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

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

Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance tebufenozide. To assess the occurrence of tebufenozide residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

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Keywords: tebufenozide, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, diacylhydrazine, insecticide, ethylphenyl-ring and dimethylphenyl-ring moiety

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Correspondence: pesticides.mrl@efsa.europa.eu
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Summary

Tebufenozide was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/60/EC and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved 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 Germany, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 2 March 2017 and finalised on 2 May 2017. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 9 June 2017.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS and Member States, EFSA prepared in November 2017 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 11 December 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of tebufenozide was assessed in fruits, cereals, root crops and leafy vegetables (tentative). A general residue definition is proposed for risk assessment: sum of tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, expressed as tebufenozide. For enforcement, the residue definition should be limited to tebufenozide only.

A validated analytical method for enforcement of the proposed residue definition in the four main analytical matrices is available.

The metabolism of rotational crops was found to be similar to the metabolism in primary crops; therefore, the same residue definitions apply.

Tebufenozide was stable to hydrolysis under standard conditions of pasteurisation, baking and sterilisation. Studies investigating the magnitude of residues in several processed commodities of citrus (oranges and mandarins), apples, tomatoes and rice are available. Robust-processing factors could be derived for citrus (peel, peeled), apples (washed, juice (unpasteurised), puree, wet pomace), grape (must (with and without skins), pomace, wine), rice (husked grain, polished grain), tomato (juice (stereilised), wet pomace, fruit (preserved), paste) and limited processing factors (not fully supported by data) were derived for citrus (washed fruits, juice, dried pulp, cold pressed oil), apple (juice (pasteurised), peel and core) and tomato (puree).

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all crops under review with the exception of chestnuts/walnuts, hazelnuts/cobnuts, pine nut kernels, cherries (sweet), plums, table/wine grapes, strawberries, tomatoes, aubergines and courgette. For lettuces/escaroles and rice grain, only tentative MRLs were derived. Due to the lack of confirmatory analytical methods for animal matrices and the fact that conversion factors were derived from metabolism studies, the MRLs in commodities of animal origin should be considered as tentative only.

All dietary burdens were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). The metabolism of tebufenozide was investigated in ruminants (lactating goats) and poultry (laying hens). A feeding study performed on ruminants (dairy cow) was also available for this MRL review. The residue definition in livestock for both enforcement and risk assessment is limited to parent compound only.

A validated analytical method for enforcement for residues in milk, meat, fat and liver is available. For eggs, a similar method was reported, but the method was not validated. No confirmatory methods are available for analytical methods in animal matrices.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing European Union (EU) MRL for an indicative calculation. The highest chronic exposure represented 29.6% of the acceptable daily intake (ADI) (DE children). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

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Apart from the MRLs evaluated in the framework of this review, internationally recommended codex maximum residue limits (CXLs) have also been established for tebufenozide. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 39.6% of the ADI (DE children).
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Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(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/EEC\(^2\) a reasoned opinion on the review of the existing MRLs for that active substance. As tebufenozide was included in Annex I to Council Directive 91/414/EEC on 1 June 2011 by means of Commission Directive 2011/60/EC\(^3\) and has been deemed to be approved under Regulation (EC) No 1107/2009\(^4\), in accordance with Commission Implementing Regulation (EU) No 540/2011\(^5\), as amended by Commission Implementing Regulation (EU) No 541/2011\(^6\), 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.

Germany, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for tebufenozide and to prepare a supporting evaluation report (Germany, 2013). The PROFile and the supporting evaluation report were submitted to EFSA on 10 September 2013 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 2 March 2017 and finalised on 2 May 2017. Additional evaluation reports were submitted by Member States France, Germany, Greece, Italy, Spain and the European Union Reference Laboratories for Pesticide Residues (EURL, 2017; France, 2017; Germany, 2017; Greece, 2017; Italy; 2017; Spain, 2017) and, after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 9 June 2017. Further clarifications were sought from Member States via a written procedure in June 2017.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission (CAC) (codex maximum residue limit; CXLs) and the additional information provided by the Member States, EFSA prepared in November 2017 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 11 December 2017 were considered by EFSA during the finalisation of the reasoned opinion.

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\(^1\) 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 Directive 2011/60/EC of 23 May 2011 amending Council Directive 91/414/EEC to include tebufenozide as active substance and amending Commission Decision 2008/934/EC. OJ No L 136, 24.5.2011, p. 58-61.

\(^4\) 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.
The evaluation report submitted by the RMS (Germany, 2013) and the evaluation reports submitted by Member States France, Germany, Greece, Italy, Spain and the EURL (EURL, 2017; France, 2017; Germany, 2017, Greece, 2017; Italy, 2017; Spain, 2017) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2017) and the Member States consultation report (EFSA, 2018). 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 exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo(EU) and PRIMo(CXL) 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

Tebufenozide is the ISO common name for \(N\text{-}\text{tert}-\text{butyl}-N^0\text{-}(4\text{-}ethylbenzoyl)\text{-}3,5\text{-}\text{dimethylbenzo-hydrazide} \) (IUPAC).

Tebufenozide belongs to the group of diacylhydrazine compounds which are used as insecticide. The compound is effective against many species of Lepidoptera pests in fruits, vegetables and other crops. It interferes with the production of the natural insect-moulting hormone, ecdysone. The larvae, upon ingesting tebufenozide from treated crops, stop feeding and within 24 hours after exposure die from premature moult.

The chemical structure of the active substance and its main metabolites is reported in Appendix F. Tebufenozide was evaluated in the framework of Directive 91/414/EEC with Germany designated as RMS. The representative uses supported for the peer review process comprise outdoor foliar spraying against insect pests on grapes and pome fruit. Since the notifier voluntarily withdrew its support to the application, a non-inclusion decision was published by Commission Decision 2008/934/EC\(^7\). Following the first decision on non-inclusion of the active substance in Annex I to Directive 91/414/EEC, the applicant submitted a new application within the framework of Commission Regulation (EC) No 33/2008\(^8\), for the inclusion of the active substance in Annex I of Directive 91/414/EEC. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2011/60/EU, which entered into force on 1 June 2011. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, tebufenozide is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as insecticide only.

The EU MRLs for tebufenozide are established in Annexes IIIA of Regulation (EC) No 396/2005 and CXLs for active substance were also established by the CAC. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

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\(^7\) Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances. OJ L 333, 11.12.2008, p. 11–14.

\(^8\) Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 9(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.
For the purpose of this MRL review, the critical uses of tebufenozide currently authorised within the EU have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAPs for active substance are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Germany, 2013), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Germany, 2005, 2009, 2010), the conclusion on the peer review of the pesticide risk assessment of the active substance tebufenozide (EFSA, 2010b), the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2001), the previous reasoned opinions on tebufenozide (EFSA, 2010a, 2014) as well as the evaluation reports submitted during the completeness check (EURL, 2017; France, 2017; Germany, 2017; Greece, 2017; Italy, 2017; Spain, 2017). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011\(^9\) and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2016; 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 tebufenozide was investigated in fruits, cereals (Germany, 2009) and root/tuber crops (Germany, 2013). In all metabolism studies, tebufenozide was radiolabelled at three different positions: A-ring \[^{14}C\text{-ethylphenyl}\]-tebufenozide; B-ring \[^{14}C\text{-dimethylphenyl}\]-tebufenozide and t-butyl \[^{14}C\text{-t-butyl}\]-tebufenozide, with the exception of the study on apples where tebufenozide was labelled on the A-ring only.

After two foliar applications of 1.1 kg a.s./ha on apples, the major component identified in any part of the crop was tebufenozide, representing 71.2–77.3% total radioactive residue (TRR) in fruit and 93.4% TRR in apple foliage. Tebufenozide levels varied between 0.3–5.3 mg eq/kg in immature fruit and 0.2 mg eq/kg in mature fruit (68 days after treatment (DAT)). Four minor metabolites were identified in fruit (RH-111788, RH-89886, RH-120282, RH-122778) and RH-120282 (an intermediate to the formation of RH-122778) was identified in foliage. After one foliar application of 1.2 kg a.s./ha on grapes, the major component of the residue was tebufenozide (89.2–92.4% TRR; 0.78–1.99 mg/kg). The parent compound was found in the fruit at 1.0–2.45 mg eq/kg and no individual metabolites were identified.

After one foliar application of 1.2 kg a.s./ha on rice, tebufenozide was the main compound detected, representing 76% TRR and 51% TRR in straw and grain, respectively. Tebufenozide was found at 68.3 mg eq/kg in straw (64 DAT, B-ring) and at 0.4 mg eq/kg in grain (64 DAT, B-ring). Minor metabolites RH-120970, RH-96595, RH-111788 and RH-89886 were detected at levels below 10% TRR.

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\(^9\) Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127–175.

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The metabolism of tebufenozide was investigated in sugarbeet roots and tops by the RMS (Germany, 2013), EFSA (EFSA, 2014) and by JMPR (FAO, 2001), but it was not peer reviewed. The study provided results of the total radioactivity at each sampling point and the metabolic profile of residues at harvest in roots and tops treated with the B-ring-labelled active substance (Germany, 2013). After one foliar application of 2.24 kg a.s./ha on sugar beets, tebufenozide was the major component of the residues in both roots and tops at harvest (120 DAT), representing about 66 % and 41 % of the TRR, respectively. In sugar beet roots, parent was the dominant residue as no individual metabolite exceeded 3.5% TRR (0.008 mg/kg). In sugar beet tops, tebufenozide accounted for 41.4% TRR (equal to 71% of identified residue compounds containing the ethylphenyl and dimethylphenyl structures). The conclusions made in sugar beet tops and apples foliage were used to depict, on a tentative basis, the metabolism of tebufenozide in leafy vegetables.

1.1.2. Nature of residues in rotational crops

Tebufenozide is authorised on crops that may be grown in rotation. The field DT90 reported in the field soil dissipation studies evaluated in the framework of the peer review were 47–512 days (EFSA, 2010b). According to the peer review, the three major transformation products of tebufenozide (RH-6595, RH-2703 and RH-2651) may be considered moderately persistent in soil. Another transformation product (M2) was observed in the soil but remained unidentified (EFSA, 2010b).

One confined rotational crop study with radiolabelled tebufenozide at three different positions (A-ring, B-ring and side chain) was assessed by the RMS (Germany, 2013), EFSA (EFSA, 2014) and by JMPR (FAO, 2001). After four applications of 280 g a.s./ha on bare soil, turnip, kale (collard) and wheat were planted at different plant back intervals (30, 90, 250, 365 or 384 for kale) DAT. Tebufenozide was recorded 30 DAT in wheat forage and straw at the highest levels (2.6 and 7.3 mg eq/kg, respectively) and at 0.4 mg eq/kg in wheat grain. Residues at 365 DAT were 0.3 mg eq/kg and 0.1 mg eq/kg in wheat straw and forage, respectively, and 0.07 mg eq/kg in grain. In kale, highest residues were observed 30 DAT (0.1 mg eq/kg), decreasing to levels below 0.01 mg eq/kg at 365 DAT. In turnip tops, residues were higher than 0.01 mg eq/kg in all sampling dates; however, in turnip roots, residues were 0.08 mg/kg at 30 DAT, decreasing to levels below 0.01 mg eq/kg in subsequent sampling dates. Only in turnip roots, a significant percentage of residues was identified as unchanged tebufenozide (20% of the TRR or 0.02 mg/kg at 30 DAT).

Tebufenozide was extensively degraded in the rotational crops. Many soil metabolites are taken up and transformed in the rotational crops in a large amount of sugar conjugates. The main component of residues was the plant metabolite RH-1788, free or conjugated. All other quantifiable components were individually present in low concentrations (< 10% of the TRR).

The data on metabolism and distribution of tebufenozide in rotational crops indicated that the metabolism of tebufenozide in rotational crops is similar to the pathway observed in primary crops, but more extensive as tebufenozide was a minor component of the residues or even undetectable.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed in the framework of the peer review (EFSA, 2010b). Studies were conducted with radiolabelled tebufenozide simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). Tebufenozide was stable to hydrolysis under standard conditions of pasteurisation, baking and sterilisation.

1.1.4. Methods of analysis in plants

During the peer review, a multiresidue analytical method using high-performance liquid chromatography with mass spectrometry (HPLC-MS) was validated for the determination of tebufenozide in high water and high acid-content commodities with a limit of quantification (LOQ) of 0.02 mg/kg (EFSA, 2010b). A multiresidue analytical method using LC-MS/MS, validated for the determination of tebufenozide in all four plant matrices with an LOQ of 0.01 mg/kg was reported by France (2017). However, extraction efficiency of the method reported by France was not demonstrated. Furthermore, the EURL reported a multiresidue analytical method using LC-MS/MS for the four main plant matrices with an LOQ of 0.01 mg/kg (EURL, 2017). Hence, it is concluded that tebufenozide can be enforced with a LOQ of 0.01 mg/kg in high water-content, high acid-content, high oil-content and dry commodities.
1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of tebufenozide was demonstrated for a period of 30 months at \(-10^\circ C\) in high water- and high acid-content matrices (EFSA, 2010b). Furthermore, the storage stability of tebufenozide was demonstrated for a period of 36 months at \(-18^\circ C\) in high water-content, for a period of 32 months at \(-18^\circ C\) in high acid-content, for a period of 42 months in high oil-content matrices and for a period of for 54 months at \(-18^\circ C\) in dry commodities (Germany, 2013).

1.1.6. Proposed residue definitions

The metabolism of tebufenozide is similar in fruits, cereals and root crops as there were no qualitative differences observed in the metabolism studies. However, it is noted that are quantitative differences in the compartmentalisation of tebufenozide in different plant parts. In addition, the metabolism in rotational crops is similar to the metabolism observed in primary crops. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all matrices is available.

In the framework of the peer review, it was concluded on a risk assessment residue definition on fruit crops and cereals as ‘tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, calculated as tebufenozide’ and a residue definition for enforcement as tebufenozide, only (EFSA, 2010b).

Therefore, a general residue definition for risk assessment can be proposed: sum of tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, expressed as tebufenozide. For enforcement, the general residue definition is proposed as tebufenozide, only.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of tebufenozide residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Germany, 2013), including residue trials evaluated in the framework of the peer review (EFSA, 2010b) or in the framework of a previous MRL application (EFSA, 2010a, 2014) and additional data submitted during the completeness check (France, 2017; Germany, 2017; Greece, 2017; Italy, 2017; Spain, 2017). All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2016). The use of the proportionality concept was proposed by the RMS in its evaluation report and by several other Member States during the completeness check. As a consequence, residue trials were scaled when considered appropriate by using the proportionality approach in accordance with the current available guidance document (OECD, 2016).

Samples from residue trials were reported for tebufenozide only and not reported for all relevant components of the residue definition for risk assessment (tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, calculated as tebufenozide).

Residue trials are not available to support the authorisations on hazelnuts/cobnuts (southern), pine nut kernels (southern), cherries (northern), plums (northern), strawberries (indoor), tomatoes (southern), aubergines (southern), courgettes (southern) and sweet peppers (southern). Therefore, MRL or risk assessment values for some of these crops could not be derived by EFSA and the following data gaps were identified:

- Four trials on hazelnuts/cobnuts and pine nut kernels compliant with the southern outdoor GAP are required;
- Five additional trials on cherries (sweet) compliant with the northern outdoor GAP are required;
- Eight trials on and plums compliant with the northern outdoor GAP are required;
- Eight trials on strawberries compliant with the northern outdoor GAP are required;
- Eight trials on courgettes compliant with the southern outdoor GAP are required;
For some crops, the number of residue trials reported is not compliant with the data requirements, only tentative MRL and risk assessment values could be derived by EFSA and the following data gaps were identified:

- Eight trials on lettuces (open head varieties) compliant with the southern outdoor GAP authorised for lettuce and escaroles and analysed according to the residue definition for enforcement and risk assessment separately are required (the existing eight trials on lettuce were analysed for tebufenozide only; therefore, the conversion factor is tentative).
- Eight trials on rice compliant with the southern outdoor GAP and analysed according to the residue definition for enforcement and risk assessment separately (the existing eight trials on rice were analysed for tebufenozide only; therefore, the conversion factor is tentative).

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

- Tomatoes, aubergines: Although appropriate MRL and risk assessment values can be derived from the indoor data, eight trials compliant with the southern outdoor GAP are still required;
- Sweet peppers/bell peppers: Although appropriate MRL and risk assessment values can be derived from the indoor data, six trials compliant with the southern outdoor GAP are still required.
- Quinces, medlars, loquats: Although tentative MRL and risk assessment values can be derived from overdosed trials on apples, eight residue trials compliant with the southern GAP are still required.
- Table/wine grapes: Although appropriate MRL and risk assessment values can be derived, one additional trial compliant with the southern GAP is still required.

For the GAP on chestnuts/walnuts (southern), two overdosed trials are available. The residue data was below the limit of detection (LOD) of 0.003 mg/kg. A no residue situation is anticipated for this GAP and no additional trials are required. Therefore, appropriate MRL and risk assessment values can be derived for chestnuts/walnuts (southern).

Since no residue trials were analysed according to the residue definition for risk assessment, no conversion factors could be derived from the residue data. Therefore, tentative conversion factors were derived from the metabolism studies. In the framework of the peer review, no conversion factor was proposed for fruit crops, since the residues were almost entirely allocated to the parent compound (EFSA, 2010b). For cereals, a conversion factor of 2 was proposed, since tebufenozide was present only at 51% of the TRR in rice grain (EFSA, 2010b). It is noted that the conversion factor for cereals may be an overestimation since it assumes that the remaining radioactivity in grains consist entirely of toxicologically relevant metabolites, whereas the metabolism study has shown that this radioactivity was also composed of unextracted material (16% TRR) and of polar and unknown compounds, present in low proportions and probably not structurally related to the parent (EFSA, 2010b). Based on the results of the metabolism study on sugar beet roots, no conversion factor was proposed for roots since metabolites were not observed at relevant quantities; however, based on the results on sugar beet tops, a conversion factor of 1.4 has been proposed for leafy vegetables (Germany, 2013; EFSA, 2014).

1.2.2. Magnitude of residues in rotational crops

Studies investigating the magnitude of residues in rotational crops were assessed by JMPR (FAO, 2001). One control and one treated plot were planted with leaf lettuce as the primary crop. Tebufenozide was sprayed four times in a foliar ground application of 280 g a.s./ha at intervals of 9–12 days between applications. The leaf lettuce was removed from the plots, and rotational crops (leaf lettuce, radish, squash, wheat, sorghum, soya bean, onion and green peppers) were planted 30 and/or 120 DAT. In high-moisture samples (leaf lettuce, radish (tops and roots), squash, onion (green and bulb) and green peppers), the levels of tebufenozide and its olefin metabolite RH-9841 (significant compounds detected in the confined rotational study) were below 0.01 mg/kg 30 DAT. In low-moisture samples (wheat, sorghum and soya beans), tebufenozide and its alcohol metabolite RH-1788 were investigated. Tebufenozide levels were below the LOQ of 0.02 mg/kg in any wheat and sorghum components 30 DAT; however, metabolite RH-1788 was detected in wheat hay, wheat straw and soya bean forage at 0.28 mg/kg, 0.12 mg/kg and 0.03 mg/kg, respectively. Therefore, the only residue present at relevant levels was the metabolite RH-1788 found in non-edible parts of wheat and soya bean. The total concentration used in the field study was of 1120 g a.s./ha, and the maximum
application rate in crops under this review that can be rotated (e.g., tomatoes, lettuces) is 540 g a.s./ha. It is also noted that application in these crops is done at a later crop stage (preharvest interval (PHI) 3–14 days); therefore, crop interception will have a meaningful impact in the amount of tebufenozide that may potentially reach the soil. Since metabolite RH-1788 toxicity can be considered covered by the toxicological reference values of the parent compound, and the application rate used in the rotational field study was approximately twice the maximum dose applied in crops that can be rotated, EFSA considers that residues in rotational crops are of no relevance for the dietary risk assessment.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on apples, citrus, grapes, tomato and rice (Germany, 2013). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors could be derived for citrus (peel, peeled), apples (washed, juice (unpasteurised), puree, wet pomace), grape (must (with and without skins), pomace, wine), rice (husked grain, polished grain), tomato (juice (sterilised), wet pomace, fruit (preserved), paste) and limited processing factors (not fully supported by data) were derived for citrus (washed fruits, juice, dried pulp, cold pressed oil), apple (juice (pasteurised), peel and core) and tomato (puree).

1.2.4. Proposed MRLs

The available data are not sufficient to derive MRL proposals as well as risk assessment values for hazelnuts/cobnuts, pine nut kernels, cherries (sweet), plums, strawberries and courgettes.

The available data are considered sufficient to derive appropriate MRL proposals as well as risk assessment values for citrus fruits, chestnuts/walnuts, apples, pears, table/wine grapes, tomatoes aubergines and sweet/bell peppers. Tentative MRLs are derived for quinces, medlars loquats, lettuces/escaroles and rice grains.

2. Residues in livestock

Tebufenozide is authorised for use on fruits and cereals that 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 all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin.

It is highlighted that for several feed items, no residue data were available (e.g., head cabbage, kale). The animal intake of tebufenozide residues via these commodities has therefore not been assessed and may have been underestimated. However, this is not expected to have a major impact on the outcome of the dietary burden considering the high/overwhelming contribution of rice bran/pollard. Furthermore, it was noted that potential residue of metabolite RH-1788 (detected in field rotational crops) may occur in wheat (hay and straw) (see Section 1.2.2). However, considering the indicative figures of the confined rotational crops study, the potential contribution of this metabolite would not significantly increase the dietary burden (< 6%). Therefore, the potential residues from rotational crops were not considered relevant for the dietary burden calculation.

2.1. Nature of residues and methods of analysis in livestock

Studies to investigate metabolism in livestock were conducted on lactating goats and laying hens (EFSA, 2010b). In these studies, goats and poultry were dosed with tebufenozide, labelled in the ethylphenyl or dimethylphenyl ring or on a side chain (t-butyl position), for 7 days, at rates equivalent to 50 mg/kg (goats) or 30 mg/kg (poultry) in the feed.

In goats, the majority of measured TRR was excreted in faeces (78–81%) and urine (7.8–8.9%). Maximum residues in milk (0.31 mg/kg, t-butyl label) were measured on day 5 and a plateau was seen on days 2–6. After sacrifice, the highest residue levels were found in liver (2.7 mg/kg) and fat (1.8 mg/kg). Major metabolites were tebufenozide (milk, fat, kidney, muscle), RH-9886 or its fatty acid conjugates (milk, fat, kidney, muscle), RH-0282 (kidney, muscle) and RH-2703 (liver).

Tebufenozide was the major component in goat fat and muscle (25–40% TRR) and accounted for 10% TRR in other goat and poultry matrices. Tebufenozide was not detected in liver where the main metabolites are RH-2703 (47% TRR, 0.3 mg/kg in goat) and isopropanol/acetaldehyde (almost 50%
TRR in goat and poultry). The metabolism in goat and poultry is similar and proceeds by oxidation of the alkyl chains on the two phenyl rings, leading to the metabolites RH-9886, RH-120282, RH-1778 and RH-2703.

In the framework of the peer review, the residue definition for enforcement was proposed as tebufenozide only; for risk assessment, the residue definition was proposed as 'tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, calculated as tebufenozide' (EFSA, 2010b). Therefore, a general residue definition for risk assessment can be proposed: sum of tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, expressed as tebufenozide. For enforcement, the general residue definition is proposed as tebufenozide, only.

Tentative conversion factors were derived from the metabolism studies. A conversion factor of 2 was derived for ruminant and poultry muscle, fat and liver as well as for milk; a conversion factor of 4 was calculated for ruminant and poultry kidney. For eggs, a conversion factor of 2 was derived.

Independent validated analytical methods for residues in milk, meat, fat, kidney and liver were reported in the DAR (Germany, 2005) using high-performance liquid chromatography with ultraviolet detector (HPLC-UV) with an LOQ of 0.02 mg/kg. For eggs, a similar method was reported, but the method was not validated. It is noted that confirmatory methods for animal matrices are not available (Germany, 2013). During the completeness check, France reported validated analytical methods for the determination of tebufenozide in matrices of animal origin (milk, fat, muscle meat, egg and liver) using LC-MS/MS with an LOQ of 0.01 mg/kg (France, 2017). However, extraction efficiency of the method reported by France was not demonstrated. No quantitative validation data are available by EURLs for tebufenozide in commodities of animal origin (EURL, 2017). Screening validation data indicated that tebufenozide can be enforced in commodities of animal origin with an LOQ of 0.005 mg/kg in meat, eggs and honey. For milk, even an LOQ of 0.0025 mg/kg would be feasible (EURL, 2017). Since there are no confirmatory methods for animal matrices, a data gap is identified. Tebufenozide is stable in eggs and milk, liver, muscle and fat stored frozen for up to 6, 23, 8 and 4 months, respectively. Metabolites RH-9526 (milk, fat), RH-0282 (milk, muscle), RH-2703 (liver), RH-9886 (muscle) were stable for up to 6, 4, 6, 8, 6 and 8 months, respectively. In addition, there were no qualitative differences between fresh and 23-month stored milk (Germany, 2005).

2.2. Magnitude of residues in livestock

The magnitude of residues in livestock was assessed in a ruminant (dairy cow) feeding study (EFSA, 2010b). In this study, tebufenozide was administered with doses of 6, 18 or 60 mg/kg DM for a period of 28 days. These levels were converted into mg/kg body weight (bw) per day, using the standard weight and feed daily consumption for dairy cows.

In milk, the highest level of tebufenozide was 0.007 mg/kg at 6 mg/kg DM, 0.01 mg/g at 18 mg/kg DM and 0.02 mg/kg at 60 mg/kg DM. Metabolite RH-0282 was not detected in milk at 6 mg/kg DM, but levels of RH-0282 were up to 0.013 and 0.01 mg/kg at 18 mg/kg DM and 60 mg/kg DM, respectively. Highest levels of RH-9526 in milk from the 6, 18 and 60 mg/kg groups were 0.006, 0.016 and 0.037 mg/kg, respectively. With the exception of one animal, a plateau was reached slowly at between days 9 and 23 of the study, and there was no correlation of time to plateau with dose.

Levels of tebufenozide in tissues following dosing at 6 mg/kg DM level (equivalent to 0.22 mg/kg bw per day) were below 0.05, 0.02 and 0.03 mg/kg in liver, kidney, muscle and fat, respectively. No residues were detected in milk, liver, kidney or muscle following a 3-day recovery period, and the only residues measured in fat above the LOQ (0.02 mg/kg) were RH-9526 (0.06 mg/kg in the highest group level of 60 mg/kg DM group).

Consequently, the available data are considered sufficient for deriving MRLs in livestock. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009) and are summarised in Appendix B.2.2. Significant residues are only expected in fat matrices and MRLs for these commodities can be proposed. For all other matrices, significant residues are not expected and MRLs for these commodities can be established at the LOQ. Considering that conversion factors were derived from the metabolism studies, that samples were not analysed for all components of the residue definition for enforcement and risk assessment and due to the lack of confirmatory analytical methods for animal matrices, the MRLs in commodities of animal origin should be considered as tentative only.
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; however, the use of tebufenozide was previously also assessed by the JMPR (FAO, 2001). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

3.1. **Consumer risk assessment without consideration of the existing CXLs**

Chronic 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). The calculation is based on the median residue levels in the raw agricultural commodities, except for citrus fruits, where the relevant peeling factor was applied. For those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D.

The tentative conversion factors derived from metabolism studies were applied to lettuce/escaroles, rice and livestock.

Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

The exposures calculated were compared with the toxicological reference value for tebufenozide, derived by EFSA (2010b) under Directive 91/414/EEC. The highest chronic exposure was calculated for DE children representing 29.6% of the acceptable daily intake (ADI).

3.2. **Consumer risk assessment with consideration of the existing CXLs**

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is also provided in Appendix D.

The tentative conversion factor derived for leafy vegetables was applied to leafy and Brassica vegetables. For sugar cane, a conversion factor of 2 derived from cereals was tentatively applied. Since there are no metabolism studies on pulses and oilseeds, the conversion factor applied to rape seed is based on the conversion factor derived from rice (CF = 2), as cereals reflected the worst-case scenario for conversion factors and were considered the most appropriate surrogate for rape seed (oilseeds).

Chronic exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposures calculated were compared with the toxicological reference value derived for tebufenozide. The highest chronic exposure was calculated for DE children representing 39.6% of the ADI. Based on these calculations, EFSA concludes that the CXLs are not expected to be of concern for European consumers.

**Conclusions**

The metabolism of tebufenozide was assessed in fruits, cereals, root crops. A general residue definition is proposed for risk assessment: sum of tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, expressed as tebufenozide. For enforcement, the general residue definition is limited to tebufenozide only.

A validated analytical method for enforcement of the proposed residue definition in the four main analytical matrices is available.

The metabolism of rotational crops was found to be similar as the metabolism in primary crops; therefore, the same residue definitions apply.

Tebufenozide was stable to hydrolysis under standard conditions of pasteurisation, baking and sterilisation. Studies investigating the magnitude of residues in several processed commodities of citrus (oranges and mandarins), apples, tomatoes and rice are available. Robust processing factors could be derived for citrus (peel, peeled), apples (washed, juice (unpasteurised), puree, wet pomace), grape
(must (with and without skins), pomace, wine), rice (husked grain, polished grain), tomato (juice (sterilised), wet pomace, fruit (preserved), paste) and limited processing factors (not fully supported by data) were derived for citrus (washed fruits, juice, dried pulp, cold pressed oil), apple (juice (pasteurised), peel and core) and tomato (puree).

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all crops under review with the exception of hazelnuts/cobnuts, pine nut kernels, cherries (sweet), plums, strawberries and courgettes. For lettuces/escaroles and rice grain, only tentative MRLs were derived.

All dietary burdens were found to exceed the trigger value of 0.1 mg/kg DM. The metabolism of tebufenozide was investigated in ruminants (lactating goats) and poultry (laying hens). A feeding study performed on ruminants (dairy cow) was also available for this MRL review. The residue definition in livestock for both enforcement and risk assessment is limited to parent compound only.

A validated analytical method for enforcement for residues in milk, meat, fat and liver is available. For eggs, a similar method was reported, but the method was not validated. No confirmatory methods are available for analytical methods in animal matrices. Due to the lack of confirmatory analytical methods for animal matrices and the fact that conversion factors were derived from metabolism studies, the MRLs in commodities of animal origin should be considered as tentative only.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was 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 represented 29.6% of the ADI (DE children). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for tebufenozide. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 39.6% of the ADI (DE children).

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 details). In particular, some tentative MRLs and/or existing EU MRLs need to be confirmed by the following data:

- Four trials on hazelnuts/cobnuts and pine nut kernels compliant with the southern outdoor GAP are required;
- Five additional trials on cherries (sweet) compliant with the northern outdoor GAP are required;
- Eight trials on and plums compliant with the northern outdoor GAP are required;
- Eight trials on strawberries compliant with the northern outdoor GAP are required;
- Eight trials on courgettes compliant with the southern outdoor GAP are required;
- Eight trials on and plums compliant with the southern outdoor GAP are authorised for lettuce and escaroles and analysed according to the residue definition for enforcement and risk assessment separately are required (the existing eight trials on lettuce were analysed for tebufenozide only; therefore, the conversion factor is tentative);
- Eight trials on rice compliant with the southern outdoor GAP and analysed according to the residue definition for enforcement and risk assessment separately are required (the existing eight trials on rice were analysed for tebufenozide only; therefore, the conversion factor is tentative);
- Confirmatory analytical methods for animal matrices are required.

It is highlighted, however, that some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Eight trials derived on quinces, medlars and loquats trials compliant with the southern GAP are still required.
- Eight trials on tomatoes compliant with the southern outdoor GAP on tomatoes and aubergines/eggplants are required;
Six additional trials on sweet peppers/bell peppers compliant with the southern outdoor GAP are required.

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:

One additional trial on table/wine grapes compliant with the southern GAP is still required.

If the above-reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Table 2: Summary table

| Code number | Commodity                  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment          |
|-------------|----------------------------|-------------------------|----------------------|-----------------------|------------------|
|             | **Enforcement residue definition (existing): tebufenozide (F)** |                         |                      |                       |                  |
| 110010      | Grapefruits                | 2                       | 2                    | 2                     | Recommended(a)   |
| 110020      | Oranges                    | 2                       | 2                    | 2                     | Recommended(a)   |
| 110030      | Lemons                     | 2                       | 2                    | 2                     | Recommended(a)   |
| 110040      | Limes                      | 2                       | 2                    | 2                     | Recommended(a)   |
| 110050      | Mandarins                  | 2                       | 2                    | 2                     | Recommended(a)   |
| 120010      | Almonds                    | 0.05*                   | 0.05                 | 0.05                  | Recommended(b)   |
| 120040      | Chestnuts                  | 0.05*                   | –                    | 0.01*                 | Recommended(b)   |
| 120060      | Hazelnuts/cobnuts          | 0.05*                   | –                    | 0.05                  | Further consideration needed(g) |
| 120080      | Pecans                     | 0.05*                   | 0.01*                | 0.01*                 | Further consideration needed(g) |
| 120090      | Pine nut kernels           | 0.05*                   | –                    | 0.05                  | Further consideration needed(g) |
| 120110      | Walnuts                    | 0.05*                   | 0.05                 | 0.05                  | Recommended(b)   |
| 130010      | Apples                     | 1                       | 1                    | 1                     | Recommended(f)   |
| 130020      | Pears                      | 1                       | 1                    | 1                     | Recommended(f)   |
| 130030      | Quinces                    | 1                       | 1                    | 1                     | Recommended(g)   |
| 130040      | Medlars                    | 1                       | 1                    | 1                     | Recommended(g)   |
| 130050      | Loquats/Japanese medlars   | 1                       | 1                    | 1                     | Recommended(g)   |
| 140020      | Cherries (sweet)           | 1                       | –                    | 1                     | Further consideration needed(g) |
| 140030      | Peaches                    | 0.5                     | 0.5                  | 0.5                   | Recommended(b)   |
| 140040      | Plums                      | 1                       | –                    | 1                     | Further consideration needed(g) |
| 151010      | Table grapes               | 3                       | 2                    | 4                     | Recommended(f)   |
| 151020      | Wine grapes                | 3                       | 2                    | 4                     | Recommended(f)   |
| 152000      | Strawberries               | 0.05*                   | –                    | 0.05                  | Further consideration needed(g) |
| 153030      | Raspberries                | 2                       | 2                    | 2                     | Recommended(b)   |
| 154010      | Blueberries                | 3                       | 3                    | 3                     | Recommended(b)   |
| 154020      | Cranberries                | 0.5                     | 0.5                  | 0.5                   | Recommended(b)   |
| 161040      | Kumquats                   | 0.05*                   | 2                    | 2                     | Recommended(b)   |
| 162010      | Kiwi                       | 0.5                     | 0.5                  | 0.5                   | Recommended(b)   |
| 163010      | Avocados                   | 1                       | 1                    | 1                     | Recommended(b)   |
| 231010      | Tomatoes                   | 1                       | 1                    | 1.5                   | Recommended(f)   |
| 231020      | Sweet peppers/bell peppers | 1                       | 1                    | 1.5                   | Recommended(f)   |
| 231030      | Aubergines/eggplants       | 0.5                     | –                    | 1.5                   | Recommended(c)   |
| 232030      | Courgettes                 | 0.1                     | –                    | 0.1                   | Further consideration needed(g) |
| 241010      | Broccoli                   | 0.5                     | 0.5                  | 0.5                   | Further consideration needed(g) |
| 242020      | Head cabbage               | 5                       | 5                    | 5                     | Further consideration needed(g) |
| 243010      | Chinese cabbage            | 0.5                     | 10                   | 10                    | Further consideration needed(g) |
| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|------------------------|----------------------|----------------------|---------|
| 243020      | Kale      | 0.5                    | 10                   | Further consideration needed | (h)    |
| 251010      | Lamb's lettuce | 10                    | 10                   | Further consideration needed | (h)    |
| 251020      | Lettuces  | 10                     | 10                   | Further consideration needed | (h)    |
| 251030      | Escaroles/broad-leaved endives | 10                    | 10                   | Further consideration needed | (i)    |
| 251040      | Cress     | 10                     | 10                   | Further consideration needed | (h)    |
| 251050      | Land cress | 10                     | 10                   | Further consideration needed | (h)    |
| 251060      | Rocket, Rucola | 10                    | 10                   | Further consideration needed | (h)    |
| 251070      | Red mustard | 10                    | 10                   | Further consideration needed | (h)    |
| 251080      | Leaves and sprouts of Brassica spp. | 10                    | 10                   | Further consideration needed | (h)    |
| 252010      | Spinach   | 10                     | 10                   | Further consideration needed | (h)    |
| 252020      | Purslane  | 10                     | 10                   | Further consideration needed | (h)    |
| 252030      | Beet leaves (chard) | 0.05*                | 10                   | Further consideration needed | (h)    |
| 253000      | Vine leaves (grape leaves) | 0.05*                | 10                   | Further consideration needed | (h)    |
| 254000      | Water cress | 0.05*                | 10                   | Further consideration needed | (h)    |
| 256000      | Chervil   | 0.05*                  | 10                   | Further consideration needed | (h)    |
| 256080      | Basil     | 20                     | 20                   | Further consideration needed | (h)    |
| 401060      | Rape seed | 2                      | 2                    | Further consideration needed | (h)    |
| 500060      | Rice grains | 3                    | 0.1                  | Further consideration needed | (h)    |
| 900020      | Sugar cane | 1                    | 1                    | Further consideration needed | (h)    |
| 1011010     | Swine muscle | 0.05*              | 0.05                 | Further consideration needed | (h)    |
| 1011200     | Swine fat tissue | 0.05*              | 0.05                 | Further consideration needed | (h)    |
| 1011300     | Swine liver | 0.05*              | 0.02*                | Further consideration needed | (i)    |
| 1011400     | Swine kidney | 0.05*              | 0.02*                | Further consideration needed | (i)    |
| 1012010     | Bovine muscle | 0.05*             | 0.05                 | Further consideration needed | (h)    |
| 1012020     | Bovine fat tissue | 0.05*             | 0.05                 | Further consideration needed | (h)    |
| 1012030     | Bovine liver | 0.05*              | 0.05                 | Further consideration needed | (h)    |
| 1012040     | Bovine kidney | 0.05*             | 0.02*                | Further consideration needed | (j)    |
| 1013010     | Sheep muscle | 0.05*             | 0.05                 | Further consideration needed | (j)    |
| 1013020     | Sheep fat tissue | 0.05*            | 0.05                 | Further consideration needed | (j)    |
| 1013030     | Sheep liver | 0.05*              | 0.02*                | Further consideration needed | (j)    |
| 1013040     | Sheep kidney | 0.05*             | 0.02*                | Further consideration needed | (j)    |
| 1014010     | Goat muscle | 0.05*              | 0.05                 | Further consideration needed | (j)    |
| 1014020     | Goat fat tissue | 0.05*           | 0.05                 | Further consideration needed | (j)    |
| 1014030     | Goat liver | 0.05*              | 0.02*                | Further consideration needed | (j)    |
| 1014040     | Goat kidney | 0.05*              | 0.02*                | Further consideration needed | (j)    |
| 1015010     | Equine muscle | 0.05*             | 0.05                 | Further consideration needed | (j)    |
| 1015020     | Equine fat tissue | 0.05*            | 0.05                 | Further consideration needed | (j)    |
| 1015030     | Equine liver | 0.05*              | 0.02*                | Further consideration needed | (j)    |
| 1015040     | Equine kidney | 0.05*             | 0.02*                | Further consideration needed | (j)    |
| 1016000     | Poultry muscle | 0.05*             | 0.02*                | Further consideration needed | (j)    |
| 1016020     | Poultry fat tissue | 0.05*           | 0.02*                | Further consideration needed | (j)    |
| 1016030     | Poultry liver | 0.05*             | 0.02*                | Further consideration needed | (j)    |
| 1020010     | Cattle milk | 0.05*              | 0.01*                | Further consideration needed | (j)    |
| 1020020     | Sheep milk | 0.05*              | 0.01*                | Further consideration needed | (j)    |
| 1020030     | Goat milk | 0.05*              | 0.01*                | Further consideration needed | (j)    |
| 1020040     | Horse milk | 0.05*              | 0.01*                | Further consideration needed | (j)    |
Review of the existing MRLs for tebufenozide

| Code number | Commodity                        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Outcome of the review                  | Comment                  |
|-------------|----------------------------------|-------------------------|----------------------|-------------|----------------------------------------|--------------------------|
| 1030000     | Birds eggs                       | 0.05*                   | 0.02*                | 0.02*       | Further consideration needed            |                          |
| –           | Other commodities of plant and/or animal origin | –                      | –                    | –           | Further consideration needed            |                          |

MRL: maximum residue level; CXL: codex maximum residue limit.

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

(F): Residue is fat soluble.

(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix E).

(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII 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. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered; existing CXL is covered by the recommended value (combination A-III in Appendix E).

(f): 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; existing CXL is covered by the recommended MRL (combination G-III in Appendix E).

(g): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix E).

(h): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).

(i): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix E).

(j): 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); existing CXL is covered by the tentative MRL (combination E-III in Appendix E).

(k): 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).

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

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Abbreviations

a.i. active ingredient
a.s. active substance
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ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
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
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 high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HPLC-UVD high-performance liquid chromatography with ultraviolet detector
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardization
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
LC-MS/MS liquid chromatography with tandem mass spectrometry
LOD limit of detection
LOQ limit of quantification
Mo monitoring
MRL maximum residue level
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
NEU northern European Union
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
QuEChERS Quick, Easy, Cheap, Effective, Rugged and Safe (analytical method)
RA risk assessment
RD residue definition
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SC suspension concentrate
SEU southern European Union
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
TRR total radioactive residue
UV ultraviolet (detector)
WHO World Health Organization
Appendix A – Summary of authorised uses considered for the review of MRLs

| Crop and/or situation | NEU, SEU, MS or country | FG or country | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|---------------|-------------|-------------|-------------------------------|------------|---------|
|                       |                         |               | Type (b)    | Conc. a.s.  | PHI                           | min–max    |         |
|                       |                         |               | Method kind |             |                               | g a.s./ha  |         |
|                       |                         |               | Range of growth stages & season (c) | Number min–max | Interval between application (min) | Water L/ha min–max |         |
|                       |                         |               |                         |             |                               |            |         |
| Apples DE F           |                         |               | SC 240 g/L  | Foliar treatment – spraying | 3          | –       | –       | 180 14 |
| Cydia pomonella larvae |                         |               |             |             |                               | g a.s./hL  |         |
| Adoxophyes orana larvae |                         |               |             |             |                               | min–max    |         |
| Pears DE F            |                         |               | SC 240 g/L  | Foliar treatment – spraying | 3          | –       | –       | 180 14 |
| Cydia pomonella larvae |                         |               |             |             |                               | g a.s./hL  |         |
| Adoxophyes orana larvae |                         |               |             |             |                               | min–max    |         |
| Quinces DE F          |                         |               | SC 240 g/L  | Foliar treatment – spraying | 3          | –       | –       | 180 14 |
| Cydia pomonella larvae |                         |               |             |             |                               | g a.s./hL  |         |
| Adoxophyes orana larvae |                         |               |             |             |                               | min–max    |         |
| Medlars DE F          |                         |               | SC 240 g/L  | Foliar treatment – spraying | 3          | –       | –       | 180 14 |
| Cydia pomonella larvae |                         |               |             |             |                               | g a.s./hL  |         |
| Adoxophyes orana larvae |                         |               |             |             |                               | min–max    |         |
| Loquats DE F          |                         |               | SC 240 g/L  | Foliar treatment – spraying | 3          | –       | –       | 180 14 |
| Cydia pomonella larvae |                         |               |             |             |                               | g a.s./hL  |         |
| Adoxophyes orana larvae |                         |               |             |             |                               | min–max    |         |
| Cherries DE F         |                         |               | SC 240 g/L  | Foliar treatment – spraying | 59 to 69   | 2       | 12      | –       | 180 n.a. |
| unprotected biting caterpillars (young larvae) |           |               |             |             |                               | Water L/ha min–max |         |
| Plums DE F            |                         |               | SC 240 g/L  | Foliar treatment – spraying | 59 to 69   | 2       | 12      | –       | 180 n.a. |
| unprotected biting caterpillars (young larvae) |           |               |             |             |                               | Water L/ha min–max |         |
| Table grapes DE F     |                         |               | SC 240 g/L  | Foliar treatment – spraying | 75         | 2       | –       | 192 21 |
| Clysia ambiguella Polychrosis botrana (2nd generation) | |               |             |             |                               | g a.s./hL  |         |

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| Crop and/or situation | NEU, SEU, MS or country | Crop | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------------------|------|-----------------------------------|-------------|-------------|--------------------------------|-----------|---------|
| **Wine grapes**       | DE F                     | F    | *Clysia ambiguella*  
Polyphagia botrana (2nd generation) | SC 240 g/L  
Foliar treatment – spraying | 75 2 | – – | 192 21 |
| **Strawberries**      | DE F                     | F    | unprotected biting caterpillars (young larvae) | SC 240 g/L  
Foliar treatment – spraying | 0 to 0 2 | 10 – – | 192 n.a. Application prior to planting |
| **Grapefruits**       | IT F                     | F    | *Phyllocnistis citrella* | SC 240 g/L  
Foliar treatment – spraying | 1-2 14 | – – | 192 14 Different GAP is authorised in ES: 2 × 280 g as/ha and PHI 14 days with 7 days between applications. This GAP is not supported by data |
| **Oranges**           | IT F                     | F    | *Phyllocnistis citrella* | SC 240 g/L  
Foliar treatment – spraying | 1-2 14 | – – | 192 14 Different GAP is authorised in ES: 2 × 280 g as/ha and PHI 14 days with 7 days between applications. This GAP is not supported by data |
| Crop and/or situation | NEU, SEU, MS or country | F or T | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------------------|--------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
|                        |                          |        |                                    | Type(b)     | Conc. a.s.  | Method kind                   | Number min-max | Interval between application (min) | g a.s./hL | Water L/ha | g a.s./ha | max | max |          | |
| Lemons IT F            | Phylloclistis citrella   | SC 240 g/L | Foliar treatment – spraying       | 1–2         | 14          | –                | –           | –                | 192      | 14      |          |     |     |          | |
| Limes IT F             | Phylloclistis citrella   | SC 240 g/L | Foliar treatment – spraying       | 1–2         | 14          | –                | –           | –                | 192      | 14      | Different GAP is authorised in ES: 2 × 280 g a.s/ha and PHI 14 days with 7 days between applications. This GAP is not supported by data |
| Mandarin EL F          | Phylloclistis citrella   | SC 240 g/L | Foliar treatment – spraying       | 1–2         | 14          | –                | –           | –                | 360      | 14      |          |     |     |          | |
| Chestnuts FR F         | Codling moth             | SC 240 g/L | Foliar treatment – spraying       | 3           | 14          | –                | –           | –                | 144      | 30      |          |     |     |          | |
| Hazelnuts ES F         | Defoliator caterpillars  | SC 244 g/L | Foliar treatment – spraying       | –           | –           | 988              | NA          | Preflowering application |
| Crop and/or situation | NEU, SEU, MS or country | F G T | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
|                       |                         |      |                                   | Type(b)     | Conc. a.s. | Method kind                    | Range of growth stages & season(c) | Number min–max | Interval between application (min) | g a.s./hl min–max | Water L/ha min–max | g a.s./ha min–max |          | |
| Pine nut kernels      | PT                      | F    |                                   | SC          | 240 g/L    | Foliar treatment – spraying    | 1          | 14      | –       | –       | 96 56         | Different GAP authorised in ES: 2 × 213.5 g a.s./ha, application in September/October |
| Walnuts               | ES, FR                  | F    | C. pomonella                      | SC          | 240 g/L    | Foliar treatment – spraying    | 3          | 14      | –       | –       | 144 30      |
| Apples                | EL                      | F    | C. pomonella, Phyllonorycter spp. | SC          | 240 g/L    | Foliar treatment – spraying    | 81         | 1–4     | 14      | –       | 216 14      |
| Pears                 | EL                      | F    | C. pomonella, Phyllonorycter spp. | SC          | 240 g/L    | Foliar treatment – spraying    | 81         | 1–4     | 14      | –       | 216 14      |
| Quinces               | FR                      | F    | Codling moth, T. (Capua and/or Pandemis, Podana, Eulia) | SC          | 240 g/L    | Foliar treatment – spraying    | 3          | –       | –       | –       | 168 21      |
| Medlars               | FR                      | F    | Codling moth, T. (Capua and/or Pandemis, Podana, Eulia) | SC          | 240 g/L    | Foliar treatment – spraying    | 3          | –       | –       | –       | 168 21      |
| Loquats               | FR                      | F    | Codling moth, T. (Capua and/or Pandemis, Podana, Eulia) | SC          | 240 g/L    | Foliar treatment – spraying    | 3          | –       | –       | –       | 168 21      |
| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Table grapes          | FR                      | F                                 | SC 240 g/L  | Foliar treatment – spraying  | g a.s./hL min–max  | Water L/ha min–max  | g a.s./ha min–max |
|                       |                         |                                   |             |            | 3                             | –          | 144     | 21      |
|                       |                         |                                   |             |            |                               | –          |         |         |
| Wine grapes           | FR                      | F                                 | SC 240 g/L  | Foliar treatment – spraying  | g a.s./hL min–max  | Water L/ha min–max  | g a.s./ha min–max |
|                       |                         |                                   |             |            | 3                             | –          | 144     | 21      |
|                       |                         |                                   |             |            |                               | –          |         |         |
| Tomatoes              | ES                      | F                                 | SC 240 g/L  | Foliar treatment – spraying  | 51–89          | 3        | 180     | 3       |
| Sweet peppers         | ES                      | F                                 | SC 240 g/L  | Foliar treatment – spraying  | 3              | 7        | 180     | 3       |
| Aubergines            | ES                      | F                                 | SC 240 g/L  | Foliar treatment – spraying  | 51–89          | 3        | 180     | 3       |
| Courgettes            | ES                      | F                                 | SC 240 g/L  | Foliar treatment – spraying  | 51–89          | 3        | 180     | 3       |
| Lettuces              | ES                      | F                                 | SC 240 g/L  | Foliar treatment – spraying  | 12–89          | 3        | 180     | 14      |
| Crop and/or situation | NEU/SEU/MS or country | F G or I(a) | Pests or Group of pests controlled | Preparation | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./ha min-max | Water L/ha min-max | g a.s./ha min-max | PHI (days) (d) | PHRemarks |
|----------------------|-----------------------|------------|----------------------------------|-------------|---------|---------|-----------|----------------------------------|----------------|--------------------------|----------------|----------------|----------------|------------|-----------|
| Escaroles            | ES        | F        | Spodoptera                       | SC          | 240 g/L | Foliar treatment – spraying | 12–89      | 3            | 7      | –          | –                | 180       | 14       |                   |            |           |
| Rice                 | ES, FR    | F        | Chilo suppressalis               | SC          | 247 g/L | Foliar treatment – spraying | -          | 3            | –      | –          | 148              | 21        |          |                   |            |           |
| Tomatoes             | EL        | I        | Spodoptera spp.                  | SC          | 240 g/L | Foliar treatment – spraying | 1–3        | 7           | –      | –          | 288              | 3         |          |                   |            |           |
| Sweet peppers        | EL        | I        | Spodoptera spp.                  | SC          | 240 g/L | Foliar treatment – spraying | 1–3        | 7           | –      | –          | 288              | 3         |          |                   |            |           |
| Aubergines           | BE        | I        | SC                              | 240 g/L     | Foliar treatment – spraying | 1–2        | 7           | –      | –          | 300              | 3         |          |                   |            |           |

NEU: northern European Union; SEU: southern European Union; MS: Member State.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no. 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(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) |
|-----------------------------------|-------------|---------|----------------|----------------|
| Fruits                            | Apples      | Foliar, 2 x 1.1 kg a.s./ha with 35 days between applications | Leaves and fruits: 0, 29, 68; |
|                                   | Grapes      | Foliar, 1 x 1.2 kg a.s./ha | Fruits: 0, 15, 31 |
| Root/tuber crops                  | Sugar beet  | Foliar: 1 x 2.24 kg a.s./ha | Roots: 0, 30, 61, 120 |
| Cereals                           | Rice        | Foliar: 1 x 1.2 kg a.s./ha | Tops: 0, 30, 61, 120 |
| Sources: Germany (2009, 2013)     |             |         |                |                |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|-------------------------------------|-------------|---------|----------------|-----------|
| Root/tuber crops                    | Turnips     | Bare soil, 4 x 280 g a.s./ha | 30, 90, 250, 365 |
| Leafy crops                         | Kale (collard) | Bare soil, 4 x 280 g a.s./ha | 30, 90, 250, 384 |
| Cereal (small grain)                | Wheat       | Bare soil, 4 x 280 g a.s./ha | 30, 90, 250, 365 |
| Source: Germany (2013)              |             |         |                |           |

| 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: EFSA (2010b), Germany (2013)    |             |               |

Can a general residue definition be proposed for primary crops? Yes

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) Tebufenozide

Plant residue definition for risk assessment (RD-RA) Sum of tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, expressed as tebufenozide

Conversion factor (monitoring to risk assessment) Leafy crops: 1.4 (tentative)
Cereals: 2 (tentative)
Fruits, roots: 1

[Conversion factors are derived from the metabolism study]
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

| LC-MS/MS (EURL, 2017): |
|--------------------------|
| • Validated in high water and high acid-content commodities using QuEChERS method, LOQ 0.005 mg/kg |
| • Validated in dry commodities using QuEChERS method, LOQ 0.01 mg/kg |
| • Validated in high oil-content commodities using QuOil method, LOQ 0.01 mg/kg |

| HPLC-MS (EFSA, 2010b): |
|------------------------|
| • Validated in high water and high acid-content commodities |
| • LOQ: 0.02 mg/kg |

| LC-MS/MS (France, 2017): |
|--------------------------|
| • Validated in high water, high acid, high oil and dry content commodities |
| • Extraction efficiency not demonstrated |
| • LOQ: 0.01 mg/kg |

| Plant products (available studies) | Category | Commodity | T (°C) | Stability(a) (months/years) |
|----------------------------------|----------|-----------|--------|-----------------------------|
| High water content | Lettuce | –18 | 36 months |
| High oil content | Walnuts | –18 | 42 months |
| Dry/high starch | Wheat (grain) | –18 | 54 months |
| High acid content | Grapes | –18 | 32 months |

(a) Stability demonstrated for parent compound only.

Source: Germany (2013).

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

B.1.1.2. Stability of residues in plants
## B.1.2. Magnitude of residues in plants

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

| 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_Mo (mg/kg)(b) | STMR_Mo (mg/kg)(c) | CF(d) |
|-----------------------|-------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|-----------------|------------------|-------|
| Grapefruits Oranges   | SEU               | [Mo (non-scaled): 0.21; 0.25; 0.36; 0.38; 0.39; 0.43; 0.48; 0.56; 0.60; 0.78] Mo (scaled): 0.08; 0.011; 0.15; 0.18; 0.20; 0.20; 0.22; 0.23; 0.26; 0.28 RA: – | Results from residue trials on oranges scaled using the proportionality approach to the last application rate in each trial (Italy, 2017). Results analysed for tebufenozide only. MRL_{OECD} = 0.54 | 0.6 | 0.28 | 0.20 | 1.0 |
| Lemons Limes          | SEU               | [Mo (non-scaled): 0.30; 0.30; 0.42; 0.59; 0.48; 0.360; 0.60; 0.84; 0.95] Mo (scaled): 0.11; 0.17; 0.21; 0.22; 0.23; 0.27; 0.27; 0.36; 0.47 RA: – | Trials performed on mandarins scaled using the proportionality approach to the last application rate in each trial (Italy, 2017). Results analysed for tebufenozide only. MRL_{OECD} = 0.77 | 0.8 | 0.47 | 0.23 | 1.0 |
| Mandarins             | SEU               | [Mo (non-scaled): 0.30; 0.30; 0.42; 0.59; 0.48; 0.360; 0.60; 0.84; 0.95] Mo (scaled): 0.21; 0.23; 0.39; 0.42; 0.43; 0.51; 0.51; 0.67; 0.87 RA: – | Trials performed on mandarins scaled using the proportionality approach to the last application rate in each trial (Greece, 2017). Results analysed for tebufenozide only. MRL_{OECD} = 1.41 | 1.5 | 0.87 | 0.43 | 1.0 |
| Chestnuts Walnuts     | SEU               | Mo: $2 \times < 0.01$ RA: – | Trials with five applications instead of three deemed acceptable (Germany, 2013; France, 2017). Extrapolation to chestnuts is applicable. Results expressed as tebufenozide only | 0.01* | < 0.01 | < 0.01 | 1.0 |
| Hazelnuts/ cobnuts    | SEU               | – | No data available | – | – | – | – |
| Pine nut kernels      | SEU               | – | No data available | – | – | – | – |
### Review of the existing MRLs for tebufenozide

| Crop                  | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR<sub>Mo</sub> (mg/kg)<sup>(b)</sup> | STMR<sub>Mo</sub> (mg/kg)<sup>(c)</sup> | CF<sup>(d)</sup> |
|-----------------------|-----------------------------|--------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|--------------------------------------|--------------------------------------|----------------|
| Apples                | NEU                         | **Mo**: 0.02; 0.07; 0.11; 0.11; 0.15; 0.16; 0.22; 0.23; 0.24; 0.35 <br> **RA**: – | Combined data set of trials on apples and pears compliant with GAP (Germany, 2005, 2013). Extrapolation to quinces, medlars and loquats is applicable. Residues analysed for tebufenozide only. MRL<sub>OECD</sub> = 0.55 | 0.6 | 0.35 | 0.16 | 1.0 |
| Pears                 |                             | **Mo**: 0.02; 0.07; 0.11; 0.11; 0.15; 0.16; 0.22; 0.23; 0.24; 0.35 <br> **RA**: – | Results from residue trials on apples scaled using the proportionality approach (Italy, 2017). Extrapolation to pears is applicable. Results analysed for tebufenozide only. MRL<sub>OECD</sub> = 0.92 | 1 | 0.54 | 0.25 | 1.0 |
| Quinces               | NEU                         | **Mo**: 0.02; 0.07; 0.11; 0.11; 0.15; 0.16; 0.22; 0.23; 0.24; 0.35 <br> **RA**: – | Combined data set of trials on apples and pears compliant with GAP (Germany, 2005, 2013). Extrapolation to quinces, medlars and loquats is applicable. Residues analysed for tebufenozide only. MRL<sub>OECD</sub> = 0.55 | 0.6 | 0.35 | 0.16 | 1.0 |
| Medlars               |                             | **Mo**: 0.09; 0.15; 0.20; 0.21; 0.23; 0.28; 0.33; 0.34 <br> **RA**: – | Results from residue trials on apples (3 × 200–250 g a.s./ha and PHI 14 days) (France, 2017) are extrapolated on a tentative basis to quinces, medlars and loquats. Results analysed for tebufenozide only. MRL<sub>OECD</sub> = 0.69 | 0.7<sup>(e)</sup> (tentative) | 0.34 | 0.22 | 1.0 |
| Loquats               |                             | **Mo**: 0.09; 0.15; 0.20; 0.21; 0.23; 0.28; 0.33; 0.34 <br> **RA**: – | Results from residue trials on apples (3 × 200–250 g a.s./ha and PHI 14 days) (France, 2017) are extrapolated on a tentative basis to quinces, medlars and loquats. Results analysed for tebufenozide only. MRL<sub>OECD</sub> = 0.69 | 0.7<sup>(e)</sup> (tentative) | 0.34 | 0.22 | 1.0 |
| Cherries (sweet)      | NEU                         | **Mo (non-scaled)**: 0.010; 0.014; 0.022 <br> **Mo (scaled)**: 0.03; 0.04; 0.07 <br> **RA**: – | Results from residue trials on cherries scaled using the proportionality approach (Germany, 2013). Results analysed for tebufenozide only. Number of data not sufficient to derive MRL and risk assessment values | – | – | – | – |
| Plums                 | NEU                         | – | No data available | – | – | – | – |
| Crop                  | Region/ indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR_{Mo} (mg/kg)(b) | STMR_{Mo} (mg/kg)(c) | CF(d) |
|-----------------------|-------------------|--------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|-------------------|---------------------|-------|
| Table grapes          | NEU               | Mo: 0.25; 0.29; 0.41; 0.45; 0.55; 0.93; 0.99; 0.99                                                                                     | Trials with three applications instead of two deemed acceptable (Germany, 2017). Extrapolation to wine grapes is applicable. Results analysed for tebufenozide only. MRL_{OECD} = 1.87 | 2                     | 0.99              | 0.50                | 1.0   |
| Wine grapes           | SEU               | Mo: 0.18; 0.28; 0.40; 0.51; 1.1; 1.3; 2.0                                                                                                   | Trials compliant with GAP (France, 2017). Extrapolation to wine grapes is applicable. Results analysed for tebufenozide only. MRL_{OECD} = 3.5 | 4                     | 2.00              | 0.51                | 1.0   |
| Strawberries          | NEU               | –                                                                                                                                             | Application done prior to planting, residue trials are needed to confirm a no-residue situation | –                     | –                 | –                   | –     |
| Tomatoes              | SEU               | –                                                                                                                                             | No data available                                                                          | –                     | –                 | –                   | –     |
| Aubergines/ eggplants| Indoor            | [Mo (non-scaled): 0.06, 0.11, 0.14; 0.19; 0.21; 0.28; 0.32; 0.62] Mo (scaled): 0.10; 0.18; 0.22; 0.30; 0.34; 0.45; 0.51; 0.99 | Results from residue trials on tomatoes scaled using the proportionality approach (Greece, 2017). Extrapolation to aubergines is applicable. Results analysed for tebufenozide only. MRL_{OECD} = 1.49 | 1.5                   | 0.99              | 0.32                | 1.0   |
| Sweet peppers/ bell peppers | SEU            | Mo: 0.193; 0.215                                                                                                                              | Trials compliant with GAP (Germany, 2017). Results analysed for tebufenozide only        | –                     | –                 | –                   | –     |
|                       | EU                | [Mo (non-scaled): 0.12; 0.14; 0.16; 0.22; 0.32; 0.34; 0.49; 0.51; 0.53] Mo (scaled): 0.20; 0.23; 0.27; 0.35; 0.53; 0.54; 0.72; 0.80; 0.83 | Results from residue trials on peppers scaled using the proportionality approach (Greece, 2017). Results analysed for tebufenozide only. MRL_{OECD} = 1.49 | 1.5                   | 0.83              | 0.53                | 1.0   |
### Review of the existing MRLs for tebufenozide

| 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\(_{Mo}\) (mg/kg)\(^{(b)}\) | STMR\(_{Mo}\) (mg/kg)\(^{(c)}\) | CF\(^{(d)}\) |
|-----------------------------------|---------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|----------------------------|-------------------------------|--------|
| Courgettes                        | SEU                       | No data available                                                                                |                                             |                       | 2\(^{(e)}\) (tentative)    | 0.83                           | 0.30              | 1.4 (tentative)                |
| Lettuces Escaroles/ broadleaved endives | SEU                       | **Mo** (Head lettuce): 0.06; 0.34; 0.67; 0.83                                                   | Trials performed on lettuce compliant with GAP (Germany, 2013). Extrapolation to escaroles is tentative. Residues expressed as tebufenozide only. Tentative conversion factor (1.4) from metabolism study on sugar beet tops is used for the risk assessment. MRL\(_{OECD} = 1.6\) |                       | 0.83                       | 0.30                           | 1.4 (tentative)                |
|                                   |                           | **Mo** (Open leaf): < 0.02; 0.06; 0.25; 0.59                                                     |                                             |                       |                           |                               |        |
|                                   |                           | **RA** (Head lettuce): –                                                                         |                                             |                       |                           |                               |        |
|                                   |                           | **RA** (Open leaf): –                                                                           |                                             |                       |                           |                               |        |
| Rice grains                       | SEU                       | **Mo**: 0.044; 0.15; 0.50; 0.99; 1.1; 1.2; 1.4; 1.5                                              | Trials compliant with GAP (EFSA, 2010a). Results expressed as tebufenozide only. Tentative conversion factor (2.0) derived from metabolism study in rice is used for the risk assessment. MRL\(_{OECD} = 3.1\) |                       | 1.50                       | 1.05                           | 2.0 (tentative)                |
|                                   |                           | **RA**: –                                                                                       |                                             |                       |                           |                               |        |
| Rice straw                        | SEU                       | **Mo**: 0.45; 0.67                                                                                | Trials compliant with GAP (Germany, 2009). Results expressed as tebufenozide only. Tentative conversion factor (2.0) derived from metabolism study in rice is used in the risk assessment |                       |                           |                               |        |
|                                   |                           | **RA**: –                                                                                       |                                             |                       |                           |                               |        |

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

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

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

(b): Highest residue according to the residue definition for monitoring.

(c): Supervised trials median residue according to the residue definition for monitoring.

(d): Conversion factor for risk assessment calculated on a tentative basis from the metabolism studies.

(e): MRL proposal is tentative because (additional) residue trials are required.
B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect) Residues of tebufenozide were higher than 0.01 mg/kg in cereals and turnip tops until 365/384 DAT. In turnip root, residues were below 0.01 mg/kg from 90 DAT onwards and in kale/collards 365 DAT.

Field rotational crop study Residues of tebufenozide were below 0.01 mg/kg 30 DAT in all crops. Metabolite RH-1788, which toxicity can be considered covered by the toxicological reference values of the parent compound, was the only component detected at levels higher than 0.01 mg/kg and only in wheat hay, wheat straw and soya bean forage 30 DAT.

B.1.2.3. Processing factors

| Processed commodity | Number of studies(a) | Processing factor (PF) | Median PF |
|---------------------|----------------------|------------------------|-----------|
|                     | Individual values    |                        |           |
| Robust processing factors (sufficiently supported by data) |
| Citrus/peel         | 17                   | 1.6, 2.4, 2.7, 2.7, 3.0, 3.0, 3.1, 3.2, 3.4, 3.5, 3.6, 3.7, 3.8, 4.0 | 3.2       |
| Citrus/peeled       | 17                   | 0.05, 0.10, 0.11, 0.11, 0.12, 0.14, 0.14, 0.15, 0.18, 0.19, 0.19, 0.20, 0.23, 0.23, 0.30, 0.30, 0.50 | 0.18      |
| Apple/washed        | 5                    | 0.55, 0.63, 0.8, 0.8, 0.8 | 0.8       |
| Apple/juice (unpasteurised) | 6          | 0.05, < 0.09, 0.13, 0.14, 0.15, 0.95 | 0.14      |
| Apple/puree         | 6                    | < 0.18, 0.2, 0.25, < 0.29 | 0.23      |
| Apple/wet pomace    | 6                    | 1.2, 1.4, 1.4, 1.5, 1.7, 4.4 | 1.45      |
| Grape/must          | 7                    | 0.08, 0.11, 0.5, 1.1, 12, 1.25, 1.4 | 1.1       |
| Grape/must without skins | 4                   | 0.11, 0.27, 0.29, 0.3 | 0.28      |
| Grape/pomace        | 3                    | 2.3, 2.8, 3.7 | 2.8       |
| Grape/wine          | 11                   | 0.07, 0.2, 0.2, 0.33, 0.33, 0.36, 0.38, 0.39, 0.43, 0.44, 0.65 | 0.36      |
| Rice/husked grain   | 11                   | 0.03, 0.05, 0.05, 0.06, 0.06, 0.07, 0.07, 0.10, 0.11, 0.22, 0.34 | 0.07      |
| Rice/polished grain | 11                   | < 0.01, 0.01, 0.01, 0.01, 0.01, < 0.02, 0.02, 0.06, 0.011, 0.012, 0.3 | 0.02      |
| Tomato/washed fruit | 4                    | 0.26, 0.36, 0.39, 0.44 | 0.38      |
| Tomato/juice (sterilised) | 3                   | 0.12, 0.17, 0.22 | 0.17      |
| Tomato/wet pomace   | 3                    | 1.07, 1.24, 1.39 | 1.24      |
| Tomato/fruit (preserved) | 3                   | 0.20, 0.30, 0.33 | 0.30      |
| Tomato/paste        | 3                    | 0.60, 0.72, 0.75, 0.83 | 0.74      |

Limited processing factors (not sufficiently supported by data)

| Processed commodity | Individual values | Median PF |
|---------------------|-------------------|-----------|
| Citrus/washed fruit | 2, 0.14, 0.26     | 0.20      |
| Citrus/dried pulp   | 2, < 0.10, < 0.23 | < 0.17(b) |
| Citrus/juice        | 2, 0.79, 0.82     | 0.81      |
| Citrus/cold pressed oil | 2              | 26        |
| Apples/juice (pasteurised) | 1        | 0.05      |
| Apples/peel and core | 2, 2.7, 3.9       | 3.3       |
| Tomato/puree        | 1, 0.31          | 0.31      |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): For citrus (dried pulp), residues were below the limit of quantification (LOQ = 0.02).
B.2. Residues in livestock

| Relevant groups | Dietary burden expressed in mg/kg bw per day | Most critical commodity(a) | Trigger exceeded (Y/N) |
|-----------------|---------------------------------------------|----------------------------|------------------------|
|                 | Med. | Max. | Med. | Max. |                        |                         |                        |
| Cattle (all diets) | 0.179 | 0.179 | 4.64 | 4.64 | Cattle (dairy) | Rice, bran/pollard | Yes |
| Cattle (dairy only) | 0.179 | 0.179 | 4.64 | 4.64 | Cattle (dairy) | Rice, bran/pollard | Yes |
| Sheep (all diets) | 0.296 | 0.296 | 6.97 | 6.97 | Sheep (lamb) | Rice, bran/pollard | Yes |
| Sheep (ewe only) | 0.236 | 0.237 | 7.09 | 7.12 | Sheep (ram/ewe) | Rice, bran/pollard | Yes |
| Swine (all diets) | 0.054 | 0.054 | 2.32 | 2.32 | Swine (breeding) | Rice, bran/pollard | Yes |
| Poultry (all diets) | 0.164 | 0.164 | 2.32 | 2.32 | Poultry (broiler) | Rice, bran/pollard | Yes |
| Poultry (layer only) | 0.079 | 0.079 | 1.16 | 1.16 | Poultry (layer) | Rice, bran/pollard | Yes |

(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 |
|-------------------------------|--------|-------------------------|-----------------|----------------|
| Laying hen                    | 1.9    | 7                       | 24 N            |
| Lactating goat                | 10     | 7                       | 42 N            |

Source: Germany, 2005
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

| Method            | Year/Location | Analytes Detected                | LOQ (mg/kg) | ILV Available |
|-------------------|---------------|----------------------------------|-------------|---------------|
| RP-HPLC-UV        | Germany 2005  | Milk, meat, fat, kidney, liver   | 0.02        |               |
|                   |               | LOQ of 0.02 mg/kg                |             | ILV available |
| LC-MS/MS (France, 2017) |   | Milk, fat, muscle meat, egg and liver | 0.01        |               |
|                   |               | Extraction efficiency of the method not demonstrated but required |             |               |
| LC-MS/MS (EURL, 2017) |   | Screening data indicate that tebufenozide can be enforced in commodities of animal origin with an LOQ of 0.005 mg/kg in meat, eggs and honey and an LOQ of 0.0025 mg/kg for milk |             |               |
|                   |               | No quantitative validation data available |             |               |

B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (a) (months) |
|-------------------------------------|--------|-----------|--------|------------------------|
|                                     | Beef   | Muscle    | –18    | 8                      |
|                                     | Beef   | Liver     | –18    | 23                     |
|                                     | Beef   | Fat       | –18    | 4                      |
|                                     | Dairy  | Milk      | –18    | 6                      |
|                                     | Hen    | Egg       | –18    | 6                      |

(a) Stability demonstrated for parent compound.

Source: EFSA (2010b)

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) | CF(c) |
|------------------|-----------------------------------------------|-------------------------------------------|-------|
|                  | Mean | Highest | STMR(a) (mg/kg) | HR(b) (mg/kg) |                                 |     |
| Cattle (all diets) |      |         |                  |               |                                 |     |
| Closest feeding level (0.22 mg/kg bw/d; 1.2 N rate) |      |         |                  |               |                                 |     |
| Muscle           | < 0.02 | < 0.2   | < 0.02           | < 0.02        | 0.02*(g) (tentative)             | 2    |
| Fat              | 0.02   | 0.03    | 0.02             | 0.025         | 0.03*(g) (tentative)             | 2    |
| Liver            | < 0.05 | < 0.05  | < 0.05           | < 0.05        | 0.05*(g) (tentative)             | 2    |
| Kidney           | < 0.02 | < 0.02  | < 0.02           | < 0.02        | 0.02*(g) (tentative)             | 4    |
| Animal commodity                      | Residues at the closest feeding level (mg/kg) | Estimated value at 1N (mg/kg) | MRL proposal (mg/kg) | CF<sup>(c)</sup> |
|--------------------------------------|-----------------------------------------------|-------------------------------|---------------------|------------------|
|                                      | Mean                           | Highest                      | STMR<sup>(a)</sup> | HR<sup>(b)</sup> |
|                                      |                               |                               |                     |                  |
| Cattle (dairy only)                  |                               |                               |                     |                  |
| Closest feeding level (0.22 mg/kg bw/d; 1.2 N rate)<sup>(d)</sup> |                               |                               |                     |                  |
| Milk<sup>(e)</sup>                   | 0.007                          | 0.007                         | 0.01*               | 0.01*            | 0.01*<sup>(g)</sup> (tentative) | 2 |
| Sheep (all diets)<sup>(f)</sup>      |                               |                               |                     |                  |
| (0. 65 mg/kg bw/d; 2.2 N rate)<sup>(g)</sup> |                               |                               |                     |                  |
| Muscle                              | < 0.02                         | 0.022                         | < 0.02              | < 0.02           | 0.02*<sup>(g)</sup> (tentative) | 2 |
| Fat                                 | 0.06                           | 0.11                          | 0.03                | 0.05             | 0.05<sup>(g)</sup> (tentative) | 2 |
| Liver                               | < 0.05                         | < 0.05                        | < 0.05              | < 0.05           | 0.05<sup>(g)</sup> (tentative) | 2 |
| Kidney                              | < 0.02                         | < 0.02                        | < 0.02              | < 0.02           | 0.02*<sup>(g)</sup> (tentative) | 4 |
| Sheep (dairy only)<sup>(f)</sup>     |                               |                               |                     |                  |
| (0.65 mg/kg bw/d; 2.8 N rate)<sup>(g)</sup> |                               |                               |                     |                  |
| Milk<sup>(e)</sup>                   | < 0.01                         | < 0.01                        | < 0.01              | < 0.01           | 0.01*<sup>(g)</sup> (tentative) | 2 |
| Swine<sup>(f)</sup>                  |                               |                               |                     |                  |
| (0.22 mg/kg bw/d; 4.4 N rate)<sup>(g)</sup> |                               |                               |                     |                  |
| Muscle                              | < 0.02                         | < 0.02                        | < 0.02              | < 0.02           | 0.02*<sup>(g)</sup> (tentative) | 2 |
| Fat                                 | 0.02                           | 0.03                          | < 0.02              | < 0.02           | 0.02*<sup>(g)</sup> (tentative) | 2 |
| Liver                               | < 0.05                         | < 0.05                        | < 0.05              | < 0.05           | 0.05<sup>(g)</sup> (tentative) | 2 |
| Kidney                              | < 0.02                         | < 0.02                        | < 0.02              | < 0.02           | 0.02*<sup>(g)</sup> (tentative) | 4 |
| Poultry (all diets)                 |                               |                               |                     |                  |
| Muscle                              | –                              | –                             | < 0.02              | < 0.02           | 0.02*<sup>(g)</sup> (tentative) | 2 |
| Fat                                 | –                              | –                             | < 0.02              | < 0.02           | 0.02*<sup>(g)</sup> (tentative) | 2 |
| Liver                               | –                              | –                             | < 0.02              | < 0.02           | 0.02*<sup>(g)</sup> (tentative) | 2 |
| Poultry (layer only)                |                               |                               |                     |                  |
| Egg                                 | –                              | –                             | < 0.02              | < 0.02           | 0.02*<sup>(g)</sup> (tentative) | 2 |

n.a.: not applicable; n.r.: not reported.

*: 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 was 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): Conversion factors derived from the metabolism study performed on lactating goats and laying hens.

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

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

(f): 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.

(g): MRL proposal is tentative because confirmatory analytical methods are not available and conversion factors were derived from metabolism studies.
B.3. Consumer risk assessment

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

| ADI | 0.02 mg/kg bw per day (EFSA, 2010b) |
| --- | ---------------------------------- |
| Highest IEDI, according to EFSA PRIMo | 29.6% ADI (DE, children) |

**Assumptions made for the calculations**
The calculation is based on the median residue levels in the raw agricultural commodities, except for citrus fruits, where the relevant peeling factor was applied.
For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation.
The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation.

**ArfD** Not necessary (EFSA, 2010a,b)

B.3.2. Consumer risk assessment with consideration of the existing CXLs

| ADI | 0.02 mg/kg bw per day (EFSA, 2010a,b) |
| --- | ---------------------------------- |
| Highest IEDI, according to EFSA PRIMo | 39.6% ADI (DE, children) |

**Assumptions made for the calculations**
For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR.
The conversion factors from enforcement to risk assessment (CF) from JMPR (0.16) for citrus fruits were applied. For rape seed, the worst case CF of 2 was considered as the most appropriate surrogate for oilseeds.
For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation.
The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation.

**ArfD** Not necessary (EFSA, 2010a,b)
### B.4. Proposed MRLs

| Code number | Commodity          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | MRL (mg/kg) | Comment                        |
|-------------|--------------------|-------------------------|----------------------|-----------------------|-------------|---------------------------------|
| 110010      | Grapefruits        | 2                       | 2                    | 2                     | Recommended (a) |
| 110020      | Oranges            | 2                       | 2                    | 2                     | Recommended (a) |
| 110030      | Lemons             | 2                       | 2                    | 2                     | Recommended (a) |
| 110040      | Limes              | 2                       | 2                    | 2                     | Recommended (a) |
| 110050      | Mandarins          | 2                       | 2                    | 2                     | Recommended (a) |
| 120010      | Almonds            | 0.05*                   | 0.05                 | 0.05                  | Recommended (b) |
| 120040      | Chestnuts          | 0.05*                   | –                    | 0.01*                 | Recommended (c) |
| 120060      | Hazelnuts/cobnuts  | 0.05*                   | –                    | 0.05                  | Further consideration needed (d) |
| 120080      | Pecans             | 0.05*                   | 0.01*                | 0.01*                 | Further consideration needed (e) |
| 120090      | Pine nut kernels   | 0.05*                   | –                    | 0.05                  | Further consideration needed (e) |
| 120110      | Walnuts            | 0.05*                   | 0.05                 | 0.05                  | Recommended (b) |
| 130010      | Apples             | 1                       | 1                    | 1                     | Recommended (b) |
| 130020      | Pears              | 1                       | 1                    | 1                     | Recommended (b) |
| 130030      | Quinces            | 1                       | 1                    | 1                     | Recommended (b) |
| 130040      | Medlars            | 1                       | 1                    | 1                     | Recommended (b) |
| 130050      | Loquats/Japanese medlars | 1               | 1                    | 1                     | Recommended (b) |
| 140020      | Cherries (sweet)   | 1                       | –                    | 1                     | Further consideration needed (d) |
| 140030      | Peaches            | 0.5                     | 0.5                  | 0.5                   | Recommended (b) |
| 140400      | Plums              | 1                       | –                    | 1                     | Further consideration needed (e) |
| 151010      | Table grapes       | 3                       | 2                    | 4                     | Recommended (b) |
| 151020      | Wine grapes        | 3                       | 2                    | 4                     | Recommended (b) |
| 152000      | Strawberries       | 0.05*                   | –                    | 0.05                  | Further consideration needed (c) |
| 153030      | Raspberries        | 2                       | 2                    | 2                     | Recommended (b) |
| 154010      | Blueberries        | 3                       | 3                    | 3                     | Recommended (b) |
| 154020      | Cranberries        | 0.5                     | 0.5                  | 0.5                   | Recommended (b) |
| 161040      | Kumpuats           | 0.05*                   | 2                    | 2                     | Recommended (b) |
| 162010      | Kiwi               | 0.5                     | 0.5                  | 0.5                   | Recommended (b) |
| 163010      | Avocados           | 1                       | 1                    | 1                     | Recommended (b) |
| 231010      | Tomatoes           | 1                       | 1                    | 1.5                   | Recommended (d) |
| 231020      | Sweet peppers/bell peppers | 1        | 1                    | 1.5                   | Recommended (d) |
| 231030      | Aubergines/eggplants | 0.5               | –                    | 1.5                   | Recommended (d) |
| 232030      | Courgettes         | 0.1                     | –                    | 0.1                   | Further consideration needed (d) |
| 241010      | Broccoli           | 0.5                     | 0.5                  | 0.5                   | Further consideration needed (d) |
| 242010      | Head cabbage       | 5                       | 5                    | 5                     | Further consideration needed (d) |
| 243010      | Chinese cabbage    | 0.5                     | 10                   | 10                    | Further consideration needed (d) |
| 243020      | Kale               | 0.5                     | 10                   | 10                    | Further consideration needed (d) |
| 251010      | Lamb's lettuce     | 10                      | 10                   | 10                    | Further consideration needed (d) |
| 251020      | Lettuces           | 10                      | 10                   | 10                    | Further consideration needed (d) |
| 251030      | Escaroles/broadleaved endives | 10    | 10                   | 10                    | Further consideration needed (d) |
| 251040      | Cress              | 10                      | 10                   | 10                    | Further consideration needed (d) |
| 251050      | Land cress         | 10                      | 10                   | 10                    | Further consideration needed (d) |
| 251060      | Rocket, Rucola     | 10                      | 10                   | 10                    | Further consideration needed (d) |
| 251070      | Red mustard        | 10                      | 10                   | 10                    | Further consideration needed (d) |
| Code number | Commodity                          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|------------------------------------|-------------------------|----------------------|-----------------------|---------|
| 251080      | Leaves and sprouts of Brassica spp. | 10                      | 10                   | 10                    | Further consideration needed<sup>(a)</sup> |
| 252010      | Spinach                            | 10                      | 10                   | 10                    | Further consideration needed<sup>(a)</sup> |
| 252020      | Purslane                           | 10                      | 10                   | 10                    | Further consideration needed<sup>(a)</sup> |
| 252030      | Beet leaves (chard)                | 0.05*                   | 10                   | 10                    | Further consideration needed<sup>(a)</sup> |
| 253000      | Vine leaves (grape leaves)         | 0.05*                   | 10                   | 10                    | Further consideration needed<sup>(a)</sup> |
| 254000      | Water cress                         | 0.05*                   | 10                   | 10                    | Further consideration needed<sup>(a)</sup> |
| 256010      | Chervil                             | 0.05*                   | 10                   | 10                    | Further consideration needed<sup>(a)</sup> |
| 256080      | Basil                               | 20                      | 20                   | 20                    | Further consideration needed<sup>(a)</sup> |
| 401060      | Rape seed                           | 2                       | 2                    | 2                     | Further consideration needed<sup>(a)</sup> |
| 500060      | Rice grains                         | 3                       | 0.1                  | 3                     | Further consideration needed<sup>(a)</sup> |
| 900020      | Sugar cane                          | 1                       | 1                    | 1                     | Further consideration needed<sup>(a)</sup> |
| 1011010     | Swine muscle                        | 0.05*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1011020     | Swine fat tissue                    | 0.05*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1011030     | Swine liver                          | 0.05*                   | 0.02*                | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1011040     | Swine kidney                         | 0.05*                   | 0.02*                | 0.02*                 | Further consideration needed<sup>(a)</sup> |
| 1012010     | Bovine muscle                        | 0.05*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1012020     | Bovine fat tissue                    | 0.05*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1012030     | Bovine liver                         | 0.05*                   | 0.02*                | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1012040     | Bovine kidney                        | 0.05*                   | 0.02*                | 0.02*                 | Further consideration needed<sup>(a)</sup> |
| 1013010     | Sheep muscle                         | 0.05*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1013020     | Sheep fat tissue                     | 0.05*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1013030     | Sheep liver                          | 0.05*                   | 0.02*                | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1013040     | Sheep kidney                         | 0.05*                   | 0.02*                | 0.02*                 | Further consideration needed<sup>(a)</sup> |
| 1014010     | Goat muscle                          | 0.05*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1014020     | Goat fat tissue                      | 0.05*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1014030     | Goat liver                           | 0.05*                   | 0.02*                | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1014040     | Goat kidney                          | 0.05*                   | 0.02*                | 0.02*                 | Further consideration needed<sup>(a)</sup> |
| 1015010     | Equine muscle                        | 0.05*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1015020     | Equine fat tissue                    | 0.05*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1015030     | Equine liver                         | 0.05*                   | 0.02*                | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 1015040     | Equine kidney                        | 0.05*                   | 0.02*                | 0.02*                 | Further consideration needed<sup>(a)</sup> |
| 1016010     | Poultry muscle                       | 0.05*                   | 0.02*                | 0.02*                 | Further consideration needed<sup>(a)</sup> |
| 1016020     | Poultry fat tissue                   | 0.05*                   | –                   | 0.02*                 | Further consideration needed<sup>(a)</sup> |
| 1016030     | Poultry liver                        | 0.05*                   | –                   | 0.02*                 | Further consideration needed<sup>(a)</sup> |
| 1020010     | Cattle milk                          | 0.05*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1020020     | Sheep milk                           | 0.05*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1020030     | Goat milk                            | 0.05*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1020040     | Horse milk                           | 0.05*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1030000     | Birds eggs                           | 0.05*                   | 0.02*                | 0.02*                 | Further consideration needed<sup>(a)</sup> |
| –           | Other commodities of plant and/or animal origin | –                     | –                   | –                    | Further consideration needed<sup>(a)</sup> |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): Residue is fat soluble.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix E).
(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII 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. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered; existing CXL is covered by the recommended value (combination A-III in Appendix E).

(f): 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; existing CXL is covered by the recommended MRL (combination G-III in Appendix E).

(g): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix E).

(h): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).

(i): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix E).

(j): 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); existing CXL is covered by the tentative MRL (combination E-III in Appendix E).

(k): 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).

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

- PRIMo(EU)

### Tebufenozide

| Status of the active substance: | Code no: | LOQ (mg/kg bw): | Proposed LOQ: |
|--------------------------------|----------|-----------------|--------------|

| Toxicological end points | ADI (mg/kg bw per day): | ARfD (mg/kg bw): | Source of ADI: | Source of ARfD: | Year of evaluation: | Year of evaluation: |
|--------------------------|-------------------------|------------------|---------------|----------------|---------------------|---------------------|
|                          | 0.02                    | n.n.             | EFSA          | EFSA           | 2010                | 2010                |

| No of diets exceeding ADI: | No of highest calculated TMDI values in % of ADI: | MS Diet        | Commodity/ group of commodities |
|----------------------------|-----------------------------------------------|----------------|---------------------------------|
|                            | minimum – maximum                             |                |                                 |
|                            | 7 – 40                                        |                |                                 |

### Chronic risk assessment – refined calculations

| Highest calculated TMDI values in % of ADI | Highest contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | pTMRLs at LOQ (in % of ADI) |
|------------------------------------------|-----------------------------------------------|---------------------------------|------------------------------------------|---------------------------------|------------------------------------------|---------------------------------|--------------------------|
| 39.6 DE child                            | 15.1 Apples                                   |                                | 3.6 Spinach                              |                                | 3.2 Table grapes                       |                                |                          |
| 38.3 NL child                            | 7.9 Apples                                    |                                | 6.5 Spinach                              |                                | 3.7 Rice                               |                                |                          |
| 37.4 WHO Cluster diet B                  | 6.3 Lettuce                                   |                                | 5.5 Rice                                 |                                | 4.9 Tomatoes                           |                                |                          |
| 29.0 FR toddler                          | 12.4 Spinach                                  |                                | 4.0 Milk and cream                       |                                | 3.7 Rice                               |                                |                          |
| 24.7 WHO cluster diet E                  | 5.7 Rape seed                                 |                                | 4.1 Wine grapes                          |                                | 2.9 Herbs                              |                                |                          |
| 24.6 WHO cluster diet D                  | 5.8 Rice                                     |                                | 3.9 Herbs                               |                                | 3.2 Chinese cabbage                    |                                |                          |
| 23.6 IE adult                            | 3.5 Other leafy brassica                     |                                | 3.2 Wine grapes                          |                                | 2.6 Herbs                              |                                |                          |
| 23.1 ES child                            | 7.3 Lettuce                                   |                                | 5.0 Rice                                 |                                | 1.6 Tomatoes                           |                                |                          |
| 22.7 IT adult                            | 6.6 Lettuce                                   |                                | 2.8 Other lettuce and other salad plants|                                | 1.9 Rice                               |                                |                          |
| 21.3 ES adult                            | 9.4 Lettuce                                   |                                | 2.5 Rice                                 |                                | 1.4 Beet leaves (chard)                |                                |                          |
| 21.1 WHO regional European diet           | 6.6 Lettuce                                   |                                | 2.1 Herbs                               |                                | 2.1 Rice                               |                                |                          |
| 20.9 FR all population                   | 10.2 Wine grapes                             |                                | 3.3 Other lettuce and other salad plants|                                | 1.6 Lettuce                            |                                |                          |
| 20.1 PT General population               | 8.2 Rice                                      |                                | 6.3 Wine grapes                          |                                | 1.4 Tomatoes                           |                                |                          |
| 19.7 IT toddler                          | 5.1 Lettuce                                   |                                | 2.3 Tomatoes                            |                                | 2.0 Rice                               |                                |                          |
| 19.1 SE general population 90th percentile| 4.2 Rice                                      |                                | 3.5 Chinese cabbage                     |                                | 1.5 Head cabbage                       |                                |                          |
| 19.1 WHO Cluster diet F                  | 5.3 Lettuce                                   |                                | 3.9 Rape seed                           |                                | 2.2 Rice                               |                                |                          |
| 17.9 NL general                          | 2.5 Spinach                                   |                                | 2.1 Lettuce                              |                                | 2.0 Scarello (broad-leaf endive)       |                                |                          |
| 16.8 FR infant                           | 7.8 Spinach                                   |                                | 3.1 Apples                              |                                | 2.6 Milk and cream                     |                                |                          |
| 15.2 UK Infant                           | 6.6 Rice                                      |                                | 3.9 Milk and cream                       |                                | 2.0 Apples                             |                                |                          |
| 15.0 UK Toddler                          | 6.0 Rice                                      |                                | 2.1 Milk and cream                       |                                | 2.1 Apples                             |                                |                          |
| 13.3 UK vegetarian                       | 4.0 Rice                                      |                                | 2.5 Lettuce                              |                                | 2.1 Wine grapes                        |                                |                          |
| 11.8 DK child                            | 2.9 Apples                                    |                                | 2.5 Lettuce                              |                                | 1.3 Milk and cream                     |                                |                          |
| 11.7 UK Adult                            | 3.8 Rice                                      |                                | 2.8 Wine grapes                          |                                | 2.0 Lettuce                            |                                |                          |
| 9.1 PL general population                | 2.6 Apples                                    |                                | 1.4 Tomatoes                            |                                | 0.9 Head cabbage                       |                                |                          |
| 8.9 LT adult                             | 2.3 Rice                                      |                                | 2.2 Lettuce                              |                                | 1.1 Lettuce                            |                                |                          |
| 8.5 DK adult                             | 3.6 Wine grapes                              |                                | 1.0 Apples                              |                                | 0.9 Rice                               |                                |                          |
| 7.0 FI adult                             | 1.4 Lettuce                                   |                                | 1.1 Rice                                 |                                | 0.8 Wine grapes                        |                                |                          |

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

Acute risk assessment/adults/general population – refined calculations

Acute risk assessment is not necessary.

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 leads to an exposure equivalent to 100% of the ARfD.

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|
| Highest % of ARfD/ADI Commodity | pTMRL/Threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodity | pTMRL/Threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodity | pTMRL/Threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodity | pTMRL/Threshold MRL (mg/kg) |

No of critical MRLs (IESTI 1): ---

No of critical MRLs (IESTI 2): ---

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

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

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

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.

No of critical MRLs (IESTI 1): ---

No of critical MRLs (IESTI 2): ---

No of commodities for which ARfD/ADI is exceeded: ---

No of commodities for which ARfD/ADI is exceeded: ---

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

Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of tebufenozide residues is unlikely to present a public health concern.

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* 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.

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 for unprocessed commodity.

Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of tebufenozide residues is unlikely to present a public health concern.
## Tebufenozide

### Toxicological endpoints

| LOQ (mg/kg bw) | Proposed LOQ | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD | Year of evaluation | Year of evaluation |
|---------------|--------------|-----------------------|----------------|---------------|----------------|-------------------|-------------------|
| Code no.      | 0.02         | EFSA                  | n.n.           | EFSA          | EFSA          | 2010              | 2010              |

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI | No of diets exceeding ADI |
|--------------------------------|--------------------------|---------------------------|
| Rice                           | 2.9                      | 28                        |
| Milk and cream                 | 2.9                      | 29                        |
| Tomatoes                       | 1.4                      | 12                        |
| Wine grapes                    | 2.0                      | 39                        |
| Apples                         | 2.1                      | 21                        |
| Plums                          | 1.6                      | 18                        |
| Lettuce                        | 1.1                      | 22                        |
| Milk and cream                 | 1.0                      | 20                        |
| Tomatoes                       | 2.1                      | 21                        |
| Wine grapes                    | 0.8                      | 18                        |
| Rice                           | 0.9                      | 29                        |
| Apple                          | 1.1                      | 22                        |
| Milk and cream                 | 1.2                      | 23                        |
| Plums                          | 1.6                      | 18                        |
| Lettuce                        | 1.1                      | 22                        |

### Conclusion:

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

Acute risk assessment is not necessary.

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

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

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

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

### Table

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|-------------------------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------|
| IESTI 1: High % of ARfD/ADI Commodity pTMRL/Threshold MRL (mg/kg) | IESTI 2: High % of ARfD/ADI Commodity pTMRL/Threshold MRL (mg/kg) | IESTI 1: High % of ARfD/ADI Commodity pTMRL/Threshold MRL (mg/kg) | IESTI 2: High % of ARfD/ADI Commodity pTMRL/Threshold MRL (mg/kg) |
| No of critical MRLs IESTI 1 | No of critical MRLs IESTI 2 |

### Table

| No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|-------------------------------------------------------------|-------------------------------------------------------------|
| IESTI 1: High % of ARfD/ADI Processed commodity pTMRL/Threshold MRL (mg/kg) | IESTI 2: High % of ARfD/ADI Processed commodity pTMRL/Threshold MRL (mg/kg) |

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**Notes:**
- 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.

### Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of tebufenozide residues is unlikely to present a public health concern.

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Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.
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 tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, expressed as tebufenozide |
| Grapefruits, dried pulp | 0.03                  | STMR × PF (0.17)       | 0.03                  | STMR × PF (0.17)       |
| Oranges, dried pulp    | 0.03                  | STMR × PF (0.17)       | 0.03                  | STMR × PF (0.17)       |
| Lemons, dried pulp     | 0.04                  | STMR × PF (0.17)       | 0.04                  | STMR × PF (0.17)       |
| Limes, dried pulp      | 0.04                  | STMR × PF (0.17)       | 0.04                  | STMR × PF (0.17)       |
| Mandarins, dried pulp  | 0.10                  | STMR × PF (0.17)       | 0.10                  | STMR × PF (0.17)       |
| Apple, pomace, wet     | 0.36                  | STMR × PF (1.45)       | 0.36                  | STMR × PF (1.45)       |
| Rice, bran/pollard     | 20.90                 | STMR × default PF (10) × CF (2) | 20.90                 | STMR × default PF (10) × CF (2) |

STMR: supervised trials median residue; PF: processing factor; CF: conversion factor for enforcement residue definition to risk assessment residue definition

D.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity                  | Chronic risk assessment |
|----------------------------|-------------------------|
|                            | Input value (mg/kg)     | Comment                |
| Risk assessment residue definition – sum of tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, expressed as tebufenozide |
| Grapefruits                | 0.04                    | STMR × PF              |
| Oranges                    | 0.04                    | STMR × PF              |
| Lemons                     | 0.04                    | STMR × PF              |
| Limes                      | 0.04                    | STMR × PF              |
| Mandarins                  | 0.08                    | STMR × PF              |
| Chestnuts                  | 0.01*                   | STMR                   |
| Hazelnuts/cobnuts          | 0.05                    | EU MRL                 |
| Pine nut kernels           | 0.05                    | EU MRL                 |
| Walnuts                    | 0.01*                   | STMR                   |
| Apples                     | 0.25                    | STMR                   |
| Pears                      | 0.25                    | STMR                   |
| Quinces                    | 0.22                    | STMR (tentative)       |
| Medlars                    | 0.22                    | STMR (tentative)       |
| Loquats/Japanese medlars   | 0.22                    | STMR (tentative)       |
| Cherries (sweet)           | 1                       | EU MRL                 |
| Plums                      | 1                       | EU MRL                 |
| Table grapes               | 0.51                    | STMR                   |
| Wine grapes                | 0.51                    | STMR                   |
| Strawberries               | 0.05                    | EU MRL                 |
| Tomatoes                   | 0.32                    | STMR                   |
| Sweet peppers/bell peppers| 0.53                    | STMR                   |
| Aubergines/eggplants       | 0.32                    | STMR                   |
| Courgettes                 | 0.1                     | EU MRL                 |
| Lettuces                   | 0.41                    | STMR × CF (tentative)  |
| Escaroles/broadleaved endives | 0.41                  | STMR × CF (tentative)  |
| Commodity         | Input value (mg/kg) | Comment                                                                                                                                 |
|------------------|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| Rice grains      | 2.1                 | $\text{STMR}_{\text{mg}} \times \text{CF}$ (tentative)                                                                                  |
| Swine meat       | 0.04                | $0.8 \times \text{STMR muscle} \times \text{CF} + 0.2 \times \text{STMR fat} \times \text{CF}$ (tentative)                               |
| Swine fat tissue | 0.04                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Swine liver      | 0.10                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Swine kidney     | 0.08                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Bovine meat      | 0.04                | $0.8 \times \text{STMR muscle} \times \text{CF} + 0.2 \times \text{STMR fat} \times \text{CF}$ (tentative)                               |
| Bovine fat tissue| 0.04                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Bovine liver     | 0.10                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Bovine kidney    | 0.08                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Sheep meat       | 0.04                | $0.8 \times \text{STMR muscle} \times \text{CF} + 0.2 \times \text{STMR fat} \times \text{CF}$ (tentative)                               |
| Sheep fat tissue | 0.06                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Sheep liver      | 0.10                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Sheep kidney     | 0.08                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Goat meat        | 0.04                | $0.8 \times \text{STMR muscle} \times \text{CF} + 0.2 \times \text{STMR fat} \times \text{CF}$ (tentative)                               |
| Goat fat tissue  | 0.06                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Goat liver       | 0.10                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Goat kidney      | 0.08                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Equine meat      | 0.04                | $0.8 \times \text{STMR muscle} \times \text{CF} + 0.2 \times \text{STMR fat} \times \text{CF}$ (tentative)                               |
| Equine fat tissue| 0.04                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Equine liver     | 0.10                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Equine kidney    | 0.08                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                             |
| Poultry meat     | 0.04                | $0.9 \times \text{STMR muscle} \times \text{CF} + 0.1 \times \text{STMR fat} \times \text{CF}$ (tentative)                               |
| Poultry fat tissue| 0.04               | $\text{STMR} \times \text{CF}$ (tentative)                                                                                            |
| Poultry liver    | 0.04                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                            |
| Cattle milk      | 0.02                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                            |
| Sheep milk       | 0.02                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                            |
| Goat milk        | 0.02                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                            |
| Horse milk       | 0.02                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                            |
| Birds eggs       | 0.04                | $\text{STMR} \times \text{CF}$ (tentative)                                                                                            |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor, CF: conversion factor for enforcement residue definition to risk assessment residue definition.

*: Indicates that the input value is proposed at the limit of quantification.
D.3. Consumer risk assessment with consideration of the existing CXLs

| Commodity                        | Input value (mg/kg) | Chronic risk assessment                                      |
|----------------------------------|---------------------|--------------------------------------------------------------|
| **Risk assessment residue definition** | – sum of tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, expressed as tebufenozide |                                                              |
| Grapefruits                      | 0.08                | STMR (CXL) × PF (CXL)                                        |
| Oranges                          | 0.08                | STMR (CXL) × PF (CXL)                                        |
| Lemons                           | 0.08                | STMR (CXL) × PF (CXL)                                        |
| Limes                            | 0.08                | STMR (CXL) × PF (CXL)                                        |
| Mandarins                        | 0.08                | STMR (CXL) × PF (CXL)                                        |
| Almonds                          | 0.02                | STMR (CXL)                                                  |
| Chestnuts                        | 0.01*               | STMR                                                         |
| Hazelnuts/cobnuts                | 0.05                | EU MRL                                                      |
| Pecans                           | 0.01                | STMR (CXL)                                                  |
| Pine nut kernels                 | 0.05                | EU MRL                                                      |
| Walnuts                          | 0.01                | STMR (CXL)                                                  |
| Apples                           | 0.25                | STMR                                                         |
| Pears                            | 0.25                | STMR                                                         |
| Quinces                          | 0.17                | STMR (CXL)                                                  |
| Medlars                          | 0.17                | STMR (CXL)                                                  |
| Loquats/Japanese medlars         | 0.17                | STMR (CXL)                                                  |
| Cherries (sweet)                 | 1.0                 | EU MRL                                                      |
| Peaches                          | 0.12                | STMR (CXL)                                                  |
| Plums                            | 1.0                 | EU MRL                                                      |
| Table grapes                     | 0.51                | STMR                                                         |
| Wine grapes                      | 0.51                | STMR                                                         |
| Strawberries                     | 0.05                | EU MRL                                                      |
| Raspberries                      | 0.56                | STMR (CXL)                                                  |
| Blueberries                      | 0.69                | STMR (CXL)                                                  |
| Cranberries                      | 0.04                | STMR (CXL)                                                  |
| Kumquats                         | 0.48                | STMR (CXL)                                                  |
| Kiwi                             | 0.14                | STMR (CXL)                                                  |
| Avocados                         | 0.18                | STMR (CXL)                                                  |
| Tomatoes                         | 0.32                | STMR                                                         |
| Sweet peppers/bell peppers       | 0.53                | STMR                                                         |
| Aubergines/eggplants             | 0.32                | STMR                                                         |
| Courgettes                       | 0.10                | EU MRL                                                      |
| Broccoli                         | 0.15                | STMR (CXL) × CF (tentative)                                 |
| Head cabbage                     | 0.48                | STMR (CXL) × CF (tentative)                                 |
| Chinese cabbage                  | 3.5                 | STMR (CXL) × CF (tentative)                                 |
| Kale                             | 3.5                 | STMR (CXL) × CF (tentative)                                 |
| Lamb’s lettuce                   | 3.5                 | STMR (CXL) × CF (tentative)                                 |
| Lettuces                         | 3.5                 | STMR (CXL) × CF (tentative)                                 |
| Escaroles/broadleaved endives    | 3.5                 | STMR (CXL) × CF (tentative)                                 |
| Cress                            | 3.5                 | STMR (CXL) × CF (tentative)                                 |
| Land cress                       | 3.5                 | STMR (CXL) × CF (tentative)                                 |
| Rocket, Rucola                   | 3.5                 | STMR (CXL) × CF (tentative)                                 |
| Commodity                                      | Input value (mg/kg) | Chronic risk assessment                                      |
|-----------------------------------------------|---------------------|-------------------------------------------------------------|
| Red mustard                                   | 3.5                 | STMR (CXL) × CF (tentative)                                  |
| Leaves and sprouts of Brassica spp.           | 3.5                 | STMR (CXL) × CF (tentative)                                  |
| Spinach                                       | 3.5                 | STMR (CXL) × CF (tentative)                                  |
| Purslane                                      | 3.5                 | STMR (CXL) × CF (tentative)                                  |
| Beet leaves (chard)                           | 3.5                 | STMR (CXL) × CF (tentative)                                  |
| Vine leaves (grape leaves)                    | 3.5                 | STMR (CXL) × CF (tentative)                                  |
| Water cress                                   | 3.5                 | STMR (CXL) × CF (tentative)                                  |
| Chervil                                       | 3.5                 | STMR (CXL) × CF (tentative)                                  |
| Basil                                         | 11.8                | STMR (CXL) × CF (tentative)                                  |
| Rape seed                                     | 1.9                 | STMR (CXL) × CF (tentative)                                  |
| Rice grains                                   | 2.1                 | STMR × CF (tentative)                                       |
| Sugar cane                                    | 0.24                | STMR (CXL) × CF (tentative)                                  |
| Swine meat                                    | 0.01                | 0.8 × STMR muscle (CXL) × CF + 0.2 × STMR (CXL) fat × CF (tentative) |
| Swine fat tissue                              | 0.03                | STMR (CXL) × CF (tentative)                                  |
| Swine liver                                   | 0.10                | STMR × CF (tentative)                                       |
| Swine kidney                                  | 0.08                | STMR × CF (tentative)                                       |
| Bovine meat                                   | 0.01                | 0.8 × STMR muscle (CXL) × CF + 0.2 × STMR (CXL) fat × CF (tentative) |
| Bovine fat tissue                             | 0.03                | STMR (CXL) × CF (tentative)                                  |
| Bovine liver                                  | 0.10                | STMR × CF (tentative)                                       |
| Bovine kidney                                 | 0.08                | STMR × CF (tentative)                                       |
| Sheep meat                                    | 0.01                | 0.8 × STMR muscle (CXL) × CF + 0.2 × STMR (CXL) fat × CF (tentative) |
| Sheep fat tissue                              | 0.06                | STMR × CF (tentative)                                       |
| Sheep liver                                   | 0.10                | STMR × CF (tentative)                                       |
| Sheep kidney                                  | 0.08                | STMR × CF (tentative)                                       |
| Goat meat                                     | 0.01                | 0.8 × STMR muscle (CXL) × CF + 0.2 × STMR (CXL) fat × CF (tentative) |
| Goat fat tissue                               | 0.06                | STMR × CF (tentative)                                       |
| Goat liver                                    | 0.10                | STMR × CF (tentative)                                       |
| Goat kidney                                   | 0.08                | STMR × CF (tentative)                                       |
| Equine meat                                   | 0.01                | 0.8 × STMR muscle (CXL) × CF + 0.2 × STMR (CXL) fat × CF (tentative) |
| Equine fat tissue                             | 0.03                | STMR (CXL) × CF (tentative)                                  |
| Equine liver                                  | 0.10                | STMR × CF (tentative)                                       |
| Equine kidney                                 | 0.08                | STMR × CF (tentative)                                       |
| Poultry meat                                  | 0.04                | 0.9 × STMR muscle × CF + 0.1 × STMR fat × CF (tentative)     |
| Poultry fat tissue                            | 0.04                | STMR × CF (tentative)                                       |
| Poultry liver                                 | 0.04                | STMR × CF (tentative)                                       |
| Cattle milk                                   | 0.02                | STMR × CF (tentative)                                       |
| Sheep milk                                    | 0.02                | STMR × CF (tentative)                                       |
| Goat milk                                     | 0.02                | STMR × CF (tentative)                                       |
| Horse milk                                    | 0.02                | STMR × CF (tentative)                                       |
| Birds eggs                                    | 0.04                | STMR × CF (tentative)                                       |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor, CF: conversion factor.

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP of DB > 0.1 mg/kg DM in EU?
  - Yes: MRL derived in Section 3?
    - No: MRL fully supported by data?
      - Yes: MRL is recommended.
      - No: Recommendations resulting from EU authorisations and import tolerances
  - No: Risk identified?
    - Yes: Tentative median/highest values are included in the RA.
      - No: Tentative median/highest values are included in the RA.
    - No: Median/highest values are included in the RA.

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

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

Recommendations resulting from EU authorisations and import tolerances

- Specific LOQ or default MRL?
  - Yes: Specific LOQ or default MRL?
    - No: Specific LOQ or default MRL?
      - Yes: Specific LOQ or default MRL?
        - No: Specific LOQ or default MRL?
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Review of the existing MRLs for tebufenozide

Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes

- No
  - Yes
    - No

- RD comparable?
  - Yes
    - CXL higher?
      - Yes

- No
  - No
  - Input values for the RA remain unchanged.
  - Input values for the RA remain unchanged.
  - Input values for the RA remain unchanged.
  - CXL supported by data?
    - Yes
      - Codex median/highest residues are included in the RA.
      - Risk identified?
        - Yes
        - No
      - Risk identified?
        - Yes
        - No

- No
  - No
  - Input values for the RA remain unchanged.
  - Input values for the RA remain unchanged.
  - CXL is included in the RA.
  - Risk identified?
    - Yes
    - No

- Yes
  - No
  - No

- CXL is included in the RA.

- Risk identified?
  - Yes
  - No

- Yes
  - No

- Yes
  - No

- Yes
  - No

- No
  - No

- No
  - No

Recommendations with consideration of the existing CXL

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

| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|-------------------|-------------------------------|--------------------|
| Tebufenozide      | \(N\text{-}\text{tert}\text{-}\text{butyl}-N'\text{-}(4\text{-}ethylbenzoyl)-3,5\text{-} \text{dimethylbenzohydrazide} \) | ![Structural formula](image1) |
| RH-9841           | 3,5-dimethylbenzoic acid-1-(1,1-dimethyl-ethyl)-2-(4-vinylbenzoyl)hydrazide | ![Structural formula](image2) |
| RH-1788           | \(N\text{-}\text{tert}\text{-}\text{butyl}-N'\text{-}[4\text{-}(1\text{-}hydroxyethyl)phenyl]carbonyl]-3,5\text{-} \text{dimethylbenzohydrazide} \) | ![Structural formula](image3) |
| RH-111788         | \(N'\text{-}4\text{-}(2\text{'-}hydroxyethyl)benzoyl)-N\text{-}(3,5\text{-}dimethylbenzoyl)-N\text{-} \text{tert} \text{butylhydrazine} \) | ![Structural formula](image4) |
| RH-120282         | \(N\text{-}\text{tert}\text{-}\text{butyl}-N'\text{-}[4\text{-}(1\text{-}hydroxyethyl)phenyl]carbonyl]-3\text{-} \text{(hydroxymethyl)-5-methylbenzohydrazide conjugates} \) | ![Structural formula](image5) |
| RH-122778         | \(N\text{-}(3,5\text{-}dihydroxymethylbenzoyl})-N'\text{-}(4\text{-}(1\text{-}hydroxyethyl)benzoyl)-N\text{-} \text{tert} \text{butylhydrazine} \) | ![Structural formula](image6) |
| RH-120970         | \(N'\text{-}(4\text{-}ethylbenzoyl)-N\text{-}(3\text{-}formyl-5\text{-}methybenzoyl)-N\text{-} \text{tert} \text{butylhydrazine} \) | ![Structural formula](image7) |
| RH-96595          | \(N'\text{-}(4\text{-}acetylbenzoyl)-N\text{-}(3,5\text{-}dimethylbenzoyl)-N\text{-} \text{tert} \text{butylhydrazine} \) | ![Structural formula](image8) |
| RH-89886          | \(N'\text{-}(4\text{-}ethylbenzoyl)-N\text{-}(3\text{-}hydroxymethyl-5\text{-}benzoyl)-N\text{-} \text{tert} \text{butylhydrazine} \) | ![Structural formula](image9) |
| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|------------------|-------------------------------|-------------------|
| RH-6595          | \(N'\)-[(4-acetylphenyl)carbonyl]-N-tert-butyl-3,5-dimethylbenzohydrazide | ![Structural formula](image1.png) |
| RH-2651          | 4-[(2-tert-butyl-2-[3,5-dimethylphenyl]carbonyl]hydrazinyl]carbonyl]benzoic acid | ![Structural formula](image2.png) |
| RH-9886          | \(N\text{-tert-butyl}-N'\)-[(4-ethylphenyl)carbonyl]-3-(hydroxymethyl)-5-methylbenzohydrazide | ![Structural formula](image3.png) |
| RH-0282          | N-(1,1-dimethylethyl)-N'-(4-ethylbenzoyl)-3,5-dimethylbenzohydrazide | ![Structural formula](image4.png) |
| RH-2703          | [4-[(2-tert-butyl-2-[(3,5-dimethylphenyl)carbonyl]hydrazinyl]carbonyl]phenyl]acetic acid | ![Structural formula](image5.png) |
| M2               | Unidentified                  | Unidentified      |

SMILES: simplified molecular-input line-entry system.