Modification of the existing maximum residue levels for tebufenozide in apricots and peaches

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Nisso Chemical Europe GmbH submitted a request to the competent national authority in Italy to modify the existing maximum residue levels (MRLs) for the active substance tebufenozide in apricots and peaches. The data submitted in support of the request were found to be sufficient to derive MRL proposals for apricots and peaches. Adequate analytical methods for enforcement are available to control the residues of tebufenozide on the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of tebufenozide according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Keywords: tebufenozide, apricots, peaches, insecticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Nisso Chemical Europe GmbH submitted an application to the competent national authority in Italy (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance tebufenozide in apricots and peaches. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 11 September 2020. To accommodate for the intended SEU uses of tebufenozide, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 to 1.5 mg/kg for apricots and from 0.5 to 1.5 mg/kg for peaches.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under a previous MRL assessment (including review of the existing tebufenozide MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review)) and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of tebufenozide following foliar applications has been investigated in crops belonging to the groups of fruit, cereals/grass and root crops. For the intended use of tebufenozide in peaches and apricots, belonging to the fruit crop group, the metabolic behaviour in primary crops is addressed.

Studies investigating the effect of processing on the nature of tebufenozide (hydrolysis studies) demonstrated that the active substance is stable under representative conditions of pasteurisation, baking and sterilisation.

As the proposed uses of tebufenozide are on permanent crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, results from hydrolysis studies and the toxicological significance of metabolites, the residue definitions for plant products were proposed by the EU pesticides peer review and the MRL review as ‘the sum of tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, expressed as tebufenozide’ for risk assessment and ‘tebufenozide’ for enforcement. These residue definitions are applicable to primary crops, rotational crops and processed products. EFSA concluded that for the crops assessed in this application, metabolism of tebufenozide in primary crops, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable. On the basis of metabolism studies, the EU pesticides peer review proposed a conversion factor of 1 from enforcement to risk assessment for fruit crops.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (limit of quantification (LOQ)).

The available residue trials are sufficient to derive an MRL proposal of 1.5 mg/kg for the intended uses on apricots and peaches.

Specific studies investigating the magnitude of tebufenozide residues in processed apricots and peaches are not required, as the contribution of tebufenozide residues in these fruits to the total theoretical maximum daily intake (TMDI) is below 10% of the acceptable daily intake (ADI).

Residues of tebufenozide in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

The toxicological profile of tebufenozide was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.02 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. The metabolites included in the residue definition are not of higher toxicity than the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) values as derived from the residue trials on the crops under assessment. For remaining commodities the STMR values as derived in the MRL review, taking also into account the codex maximum residue limit (CXL) values that were adopted into the EU regulation, and the existing EU MRLs for pine nut kernels, cherries (sweet), plums, strawberries and courgettes were used as input values in the consumer exposure assessment. Crops on which no uses were reported in the MRL review were excluded from the calculations and tentative conversion factors from
enforcement to risk assessment that were derived for some crops in the framework of the MRL review were applied.

The estimated long-term dietary intake accounted for a maximum of 69% of the ADI (NL toddler). The contribution of residues in apricots and peaches to the overall long-term exposure is very low (0.55% of the ADI). EFSA concluded that the authorised use of tebufenozide on apricots and peaches will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

EFSA proposes to amend the existing MRLs as reported in the summary table below. Full details of all endpoints and the consumer risk assessment can be found in Appendices B-D.

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------------|-----------|------------------------|-------------------------|-----------------------|
| 140010 | Apricots | 0.01* | 1.5 | The submitted data are sufficient to derive an MRL proposal for the SEU use. Risk for consumers unlikely. |
| 140030 | Peaches | 0.5 | 1.5 |

MRL: maximum residue level; SEU: southern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for tebufenozide in apricots and peaches. The detailed description of the intended uses of tebufenozide, which are the basis for the current MRL application, is reported in Appendix A.

Tebufenozide is the ISO common name for $N$-tert-butyl-$N'$-(4-ethylbenzoyl)-3,5-dimethylbenzohydrazide (IUPAC). The chemical structure of tebufenozide is reported in Appendix E.

Tebufenozide was evaluated in the framework of Directive 91/414/EEC1 with Germany designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on grapes and pome fruit. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2010). Tebufenozide was approved2 for the use as insecticide on 1 June 2011.

The EU MRLs for tebufenozide are established in Annex III of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2018b) and the proposed modifications have been implemented in the MRL legislation.4

In accordance with Article 6 of Regulation (EC) No 396/2005, Nisso Chemical Europe GmbH submitted an application to the competent national authority in Italy (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance tebufenozide in apricots and peaches. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 11 September 2020. To accommodate for the intended SEU uses of tebufenozide, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 to 1.5 mg/kg for apricots and from 0.5 to 1.5 mg/kg for peaches.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

EFSA based its assessment on the evaluation report submitted by the EMS (Italy, 2020), the draft assessment report (DAR) (and its addenda) (Germany, 2005, 2009, 2010) prepared under Council Directive 91/414/EEC, the Commission review report on tebufenozide (European Commission, 2011), the conclusion on the peer review of the pesticide risk assessment of the active substance tebufenozide (EFSA, 2010) and the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2018b).

For this application, the data requirements established in Regulation (EU) No 544/20115 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/20116.

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

The evaluation report submitted by the EMS (Italy, 2020) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 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.
3 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
4 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
5 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1-66.
6 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
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 in primary crops after foliar applications was evaluated in the framework of the EU pesticides peer review in fruits (apples, grapes), cereals/grass (rice) (EFSA, 2010) and in a previous MRL application in root crops (sugar beet roots and tops) (EFSA, 2014). In apples after two foliar applications at 1.1 kg a.s./ha, the parent compound was the main residue, representing 71.2–77.3% of the total radioactive residues (TRR) in fruit and 93.4% TRR in apple foliage. In grapes after one foliar application at 1.2 kg a.s./ha, the major component of the residue was tebufenozide (89.2–92.4% TRR; 0.78–1.99 mg/kg). The levels of radioactivity found in grape fruit were 1.0–2.45 mg eq/kg and no other individual metabolites were identified (Germany, 2005; EFSA, 2018b).

For the intended use of tebufenozide on apricots and peaches, belonging to the fruit crop group, the metabolic behaviour in primary crops is satisfactorily addressed.

1.1.2. Nature of residues in rotational crops

As the proposed uses of tebufenozide are on permanent crops, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of tebufenozide was investigated in the framework of the EU pesticides peer review (EFSA, 2010). EFSA concluded that the compound is hydrolytically stable under the representative processing conditions of pasteurisation, baking/brewing/boiling and sterilisation.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of tebufenozide residues in plant commodities were assessed during the EU pesticides peer review and the MRL review (EFSA, 2010, 2018). A multiresidue method based on 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. An independent laboratory validation (ILV) was available for high water content matrices (EFSA, 2010). A multi-residue method is also available using LC-MS/MS with an LOQ of 0.01 mg/kg and validated for the determination of tebufenozide in all four plant matrices (high water, high acid, high oil content and dry commodities), however extraction efficiency needs to be demonstrated (EFSA, 2018b).

1.1.5. Storage 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°C in high water and high acid content matrices (EFSA, 2010). Furthermore, the storage stability of tebufenozide was demonstrated for a period of 36 months at –18°C in high water content (EFSA, 2014), for a period of 32 months at –18°C in high acid content, for a period of 42 months in high oil content matrices and for a period of 54 months at –18°C in dry commodities (EFSA, 2018b).

Additionally, a study on the storage stability of tebufenozide residues in peach and apricot sample extracts was provided which demonstrated that tebufenozide residues were stable for up to 15 days when stored at ≤ –18°C (Italy, 2020).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in primary and rotational crop metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the EU pesticides peer review (EFSA, 2010) for all primary crop groups:
• residue definition for risk assessment: tebufenozide and all metabolites including ethylphenyl and dimethylphenyl structures, expressed as tebufenozide.
• residue definition for enforcement: tebufenozide

The same residue definitions are applicable to rotational crops and processed products. Tentative conversion factors from enforcement to risk assessment residue definition were proposed by the EU pesticides peer review and the MRL review for cereals/grass and leafy crop groups on the basis of metabolism studies (EFSA, 2018b). For fruit crops, a conversion factor of 1 is applicable.

The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement and risk assessment derived in the EU pesticides peer review.

EFSA concludes that these residue definitions are appropriate for the proposed uses assessed in this application, and no modification is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted four GAP compliant residue decline trials performed on apricots and four GAP compliant decline residue trials performed on peaches, supporting the SEU GAP. Trials were performed over one growing season of 2019 in Italy, Spain, Greece and France, representing a wide geographical area, thus partially compensating the deviation from the requirement that for major crops the trials shall be carried out over at least two growing seasons.

The applicant provided residue data both in the whole fruit and in fruit without stone. In contrast to the EMS, the risk assessment values were derived by EFSA for the whole fruit, since, according to Regulation (EC) No 396/2005, the MRL applies to the whole fruit (and not to the fruit without stone). The applicant proposes to merge residue data in apricots and peaches to derive an MRL proposal. Apricots and peaches are both major crops and eight trials are required for each crop; however, a combination of trials from apricots and peaches is possible, provided that 50% of the trials are performed on apricots (European Commission, 2017). Thus, the number of trials is sufficient to derive an MRL of 1.5 mg/kg for apricots and peaches.

The samples were analysed for the parent compound and no data were provided according to the residue definition for risk assessment. This is not considered a data gap, since in fruit crops, according to metabolism studies, residues were almost entirely allocated to the parent compound and therefore the EU pesticides peer review did not propose a conversion factor (CF of 1) for fruit crops (EFSA, 2010).

The samples of all the residue trials were stored under conditions for which integrity of the residues has been demonstrated. According to the assessment of the EMS, the methods of analysis used were sufficiently validated and fit for purpose (Italy, 2020).

1.2.2. Magnitude of residues in rotational crops

As the proposed uses of tebufenozide are on permanent crops, investigations on the magnitude of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Studies to assess the magnitude of tebufenozide residues during the processing of the crops under assessment have not been submitted and are not required, as the individual contribution of tebufenozide residues in peaches and apricots to total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI) (European Commission, 1997d).

1.2.4. Proposed MRLs

EFSA concludes that the data submitted are sufficient to derive an MRL of 1.5 mg/kg in support of the intended SEU use of tebufenozide on peaches and apricots. In Section 3, EFSA assessed whether residues in peaches and apricots resulting from the intended uses of tebufenozide in the SEU are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as apricots and peaches are not used for feed purposes.
3. Consumer risk assessment

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO rev.3.1). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018a, 2019).

The toxicological reference value for tebufenozide used in the risk assessment (i.e. ADI value of 0.02 mg/kg body weight (bw) per day) was derived in the framework of the EU pesticides peer review (European Commission, 2011). An acute reference dose (ARfD) was not allocated as not considered necessary.

The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) values from the crops under assessment. For the remaining crops, the input values were the STMR values derived in the review of the existing MRLs under Article 12 of Regulation 396/2005, taking also into account the CXLs that were adopted into the EU regulation and the existing EU MRL for pine nut kernels, cherries (sweet), plums, strawberries and courgettes which were set recently at the LOQ according to the Regulation (EU) 2019/973. Crops on which no uses were reported in the MRL review were excluded from the calculation.

The tentative conversion factors from enforcement to risk assessment that were derived in the framework of the EU MRL peer review (EFSA, 2018b) were taken into account and applied to leafy and brassica vegetables, sugar cane, rape seed, rice and animal commodities.

The estimated long-term dietary intake accounted for a maximum of 69% of the ADI (NL toddler). The contribution of residues in apricots and peaches, to the overall long-term exposure is very low (0.55% of the ADI). EFSA concluded that the authorised use of tebufenozide on apricots and peaches will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health.

The list of input values is presented in Appendix D.1.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMO is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for apricots and peaches.

EFSA concluded that the proposed use of tebufenozide on apricots and peaches will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement to risk assessment residue definition
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DM dry matter
DP dustable powder
DS powder for dry seed treatment
EC emulsifiable concentrate
EMS evaluating Member State
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
| Abbreviation | Full Form |
|--------------|-----------|
| FID          | flame ionisation detector |
| GAP          | Good Agricultural Practice |
| GS           | growth stage |
| HPLC-MS      | high-performance liquid chromatography with mass spectrometry |
| HPLC-MS/MS   | high-performance liquid chromatography with tandem mass spectrometry |
| HR           | highest residue |
| IEDl         | international estimated daily intake |
| ILV          | independent laboratory validation |
| ISO          | International Organisation for Standardisation |
| IUPAC        | International Union of Pure and Applied Chemistry |
| LC           | liquid chromatography |
| LOQ          | limit of quantification |
| MRL          | maximum residue level |
| MS           | Member States |
| MS/MS        | tandem mass spectrometry detector |
| NEU          | northern Europe |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant back interval |
| PF           | processing factor |
| PHI          | preharvest interval |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SC           | suspension concentrate |
| SEU          | southern Europe |
| STMR         | supervised trials median residue |
| TMDI         | theoretical maximum daily intake |
| TRR          | total radioactive residue |
| WHO          | World Health Organization |
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|------------|------------------------------------|-------------|------------|-------------------------------|---------------|---------|
|                       |                         |            |                                    | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | kg a.s./hL min-max | Water L/ha min-max | Rate | Unit |         |
| **Apricots**          | SEU                     | F          | Oriental fruit moth, Anarsia       | SC        | 240 g/L   | Foliar treatment – broadcast spraying | BBCH 51–87 | 2               | 10–14 | 0.0144–0.0216 | 1,000–1,500 | 0.22 | kg a.s./ha | 14  |
| **Peaches**           | SEU                     | F          | Oriental fruit moth, Anarsia       | SC        | 240 g/L   | Foliar treatment – broadcast spraying | BBCH 51–87 | 2               | 10–14 | 0.0144–0.0216 | 1,000–1,500 | 0.22 | kg a.s./ha | 14  |

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

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                      |             |         |                |                |                |
|                                  |             | Apples  | Foliar, 2 × 1.1 kg a.s./ha with 35 days between applications | Leaves and fruits: 0, 29, 68 | Radiolabelling: [14C-ethyl(phenyl)-tebufenozide; [14C-dimethyl(phenyl)-tebufenozide; and t-butyl [14C-t-butyl]-tebufenozide (EFSA 2010, 2014) |
|                                  |             | Grapes  | Foliar, 1 × 1.2 kg a.s./ha | Fruits: 0, 15, 31 |
| Root crops                       |             | Sugar beet | Foliar: 1 × 2.24 kg a.s./ha | Roots: 0, 30, 61, 120 |
|                                  |             |         |                | Tops: 0, 30, 61, 120 |
| Cereals/ grass                   |             | Rice    | Foliar: 1 × 1.2 kg a.s./ha | 0, 15, 30, 64 |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Turnips     | Bare soil, 4 × 280 g a.s./ha | 30, 90, 250, 365 | Radiolabelling: [14C-ethyl(phenyl)-tebufenozide; [14C-dimethyl(phenyl)-tebufenozide; and t-butyl [14C-t-butyl]-tebufenozide EFSA (2014) |
| Leafy crops                         | Kale (collard) | Bare soil, 4 × 280 g a.s./ha | 30, 90, 250, 384 |
| Cereal (small grain)                | Wheat       | Bare soil, 4 × 280 g a.s./ha | 30, 90, 250, 365 |
| Other                               |             |         |                |           |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Yes        |         | EFSA (2010)    |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes        |         | EFSA (2010)    |
| Sterilisation (20 min, 120°C, pH 6)      | Yes        |         | EFSA (2010)    |
| Other processing conditions              | –          | –       |                |
Can a general residue definition be proposed for primary crops?  
Yes  
EFSA (2010, 2018b)

Rotational crop and primary crop metabolism similar?  
Yes  
EFSA (2010, 2018b)

Residue pattern in processed commodities similar to residue pattern in raw commodities?  
Yes  
EFSA (2010, 2018b)

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.

Tentative conversion factors (CF) were derived from metabolism studies (EFSA, 2018b):  
1.4: Leafy and brassica vegetables  
2: Sugar cane, rape seed and rice

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

| Analytical Technique | Commodity Groups | LOQ | Sources |
|----------------------|------------------|-----|---------|
| HPLC–MS (EFSA, 2010) | Validated in high water and high acid content commodities | 0.02 mg/kg | EFSA (2014) |
| ILV method available for water content commodities. | ELV method available for water content commodities. | 0.02 mg/kg | EFSA (2018b) |
| LC–MS/MS (EFSA, 2018b) | Validated in high water, high acid, high oil and dry content commodities | 0.01 mg/kg | EFSA (2018b) |
| Extraction efficiency not demonstrated | Extraction efficiency not demonstrated | - | - |

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

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

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|-----------------|-------------------|----------------|
|                                    | High water content | Lettuce | -18 | 36 Months | Tebufenozide | EFSA (2014) |
|                                    | High oil content | Walnuts | -18 | 42 Months | Tebufenozide | EFSA (2018b) |
|                                    | Dry/High starch | Wheat (grain) | -18 | 54 Months | Tebufenozide | EFSA (2018b) |
|                                    | High acid content | Grapes | -18 | 32 Months | Tebufenozide | EFSA (2018b) |
|                                    | Others |          |      |             |                   |                 |
## B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|-----------------------|------------------------|------------------------|----------------|
| Peaches   | SEU                         | **Mo:** 0.11; 0.13; 0.20; 0.21; 0.36; 0.45; 0.54; 0.64<br><br>**RA:** – | Combined residue trials on peaches and apricots compliant with the intended GAP. Underlined values refer to trials on peaches. | 1.5 | 0.64 | 0.29 | 1 |
| Apricots  |                             |                                                               |                 |                       |                        |                        |                 |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.

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

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

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Not triggered | Study not required (permanent crops) |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered | Study not required (permanent crops) |

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

A short-term consumer risk assessment is not relevant since no ARfD has been considered necessary.

|                | 0.02 mg/kg bw per day (European Commission, 2011) |
|----------------|--------------------------------------------------|
| ADI            | 69% ADI (NL toddler)                             |
| Highest IEDI, according to EFSA PRIMo            | Contribution of crops assessed: Apricots/Peaches: 0.55% of ADI |

Assumptions made for the calculations

The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) values from the crops under assessment. For remaining commodities of plant and animal origin, the input values were the STMR values derived in the review of the existing MRLs under Article 12 of Regulation (EU) No 396/2005, taking also into account the CXLs that were adopted into the EU regulation. For pine nut kernels, cherries, plums, strawberries and courgettes, existing EU MRLs which were set at the LOQ recently in the Regulation (EU) 2019/973 were used as input values. Crops on which no uses were reported in the MRL review were excluded from the calculation.

The tentative conversion factors (CF) from enforcement to risk assessment, that were derived in the framework of the MRL review (EFSA, 2018b), were applied to input values of leafy and brassica vegetables (CF of 1.4), sugar cane (CF of 2), rape seed (CF of 2), rice (CF of 2) and animal commodities (CF ranging from 2 to 4).

The conversion factor applied to rape seed is based on the conversion factor derived from rice (CF of 2), as cereals reflected the worst-case scenario.

Calculations were performed with the EFSA Pesticide Residues Intake Model (PRIMo) revision 3.1.
B.4. **Recommended MRLs**

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|------------|------------------------|------------------------|------------------------|
| 140010            | Apricots   | 0.01*                  | 1.5                    | The submitted data are sufficient to derive an MRL proposal for the SEU use. Risk for consumers unlikely. |
| 140030            | Peaches    | 0.5                    | 1.5                    |                        |

**Enforcement residue definition:** tebufenozide<sup>(F)</sup>

MRL: maximum residue level; SEU: southern Europe.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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

(F): Fat soluble.
Appendix C – Pesticide Residue Intake Model (PRIMo)

**Tebufenozide (F)**

| Textological reference values |
|-------------------------------|
| ADI (mg/kg bw per day) | 0.02 |
| Source of ADI | EFSA PRIMo revision 3.1; 2019/03/19 |
| ARfD (mg/kg bw) | not necessary |
| Source of ARfD | EFSA PRIMo revision 3.1; 2019/03/19 |
| Year of evaluation | 2011 |
| No of diets exceeding the ADI | --- |

**Revised calculation mode**

### Chronic risk assessment - JMPR methodology (IEDI/TMDI)

**Calculation exposure**

| Commodity/group of commodities | Exposure resulting from |
|--------------------------------|------------------------|
| Rapeseeds/canola seeds | 69% 13.81 13% 13% 9% |
| Table grapes | 45% 6.27 36% 36% 35% |
| Chinese cabbages/pe-tsai | 38% 7.64 16% 6% 3% |
| Rapeseeds/canola seeds | 33% 6.56 7% 4% 4% |
| Wine grapes | 28% 5.63 5% 4% 4% |
| Chinese cabbages/pe-tsai | 26% 5.18 7% 5% 2% |
| Rice | 23% 4.59 7% 3% 3% |
| Kales | 22% 4.41 3% 3% 2% |
| Tomatoes | 22% 4.36 3% 3% 2% |
| Sugar canes | 21% 4.11 6% 3% 3% |
| Milk: Cattle | 21% 4.11 6% 3% 3% |
| Tomatoes | 19% 3.90 4% 3% 3% |
| Apples | 19% 3.79 3% 2% 2% |
| Spinaches | 18% 3.66 3% 2% 2% |
| Tomatoes | 17% 3.31 7% 2% 2% |
| Apples | 15% 3.08 7% 4% 2% |
| Milk: Cattle | 15% 3.04 3% 2% 2% |
| Lettuces | 15% 2.96 5% 2% 2% |
| Rice | 14% 2.86 3% 3% 2% |
| Lettuces | 14% 2.84 3% 2% 2% |
| Apples | 13% 2.65 6% 1% 1% |
| Spinaches | 13% 2.62 6% 2% 1% |
| Apples | 12% 2.59 4% 2% 2% |
| Lettuces | 11% 2.26 4% 1% 1% |
| Spinaches | 11% 2.17 5% 2% 2% |
| Milk: Cattle | 10% 1.98 2% 2% 1% |
| Lettuces | 9% 1.77 2% 2% 1% |
| Tomatoes | 8% 1.58 2% 1% 0.9% |
| Head cabbages | 7% 1.43 3% 1% 0.9% |
| Milk: Cattle | 5% 0.95 3% 0.4% 0.4% |
| Nutrition/Health Risk Group (NHLRGN) | Exposure resulting from |
|--------------------------------|------------------------|
| Apples | 69% 13.81 13% 13% 9% |
| Rapeseeds/canola seeds | 45% 6.27 36% 36% 35% |
| Table grapes | 38% 7.64 16% 6% 3% |
| Chinese cabbages/pe-tsai | 33% 6.56 7% 4% 4% |
| Rapeseeds/canola seeds | 28% 5.63 5% 4% 4% |
| Chinese cabbages/pe-tsai | 26% 5.18 7% 5% 2% |
| Rice | 23% 4.59 7% 3% 3% |
| Kales | 22% 4.41 3% 3% 2% |
| Tomatoes | 22% 4.36 3% 3% 2% |
| Sugar canes | 21% 4.11 6% 3% 3% |
| Milk: Cattle | 21% 4.11 6% 3% 3% |
| Tomatoes | 19% 3.90 4% 3% 3% |
| Apples | 19% 3.79 3% 2% 2% |
| Spinaches | 18% 3.66 3% 2% 2% |
| Tomatoes | 17% 3.31 7% 2% 2% |
| Apples | 15% 3.08 7% 4% 2% |
| Milk: Cattle | 15% 3.04 3% 2% 2% |
| Lettuces | 15% 2.96 5% 2% 2% |
| Rice | 14% 2.86 3% 3% 2% |
| Lettuces | 14% 2.84 3% 2% 2% |
| Apples | 13% 2.65 6% 1% 1% |
| Spinaches | 13% 2.62 6% 2% 1% |
| Apples | 12% 2.59 4% 2% 2% |
| Lettuces | 11% 2.26 4% 1% 1% |
| Spinaches | 11% 2.17 5% 2% 2% |
| Milk: Cattle | 10% 1.98 2% 2% 1% |
| Lettuces | 9% 1.77 2% 2% 1% |
| Tomatoes | 8% 1.58 2% 1% 0.9% |
| Head cabbages | 7% 1.43 3% 1% 0.9% |
| Milk: Cattle | 5% 0.95 3% 0.4% 0.4% |
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Show results for all crops

| IESTI | Results for children | Results for adults |
|-------|----------------------|--------------------|
|       | No of commodities for which ARfD/ADI is exceeded (IESTI) | No of commodities for which ARfD/ADI is exceeded (IESTI) |

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

Expand/collapse list

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

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

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

Expand/collapse list

### Conclusion:

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)
### Appendix D – Input values for the exposure calculations

#### D.1. Consumer risk assessment

| Commodity                     | Existing/proposed MRL (mg/kg) | Source/type of MRL | Input value (mg/kg) | Comment<sup>(a)</sup> |
|-------------------------------|-------------------------------|--------------------|---------------------|---------------------|
| Grapefruits                   | 2                             | EFSA (2018b)       | 0.079               | STMR-RAC            |
| Oranges                       | 2                             | EFSA (2018b)       | 0.079               | STMR-RAC            |
| Lemons                        | 2                             | EFSA (2018b)       | 0.079               | STMR-RAC            |
| Limes                         | 2                             | EFSA (2018b)       | 0.079               | STMR-RAC            |
| Mandarin                      | 2                             | EFSA (2018b)       | 0.079               | STMR-RAC            |
| Other citrus fruit            | 2                             | EFSA (2018b)       | 0.079               | STMR-RAC            |
| Almonds                       | 0.05                           | EFSA (2018b)       | 0.02                |                     |
| Chestnuts                     | 0.01                           | EFSA (2018b)       | 0.01                |                     |
| Pecans                        | 0.01                           | EFSA (2018b)       | 0.01                |                     |
| Pine nut kernels              | 0.01                           | EU MRL             | 0.01                | LOQ                 |
| Walnuts                       | 0.05                           | EFSA (2018b)       | 0.01                | STMR-RAC            |
| Apples                        | 1                              | EFSA (2018b)       | 0.25                | STMR-RAC            |
| Pears                         | 1                              | EFSA (2018b)       | 0.25                | STMR-RAC            |
| Quinces                       | 1                              | EFSA (2018b)       | 0.22                | STMR-RAC            |
| Medlar                        | 1                              | EFSA (2018b)       | 0.22                | STMR-RAC            |
| Loquats/Japanese medlars       | 1                              | EFSA (2018b)       | 0.22                | STMR-RAC            |
| Apricots                      | 0.01                           | STMR                | 0.29                |                     |
| Cherries (sweet)              | 0.01                           | Existing EU MRL    | 0.01                | LOQ                 |
| Peaches                       | 0.5                            | STMR                | 0.29                | STMR-RAC            |
| Plums                         | 0.01                           | EU MRL             | 0.01                | LOQ                 |
| Table grapes                  | 4                              | EFSA (2018b)       | 0.51                | STMR-RAC            |
| Wine grapes                   | 4                              | EFSA (2018b)       | 0.51                | STMR-RAC            |
| Strawberries                  | 0.01                           | EFSA (2018b)       | 0.01                | LOQ                 |
| Raspberries (red and yellow)  | 2                              | EFSA (2018b)       | 0.56                | STMR-RAC            |
| Blueberries                   | 3                              | EFSA (2018b)       | 0.69                | STMR-RAC            |
| Cranberries                   | 0.5                            | EFSA (2018b)       | 0.04                | STMR-RAC            |
| Kumquats                      | 2                              | EFSA (2018b)       | 0.48                | STMR-RAC            |
| Kiwi fruits (green, red, yellow) | 0.5                         | EFSA (2018b)       | 0.14                | STMR-RAC            |
| Avocados                      | 1                              | EFSA (2018b)       | 0.18                | STMR-RAC            |
| Tomatoes                      | 1.5                            | EFSA (2018b)       | 0.32                |                     |
| Sweet peppers/bell peppers    | 1.5                            | EFSA (2018b)       | 0.53                | STMR-RAC            |
| Aubergines/egg plants         | 1.5                            | EFSA (2018b)       | 0.32                | STMR-RAC            |
| Courgettes                    | 0.01                           | EU MRL             | 0.01                | LOQ                 |
| Broccoli                      | 0.5                            | EFSA (2018b)       | 0.15                | STMR-RAC (0.11) × CF (1.4) |
| Head cabbages                 | 5                              | EFSA (2018b)       | 0.48                | STMR-RAC (0.34) × CF (1.4) |
| Chinese cabbages/pe-tsai      | 10                             | EFSA (2018b)       | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Kales                         | 10                             | EFSA (2018b)       | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Lamb’s lettuce/corn salads    | 10                             | EFSA (2018b)       | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Commodity                                      | Existing/proposed MRL (mg/kg) | Source/type of MRL | Input value (mg/kg) | Chronic risk assessment |
|------------------------------------------------|------------------------------|-------------------|---------------------|------------------------|
| Lettuces                                      | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Escaroles/broad-leaved endives                | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Cress and other sprouts and shoots            | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Land cress                                    | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Roman rocket/rucola                           | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Red mustards                                  | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Baby leaf crops (including brassica species)  | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Spinaches                                     | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Purslanes                                     | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Chards/beet leaves                            | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Grape leaves and similar species              | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Watercress                                    | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Chervil                                       | 10                           | EFSA (2018b)      | 3.5                 | STMR-RAC (2.5) × CF (1.4) |
| Basil and edible flowers                      | 20                           | EFSA (2018b)      | 11.8                | STMR-RAC (8.4) × CF (1.4) |
| Rapeseeds/canola seeds                        | 2                            | EFSA (2018b)      | 1.9                 | STMR-RAC (0.95) × CF (2)  |
| Rice                                           | 3                             | EFSA (2018b)      | 2.1                 | STMR-RAC (1.05) × CF (2)  |
| Sugar canes                                   | 1                             | EFSA (2018b)      | 0.24                | STMR-RAC (0.12) × CF (2)  |
| Swine: Muscle/meat(b)                         | 0.02                          | EFSA (2018b)      | 0.04                | 0.8 × STMR muscle (0.02) × CF (2) + 0.2 × STMR fat (0.02) × CF (2) |
| Swine: Fat tissue                             | 0.02                          | EFSA (2018b)      | 0.04                | STMR-RAC (0.02) × CF (2)  |
| Swine: Liver                                  | 0.05                          | EFSA (2018b)      | 0.1                 | STMR-RAC (0.05) × CF (2)  |
| Swine: Kidney                                 | 0.02                          | EFSA (2018b)      | 0.08                | STMR-RAC (0.02) × CF (4)  |
| Bovine: Muscle/meat(b)                        | 0.02                          | EFSA (2018b)      | 0.04                | 0.8 × STMR muscle (0.02) × CF (2) + 0.2 × STMR fat (0.02) × CF (2) |
| Bovine: Fat tissue                            | 0.02                          | EFSA (2018b)      | 0.04                | STMR-RAC (0.02) × CF (2)  |
| Bovine: Liver                                 | 0.05                          | EFSA (2018b)      | 0.1                 | STMR-RAC (0.05) × CF (2)  |
| Bovine: Kidney                                | 0.02                          | EFSA (2018b)      | 0.08                | STMR-RAC (0.02) × CF (4)  |
| Sheep: Muscle/meat(b)                         | 0.02                          | EFSA (2018b)      | 0.04                | 0.8 × STMR muscle (0.02) × CF (2) + 0.2 × STMR fat (0.03) × CF (2) |
| Sheep: Fat tissue                             | 0.03                          | EFSA (2018b)      | 0.06                | STMR-RAC (0.03) × CF (2)  |
| Sheep: Liver                                  | 0.05                          | EFSA (2018b)      | 0.1                 | STMR-RAC (0.05) × CF (2)  |
| Sheep: Kidney                                 | 0.02                          | EFSA (2018b)      | 0.08                | STMR-RAC (0.02) × CF (4)  |
| Goat: Muscle/meat(b)                          | 0.02                          | EFSA (2018b)      | 0.04                | 0.8 × STMR muscle (0.02) × CF (2) + 0.2 × STMR fat (0.03) × CF (2) |
| Goat: Fat tissue                              | 0.03                          | EFSA (2018b)      | 0.06                | STMR-RAC (0.03) × CF (2)  |
| Goat: Liver                                   | 0.05                          | EFSA (2018b)      | 0.1                 | STMR-RAC (0.05) × CF (2)  |
| Goat: Kidney                                  | 0.02                          | EFSA (2018b)      | 0.08                | STMR-RAC (0.02) × CF (4)  |
| Equine: Muscle/meat(b)                        | 0.02                          | EFSA (2018b)      | 0.04                | 0.8 × STMR muscle (0.02) × CF (2) + 0.2 × STMR fat (0.02) × CF (2) |
## Modification of the existing MRLs for tebufenozide in apricots and peaches

| Commodity | Existing/proposed MRL (mg/kg) | Source/type of MRL | Input value (mg/kg) | Chronic risk assessment |
|-----------|-------------------------------|-------------------|-------------------|------------------------|
| Equine: Fat tissue | 0.02 EFSA (2018b) | 0.04 STMR-RAC (0.02) × CF (2) | | |
| Equine: Liver | 0.05 EFSA (2018b) | 0.1 STMR-RAC (0.05) × CF (2) | | |
| Equine: Kidney | 0.02 EFSA (2018b) | 0.08 STMR-RAC (0.02) × CF (4) | | |
| Poultry: Muscle/meat\(^{(b)}\) | 0.02 EFSA (2018b) | 0.04 STMR-RAC (0.02) × CF (2) | | |
| Poultry: Fat tissue | 0.02 EFSA (2018b) | 0.04 STMR-RAC (0.02) × CF (2) | | |
| Poultry: Liver | 0.02 EFSA (2018b) | 0.04 STMR-RAC (0.02) × CF (2) | | |
| Milk: Cattle | 0.01 EFSA (2018b) | 0.02 STMR-RAC (0.01) × CF (2) | | |
| Milk: Sheep | 0.01 EFSA (2018b) | 0.02 STMR-RAC (0.01) × CF (2) | | |
| Milk: Goat | 0.01 EFSA (2018b) | 0.02 STMR-RAC (0.01) × CF (2) | | |
| Milk: Horse | 0.01 EFSA (2018b) | 0.02 STMR-RAC (0.01) × CF (2) | | |
| Eggs: Chicken | 0.02 EFSA (2018b) | 0.04 STMR-RAC (0.02) × CF (2) | | |

MRL: maximum residue limit; STMR-RAC: supervised trials median residue in raw agricultural commodity; LOQ: limit of quantification; CF: conversion factor for enforcement to risk assessment residue definition.

(a): Tentative conversion factors for enforcement to risk assessment residue definition were applied (EFSA, 2018b).

(b): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR and HR residue values were calculated considering an 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).
**Appendix E – Used compound codes**

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|-------------------|-----------------------------------------------|-----------------------------|
| Tebufenozide      | \( N\text{-}\text{tert-butyl-N'-(4-ethylbenzoyl)-3,5-dimethylbenzohydrazide} \) | ![Structural formula of Tebufenozide](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

<sup>(a)</sup> ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).

<sup>(b)</sup> ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).