              | HR^{(a)}                     |
| Bovine liver         | 0.01                      | STMR^{(a)}                  | 0.044              | HR^{(a)}                     |
| Bovine kidney        | 0.01                      | STMR^{(a)}                  | 0.019              | HR^{(a)}                     |
| Equine meat          | 0.01*                     | $0.8 \times \text{STMR muscle} + 0.2 \times \text{STMR fat}^{(d)}$ | 0.01*              | $0.8 \times \text{HR muscle} + 0.2 \times \text{HR fat}^{(d)}$ |
| Equine fat tissue    | 0.01*                     | STMR^{(a)}                  | 0.01*              | HR^{(a)}                     |
| Equine liver         | 0.01                      | STMR^{(a)}                  | 0.044              | HR^{(a)}                     |
| Equine kidney        | 0.01                      | STMR^{(a)}                  | 0.019              | HR^{(a)}                     |
| Cattle milk          | 0.01*                     | STMR^{(a)}                  | 0.01*              | HR^{(a)}                     |
| Horse milk           | 0.01*                     | STMR^{(a)}                  | 0.01*              | HR^{(a)}                     |
| Horse milk           | 0.01*                     | STMR^{(a)}                  | 0.01*              | HR^{(a)}                     |

**STMR**: supervised trials median residue; **HR**: highest residue; **MRL**: maximum residue level.

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

(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in Section 3 are used for the exposure calculations.

(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in Section 3 are used for indicative exposure calculations (also assuming the existing residue definition).

(c): Use reported by the RMS is not supported by data; the existing EU MRL is used for indicative exposure calculations (also assuming the existing residue definition).

(d): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is fully supported by data; the risk assessment values derived in Section 3 are used for the exposure calculations.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg DM in EU?
  - No
  - Yes
    - MRL derived in Section 3?
      - No
      - Yes
        - MRL fully supported by data?
          - No
          - Yes
            - GAP or DB > 0.1 mg/kg DM in EU?
              - No
              - Yes
                - MRL derived in Section 3?
                  - No
                  - Yes
                    - MRL fully supported by data?
                      - No
                      - Yes
                        - GAP or DB > 0.1 mg/kg DM in EU?
                          - No
                          - Yes
                            - MRL derived in Section 3?
                              - No
                              - Yes
                                - MRL fully supported by data?
                                  - No
                                  - Yes
                                    - GAP or DB > 0.1 mg/kg DM in EU?
                                      - No
                                      - Yes
                                        - MRL derived in Section 3?
                                          - No
                                          - Yes
                                            - MRL fully supported by data?
                                              - No
                                              - Yes
                                                - GAP or DB > 0.1 mg/kg DM in EU?
                                                  - No
                                                  - Yes
                                                    - MRL derived in Section 3?
                                                      - No
                                                      - Yes
                                                        - MRL fully supported by data?
                                                          - No
                                                          - Yes
                                                            - GAP or DB > 0.1 mg/kg DM in EU?
                                                              - No
                                                              - Yes
                                                                - MRL derived in Section 3?
                                                                  - No
                                                                  - Yes
                                                                    - MRL fully supported by data?
                                                                      - No
                                                                      - Yes
                                                                        - GAP or DB > 0.1 mg/kg DM in EU?
                                                                          - No
                                                                          - Yes
                                                                            - MRL derived in Section 3?
                                                                              - No
                                                                              - Yes
                                                                                - MRL fully supported by data?
                                                                                  - No
                                                                                  - Yes
                                                                                    - GAP or DB > 0.1 mg/kg DM in EU?
                                                                                      - No
                                                                                      - Yes
                                                                                       - MRL derived in Section 3?
                                                                                         - No
                                                                                         - Yes
                                                                                           - MRL fully supported by data?
                                                                                             - No
                                                                                             - Yes
                                                                                               - GAP or DB > 0.1 mg/kg DM in EU?
                                                                                                 - No
                                                                                                 - Yes
                                                                                                   - MRL derived in Section 3?
                                                                                                     - No
                                                                                                     - Yes
                                                                                                       - MRL fully supported by data?
                                                                                                         - No
                                                                                                         - Yes
                                                                                                           - GAP or DB > 0.1 mg/kg DM in EU?
                                                                                                              - No
                                                                                                              - Yes
                                                                                                                - MRL derived in Section 3?
                                                                                                                  - No
                                                                                                                  - Yes
                                                                                                                    - MRL fully supported by data?
                                                                                                                     - No
                                                                                                                     - Yes
                                                                                                                       - GAP or DB > 0.1 mg/kg DM in EU?
                                                                                                                         - No
                                                                                                                         - Yes
                                                                                                                            - MRL derived in Section 3?
                                                                                                                             - No
                                                                                                                             - Yes
                                                                                                                               - MRL fully supported by data?
                                                                                                                                - No
                                                                                                                                - Yes
                                                                                                                                   - GAP or DB > 0.1 mg/kg DM in EU?
                                                                                                                                       - No
                                                                                                                                       - Yes
                                                                                                                                            - MRL derived in Section 3?
                                                                                                                                             - No
                                                                                                                                             - Yes
                                                                                                                                                - MRL fully supported by data?
                                                                                                                                                 - No
                                                                                                                                                 - Yes
                                                                                                                                                    - GAP or DB > 0.1 mg/kg DM in EU?
                                                                                                                                                       - No
                                                                                                                                                       - Yes
                                                                                                                                                           - MRL derived in Section 3?
                                                                                                                                                               - No
                                                                                                                                                               - Yes
                                                                                                                                                                - MRL fully supported by data?
                                                                                                                                                                    - No
                                                                                                                                                                    - Yes
                                                                                                                                                                       - GAP or DB > 0.1 mg/kg DM in EU?
                                                                                                                                                                             - No
                                                                                                                                                                             - Yes
                                                                                                                                                                                - MRL derived in Section 3?
                                                                                                                                                                                    - No
                                                                                                                                                                                    - Yes
                                                                                                                                                                                       - MRL fully supported by data?
                                                                                                                                                                                        - No
                                                                                                                                                                                        - Yes
                                                                                                                                                                                           - GAP or DB > 0.1 mg/kg DM in EU?
                                                                                                                                                                                               - No
                                                                                                                               Consumer risk assessment for GAPs evaluated at EU level – EU scenarios

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

Recommendations resulting from EU authorisations and import tolerances

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

| Code/trivial name                  | Chemical name/SMILES notation                                                                 | Structural formula |
|-----------------------------------|------------------------------------------------------------------------------------------------|--------------------|
| Tembotrione (AE 0172747)          | 2-[(2-chloro-4-mesy]-3-[[2,2,2-trifluoroethoxy)methyl]benzoyl]cyclohexane-1,3-dione             | ![Structural formula](image1) |
| Metabolite M5 (4,6 dihydroxy tembotrione, AE 1417268) | 2-[(2-Chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-4,6-dihydroxycyclohexane-1,3-dione | ![Structural formula](image2) |
| Metabolite M6 (benzoic acid, AE 0456148) | 2-Chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoic acid          | ![Structural formula](image3) |
| Metabolite M2 (carboxy benzylic alcohol, AE 1392936) | 2-Chloro-3-(hydroxymethyl)-4-(methylsulfonyl)benzoic acid | ![Structural formula](image4) |

SMILES: simplified molecular-input line-entry system.