Modification of the existing maximum residue level for tefluthrin in carrots

European Food Safety Authority (EFSA)
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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta France S.A.S. submitted a request to the competent national authority in France to modify the existing maximum residue level (MRL) for the active substance tefluthrin in carrots. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for carrots. Adequate analytical methods for enforcement are available to control the residues of tefluthrin in carrots 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 tefluthrin according to the reported agricultural practices is unlikely to present a risk to consumer health. The reliable end points, appropriate for use in regulatory risk assessment are presented.

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Keywords: tefluthrin, carrot, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta France S.A.S. submitted an application to the competent national authority in France (evaluating Member State (EMS)) to modify the existing maximum residue level (MRL) for the active substance tefluthrin in carrots. 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 10 November 2016. To accommodate for the intended use of tefluthrin on carrots, the EMS proposed to raise the existing MRL from 0.05 to 0.06 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of Regulation (EC) no 396/2005. The assessment was based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessment and the data provided by the EMS in the framework of this application.

Based on the metabolic pattern identified in primary and rotational crops, the residue definition for plant products was proposed as tefluthrin for enforcement and risk assessment. EFSA concluded that for the use on carrots assessed in this application, the previously derived residue definition is applicable. Adequate analytical methods for enforcement are available to control the residues of tefluthrin in carrots at the validated limit of quantification (LOQ) of 0.01 mg/kg.

As carrots are used as feed products, a potential carry-over into food of animal origin was assessed. EFSA concluded that following the intended use, carrots as a feed item does not contribute significantly to the livestock dietary burden and there is no need to modify the existing EU MRLs in ruminant matrices set at 0.05 mg/kg. It is highlighted that these assessments are provisional as MRLs for products of animal origin will be reconsidered in the framework of the Article 12 MRL review.

The toxicological profile of tefluthrin was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.005 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.005 mg/kg bw. Toxicological studies submitted with the present application on plant metabolites of tefluthrin (Compound IV, VI and Ia) confirmed that these metabolites are less toxic than the parent compound and therefore are not relevant for inclusion in the residue definition.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). EFSA concludes that the long-term intake of residues of tefluthrin resulting from the existing and the intended uses is unlikely to present a risk to consumer health. The short-term exposure assessment was performed for carrots and the international estimated short-term intake (IESTI) accounted for 82.4% of the ARfD for UK infant. Based on these calculations, EFSA concludes that the proposed use of tefluthrin on carrots is unlikely to pose a risk for the consumers.

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

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0213020 | Carrots   | 0.05                   | 0.08                    | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU uses. Risk for consumers unlikely |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
Table of contents

Abstract ................................................................................................................................................... 1
Summary .................................................................................................................................................. 3
Assessment ............................................................................................................................................. 5
1. Residues in plants ........................................................................................................................ 5
1.1. Nature of residues and methods of analysis in plants ................................................................. 5
1.1.1. Nature of residues in primary crops ......................................................................................... 5
1.1.2. Nature of residues in rotational crops ...................................................................................... 5
1.1.3. Nature of residues in processed commodities .......................................................................... 6
1.1.4. Methods of analysis in plants .................................................................................................. 6
1.1.5. Stability of residues in plants .................................................................................................. 6
1.1.6. Proposed residue definitions .................................................................................................... 6
1.2. Magnitude of residues in plants .................................................................................................. 6
1.2.1. Magnitude of residues in primary crops .................................................................................. 6
1.2.2. Magnitude of residues in rotational crops .............................................................................. 6
1.2.3. Magnitude of residues in processed commodities ................................................................. 7
1.2.4. Proposed MRLs ....................................................................................................................... 7
2. Residues in livestock ......................................................................................................................... 7
2.1. Nature of residues and methods of analysis in livestock ............................................................. 7
2.2. Magnitude of residues in livestock .............................................................................................. 7
3. Consumer risk assessment ............................................................................................................. 8
Conclusion and recommendations ....................................................................................................... 8
References ............................................................................................................................................. 8
Abbreviations ........................................................................................................................................ 9
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs ............. 11
Appendix B – List of end points .......................................................................................................... 12
Appendix C – Pesticide Residue Intake Model (PRIMo) ................................................................... 18
Appendix D – Input values for the exposure calculations ................................................................. 20
Appendix E – Used compound codes ............................................................................................... 21
Assessment

Tefluthrin is the ISO common name for 2,3,5,6-tetrafluoro-4-methylbenzyl (1RS, 3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-etyl]-2,2-dimethylcyclopropanecarboxylate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Tefluthrin was approved for the use as insecticide on 1 January 2012. The European Union (EU) maximum residue levels (MRLs) for tefluthrin are established in Annexes IIIA of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been performed.

The toxicological profile of tefluthrin was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.005 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.005 mg/kg bw.

The European Food Safety Authority (EFSA) has based its assessment on the evaluation report submitted by the evaluating Member State (EMS) (France, 2016), the draft assessment report (DAR), the additional DAR and its addendum prepared under Directive 91/414/EEC (Germany, 2006, 2009, 2010), the European Commission review report on tefluthrin (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance tefluthrin (EFSA, 2010), as well as the conclusions from a previous EFSA reasoned opinion on tefluthrin (EFSA, 2015).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2016; FAO, 2009; 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 546/2011.

The detailed description of the intended use of tefluthrin in carrots, which is the basis for the current MRL application, is reported in Appendix A.

A selected list of end points of the studies assessed by EFSA and considered as acceptable, including the end points of studies submitted in support of the current MRL application, are presented in Appendix B. The MRL recommendations are summarised in Appendix B.4.

The evaluation report submitted by the EMS (France, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo rev.2A) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo calculation is presented in Appendix C.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

During the EU pesticides peer review (EFSA, 2010), the metabolism of tefluthrin following either soil treatment or seed treatment was investigated in primary crops belonging to the groups of root and tuber vegetables (sugar beet), cereals (maize) and leafy vegetables (cabbage).

1.1.2. Nature of residues in rotational crops

Carrots can be grown in rotation with other plants, and therefore, the possible occurrence of residues in rotational crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated the high persistence of tefluthrin. The maximum DT$_{90}$ observed in the field dissipation studies ranged between 98 and 424 days for the granule formulation, which is

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1 Commission Implementing Regulation (EU) No 800/2011 of 9 August 2011 approving the active substance tefluthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and amending Commission Decision 2008/934/EC. OJ L 205, 10.8.2011, p. 22–26.

2 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Regulation (EU) No 540/2011. OJ L 155, 11.6.2011, p. 1–66.

3 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.
above the value of 100 days triggering the need for further investigations of the nature and magnitude of tefluthrin residues in rotational crops (EFSA, 2010). During the EU pesticides peer review (EFSA, 2010), the metabolism of tefluthrin following soil treatment was investigated in rotational crops belonging to the groups of root and tuber vegetables (sugar beet), cereals (wheat), leafy vegetables (lettuce) and pulses and oilseeds (soya bean). The metabolic pathway of tefluthrin in rotational crops was concluded to be similar to the pathway observed in primary crops. Thus, the same residue definition as in primary crops applies (EFSA, 2010).

1.1.3. Nature of residues in processed commodities

Studies investigating the effect of processing on the nature of tefluthrin (hydrolysis studies) are not available. Nevertheless as residues of tefluthrin exceeding 0.1 mg/kg are not expected in carrots and the chronic exposure does not exceed 10% of the ADI (theoretical maximum daily intake (TMDI) is up to 3.4% of the ADI), there is no need to investigate the effect of industrial and/or household processing on the nature of the residues.

1.1.4. Methods of analysis in plants

Adequate analytical methods for enforcement are available to control the residues of tefluthrin in carrots at the validated LOQ of 0.01 mg/kg (EFSA, 2010).

1.1.5. Stability of residues in plants

The storage stability of tefluthrin and metabolites Ia and VI residues in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2010). The storage stability data are acceptable.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in primary crops and in rotational crops, the residue definition for plant products was proposed as tefluthrin for enforcement and risk assessment. EFSA concludes that for the use on carrots assessed in this application, the proposed residue definitions are still applicable.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Eleven residue trials compliant with the northern Europe (NEU) good agricultural practice (GAP) and 12 residue trials compliant with the southern Europe (SEU) GAP were submitted and considered as acceptable. Seven NEU and eight SEU GAP-compliant residue trials were conducted in parallel with the granule formulations containing, respectively, 5 and 15 g a.s./kg. The application rates given per hectare and per 100 m linear row were identical for the parallel plots. The data sets of residue trials conducted in parallel were not statistically different and it can be concluded that the different concentrations of tefluthrin in the two granule formulations have no impact on the outcome of the residue trials. Therefore, the average residue values derived from the residue trials conducted in the parallel plots were taken to derive input values for the MRL proposal and risk assessment.

In addition, limiting the GAP by expressing the application rate in terms of both per hectare and per 100 m linear row was not sufficiently justified and considered as not relevant for the MRL proposal and risk assessment.

1.2.2. Magnitude of residues in rotational crops

The magnitude of tefluthrin residues in rotational crops was investigated in the framework of the EU pesticides peer review (EFSA, 2010) and an Article 10 MRL assessment (EFSA, 2015). Based on the rotational crops field trials on cereals, root crops and pulses and oilseeds, no quantifiable residue levels of tefluthrin and metabolites Ia and XI are expected in the edible parts of the rotational crops (residues below the LOQ at all plant back intervals in all the edible parts of the crops), provided that the active substance is used according to the intended use on the crop under consideration. In
contrast residue levels of metabolites IV and VI ranging between $< 0.01$ and $0.03 \text{ mg/kg}$ were found in rotational crops at the shortest plant back interval (26–35 days). It is highlighted that the validity of these field trials should be reconsidered pending upon the outcome of the outstanding storage stability data regarding these metabolites in high water content-, high oil content- and dry/starch commodities. However, in view of the additional toxicological data submitted on metabolites IV and VI (see Appendix B.3) it can be concluded that these metabolites display significantly lower toxicity compared to the parent compound. EFSA therefore does not recommend the setting of a plant back restriction in the case of a crops failure situation.

1.2.3. Magnitude of residues in processed commodities

As residues of tefluthrin exceeding 0.1 mg/kg are not expected in carrots and the chronic exposure does not exceed 10% of the ADI (TMDI is up to 3.4% of the ADI), there is no need to investigate the effect of industrial and/or household processing on the magnitude of the residues.

1.2.4. Proposed MRLs

The available residue trials are sufficient to derive a MRL proposal for carrots.

2. Residues in livestock

2.1. Nature of residues and methods of analysis in livestock

Metabolism studies in ruminants have been assessed previously in the framework of the EU pesticides peer review (EFSA, 2010) and the residue definitions for ruminants matrices were proposed as follows:

- residue definition for enforcement: tefluthrin
- residue definition for risk assessment: tefluthrin + compound Ia + compound VI, expressed as parent equivalent.

Adequate analytical methods for enforcement are available to control the residues of tefluthrin in products of animal origin (EFSA, 2010).

The residue definition set in Regulation (EC) No 396/2005 is identical with the before mentioned residue definition for enforcement.

2.2. Magnitude of residues in livestock

As carrots are used as feed products, a potential carry-over into food of animal origin was assessed. The median and maximum dietary burden for livestock was calculated using the agreed European methodology (European Commission, 1996) and the latest FAO recommendations (FAO, 2009). However, in the absence of the Article 12 MRL review, calculations were mainly based on MRL values and not on the risk assessment values (STMR, HR) leading to considerable overestimation of the actual animal intakes. The previous Article 10 MRL assessment on tefluthrin in various crops concluded that a change of the existing EU MRL of 0.05 mg/kg set on ruminant products is not necessary, whereas the need for a poultry feeding study will have to be assessed based on the outcome of the outstanding metabolism data in poultry (EFSA, 2015). EFSA recalculated the livestock dietary burden according to OECD guidance (OECD, 2013) with the STMR and HR levels derived for carrots, swedes, turnips, sugar beet, dried pulp and sugar beet tops and leaves, and the MRL values listed for the food/feed commodities under Regulation (EC) No 149/20084 (see Appendix D.1). EFSA concluded that following the intended use, carrots as a feed item does not contribute significantly to the livestock dietary burden (see Appendix B.2) and there is no need to modify the existing EU MRLs in ruminant matrices set at 0.05 mg/kg. It is highlighted that these assessments are provisional as MRLs for products of animal origin will be reconsidered in the framework of the Article 12 MRL review.

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4 Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto. OJ L 58, 1.3.2008, p. 1–398.
3. Consumer risk assessment

The toxicological profile of tefluthrin 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 0.005 mg/kg bw per day and an ARFD of 0.005 mg/kg bw. Toxicological studies on plant metabolites of tefluthrin (Compounds IV, VI and Ia) presented in the current application confirmed that these metabolites are less toxic than the parent compound and therefore are not relevant for the residue definition. The studies demonstrated that the acute toxicity of these metabolites is significantly lower compared to tefluthrin and the in vitro Ames test does not indicate a genotoxic potential (see Appendix B.3).

The consumer risk assessment was performed with revision 2 of the EFSA PRIMO (EFSA, 2007).

The short-term exposure assessment was performed for carrots in accordance with the internationally agreed methodology. The calculations were based on the HR derived from supervised field trials on carrots and the international estimated short-term intake (IESTI) accounted for 82.4% of the ARFD for UK infant. The complete list of input values can be found in Appendix D.2.

The long-term exposure assessment was performed, taking into account the STMR values derived for the commodities assessed in this application; for the remaining commodities covered by the MRL regulation, the existing EU MRLs and STMR values derived in previous MRL applications were selected as input values (EFSA, 2015). The complete list of input values is presented in Appendix D.2.

The estimated long-term dietary intake accounted for up to 59.4% of the ADI for FR toddler. The contribution of residues expected in carrots according to the intended use to the overall long-term exposure is up to 3.4% of the ADI for FR infant (see Appendix C). EFSA concludes that the long-term intake of residues of tefluthrin resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

Based on these calculations, EFSA concludes that the proposed use of tefluthrin on carrots is unlikely to pose a risk for the consumers.

It should be highlighted that the above assessment does not consider the possible impact of plant and animal metabolism on the isomer ratio of the active substance and further investigation on this matter would in principle be required. Since guidance is not yet available on the consideration of isomer ratios in the consumer risk assessment, EFSA recommends that this issue is reconsidered when such guidance is available.

Conclusion and recommendations

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

Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of tefluthrin according to the reported agricultural practice is unlikely to present a risk to consumer health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

- a.i. active ingredient
- a.s. active substance
- ADI acceptable daily intake
- AR applied radioactivity
- ARfD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- DAR draft assessment report
- DAT days after treatment
- DM dry matter
- DT90 period required for 90% dissipation (define method of estimation)
- EMS evaluating Member State
- eq residue expressed as a.s. equivalent
- FAO Food and Agriculture Organization of the United Nations
- GAP Good Agricultural Practice
- GC-ECD gas chromatography with electron capture detector
- GC-MS gas chromatography with mass spectrometry
- GLP Good Laboratory Practice
- GR granule
- HR highest residue
- IEDI international estimated daily intake
- IESTI international estimated short-term intake
- ILV independent laboratory validation
- ISO International Organisation for Standardisation
- IUPAC International Union of Pure and Applied Chemistry
- JMPR Joint FAO/WHO Meeting on Pesticide Residues
| Abbreviation | Description |
|--------------|-------------|
| LOQ          | limit of quantification |
| Mo           | monitoring |
| MRL          | maximum residue level |
| 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 |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SEU          | southern Europe |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TMDI         | theoretical maximum daily intake |
| 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 or G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|-------------------------|----------------|-----------------------------------|-------------|-------------|------------------------------|---------|
| Carrots               | NEU SEU                 | F              | Wireworm, Atomaria sp.            | GR 15 g/kg Soil application in furrow BBCH 00 | 1 | N/A | N/A | The product application rate in terms of 40 (± 25%) g product/100 m linear row (i.e. 0.45–0.75 g a.i./100 m linear row(e)) |

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; GR: granule; a.i.: active ingredient.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
(e): was proposed by the applicant, but was not considered relevant.
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 |
|-----------------------------------|-------------|---------|----------------|----------------|---------|--------|
| Root crops                        | Sugar beet  | Soil (granule band) (470–520 g/ha) | Foliage and root (76, 77 days) | EFSA (2010) |
| Leafy crops                       | Cabbage     | Seed (0.16–0.17 mg/kg seed or 0.71–0.83 mg/kg seed) | Immature leaves (111 days), mature heads (147 days) | EFSA (2010) |
| Cereals/grass                     | Maize       | Soil drench (490–510 g/ha) | EFSA (2010) |

Radiolabelled active substance: Studies conducted with [U-14C]-phenyl- and [1-14C]-cyclopropyl-labelled tefluthrin, respectively.

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment | Source |
|--------------------------------------|-------------|---------|----------------|-----------|---------|--------|
| Root/tuber crops                     | Sugar beet  | Glasshouse/protected indoor, bare soil application (1 × 0.516 kg a.s./ha) | 30–40, 121, 400 | EFSA (2010) |
| Leafy crops                          | Lettuce     | Glasshouse/protected indoor, granule, bare soil application (1 × 0.653 kg a.s./ha) | 30–40, 121, 400 | EFSA (2010) |
| Cereal (small grain)                 | Wheat       | Glasshouse/protected indoor, granule, bare soil application (1 × 0.653 kg a.s./ha) | 30–40, 121, 400 | EFSA (2010) |
| Other (legume vegetables)            | Soya beans  | Glasshouse/protected indoor, granule, bare soil application (1 × 0.653 kg a.s./ha) | 30–40, 121, 400 | EFSA (2010) |

DAT: days after treatment; PBI: plant back interval; a.s.: active substance.

Processed commodities (hydrolysis study):

| Processed commodities (hydrolysis study) | Conditions | Residue stable? | Comment | Source |
|------------------------------------------|------------|----------------|---------|--------|
| Pasteurisation (20 min, 90°C, pH 4)     |            |                | Not submitted, not relevant |        |
| Baking, brewing and boiling (60 min, 100°C, pH 5) |          |                |         |        |
| Sterilisation (20 min, 120°C, pH 6)     |            |                |         |        |
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?
Not triggered
Plant residue definition for monitoring (RD-Mo)
Tefluthrin
Plant residue definition for risk assessment (RD-RA)
Tefluthrin
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
Matrices with high water content, high oil content, high acid content and dry matrices: GC-ECD, LOQ 0.01 mg/kg (EFSA, 2010)
Confirmatory method and ILV available

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category                | Commodity                  | T (°C) | Stability (months) |
|-----------------------------------|-------------------------|----------------------------|--------|-------------------|
|                                    | High water content      | Sugar beet roots, broccoli| −18    | 24                |
|                                    | High oil content        | Soya beans                 | −18    | 24                |
|                                    | Dry/high starch         | Maize kernels              | −18    | 24                |
|                                    | Various matrix          | Maize fodder and forage    | −18    | 24                |

Compound Ia: stable in high water-, high starch- and high oil content matrices for 24 months at −18°C
Compound VI: stable in high water-content matrices (maize foliage and sugar beet) for 17 months
Reference: EFSA (2010)
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 (mg/kg) | Comments                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|--------------------|------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Carrots (1 x 150 g/ha, PHI: N/A) | NEU              | Mo: 5 x < 0.01, 2 x 0.01, 0.02, 0.3, 0.04, 0.05; RA: 5 x < 0.01, 2 x 0.01, 0.02, 0.3, 0.04, 0.05 | Trials are compliant with the GAP. MRL, STMR and HR derived from the merged NEU and SEU residue data sets                                                                                               | 0.08                   | 0.065        | 0.01           | –     |
|                    | SEU              | Mo: 3 x < 0.01, 4 x 0.01, 4 x 0.02, 2 x 0.03, 0.065; RA: 3 x < 0.01, 4 x 0.01, 4 x 0.02, 2 x 0.03, 0.065 |

MRL: maximum residue levels; GAP: good agricultural practice; Mo: monitoring; RA: risk assessment.

*: 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 to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in succeeding crops

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

Yes

Residue levels of tefluthrin and metabolites Ia and XI are below the LOQ of the method at all plant back intervals, provided that the active substance is used according to the intended use on carrots. In contrast, residue levels of metabolites IV and VI ranged between 0.01 and 0.03 mg/kg in rotational crops at the shortest plant back interval (26–35 days). However, compounds IV and VI were concluded to be less toxic compared to the parent compound based on the submitted toxicological studies.

B.1.2.3. Processing factors

Not relevant. No processing studies available.

B.2. Residues in livestock

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

| Relevant groups       | Animal          | Dose (mg/kg bw per day) | Duration (days) | N rate/comment                                      |
|----------------------|-----------------|-------------------------|-----------------|-----------------------------------------------------|
| Cattle (all diets)   | Laying hen      | –                       | –               | Not provided                                        |
|                      | Lactating goat  | 0.43                    | 4               | Extensive metabolism; rapid excretion. Low levels of tefluthrin residues in milk, muscle and fat; higher residue levels in liver and kidneys |
|                      | Pig             | –                       | –               | Not required                                        |

bw: body weight; DM: dry matter.

(a): When several diets are relevant (e.g., cattle, sheep and poultry ‘all diets’), the most critical diet is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

Reference: EFSA (2010)
### Time needed to reach a plateau concentration in milk and eggs (days)

|            |            |
|------------|------------|
| Milk       | Milk: 3 days (metabolism study with goats), 5 days (feeding study with dairy cows) |
|            |            |

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

|            | Yes |
|------------|-----|
|            |     |

### Animal residue definition for monitoring (RD-Mo)

|            | Tefluthrin |
|------------|-----------|
|            |           |

### Animal residue definition for risk assessment (RD-RA)

|            | Tefluthrin + compound Ia + compound VI, expr. as parent eq. |
|------------|----------------------------------------------------------|
|            |                                                          |

### Conversion factor (monitoring to risk assessment)

|            | N/A |
|------------|-----|
|            |     |

### Fat soluble residues (Yes/No)

|            | No |
|------------|----|
|            |    |

### Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)

|            | GC–MS: Eggs, meat, fat, liver, kidney LOQ 0.002 mg/kg; milk LOQ 0.001 mg/kg (EFSA, 2010). Confirmatory method and ILV available |
|------------|----------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                  |

#### B.2.2. Metabolism studies, methods of analysis and residue definitions in livestock

#### B.2.2.1. Summary of the residue data from livestock metabolism studies

Not relevant.

#### B.2.3. Magnitude of residues in livestock

#### B.2.3.1. Summary of the residue data from livestock feeding studies

Not relevant.

#### B.2.3.2. Conversion factors for risk assessment in animal products

Not relevant.
B.3. Consumer risk assessment

**ARfD**

| Highest IESTI, according to EFSA PRIMo | 0.005 mg/kg bw (EFSA, 2010) |
|----------------------------------------|-------------------------------|
| **Assumptions made for the calculations** | **Scenario 1:** Carrots: 82.4% of ARfD (UK infant) |
| **Scenario 1:** The calculation is based on the highest residue levels expected in carrots |

| ADI | 0.005 mg/kg bw per day (EFSA, 2010) |
|------------------------------------|-----------------------------------|
| **Highest IEDI, according to EFSA PRIMo** | **Scenario 1:** 59.4% ADI (FR toddler) |
| **Contribution of carrots:** 3.4% of ADI (FR infant) |
| **Assumptions made for the calculations** | **Scenario 1:** The calculation is based on the median residue levels derived for raw agricultural commodities, using the input values derived from the reasoned opinion (EFSA, 2015), the proposed value for carrots and for other commodities the MRLs in Regulation (EU) No 149/2008 |

Other toxicological studies performed on metabolites

**In vitro genotoxicity**

- Metabolites: R54170 (compound IV), PP890 (compound Ia) and R173204 (compound VI)
- Ames test negative

**Acute toxicity:**

- Metabolites: R54170 (compound IV), and R173204 (compound VI)
- Rat LD₅₀ oral > 5,000 mg/kg bw
- PP890 (Compound Ia)
- Rat LD₅₀ oral > 4,990 mg/kg bw
- Rat LD₅₀ dermal > 2,000 mg/kg bw
- Rat LD₅₀ inhalation > 1 mg/L

B.4. Recommended MRLs

| Code⁽ᵃ⁾ | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|-------------------------|-------------------------|-----------------------|
| 0213020 | Carrots   | 0.05                    | 0.08                    | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. Risk for consumers unlikely |

**Enforcement residue definition:** Tefluthrin⁽ᶠ⁾

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.

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

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

### Tefluthrin

| Status of the active substance: | Included |
|--------------------------------|----------|
| LOQ (mg/kg bw)                 | 0.05     |
| Proposed LOQ                   |          |

#### Toxicological end points

| ADI (mg/kg bw per day): | 0.005 |
|-------------------------|-------|
| Proposed LOQ (mg/kg bw) | 0.005 |

| Source of ADI: | Source of ARfD: | Year of evaluation |
|----------------|-----------------|--------------------|
| EFSA           | EFSA            | 2010               |

#### Year of evaluation:

| 2010 |
|------|

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|--------------------------------|---------------------------------------------|
|                                |                                             |

#### No of diets exceeding ADI

| Commodity/group of commodities | TMDI values in % of ADI | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) | pTMRLs at LOQ (in % of ADI) |
|--------------------------------|-------------------------|---------------------------------------------|-----------------------------------------|-----------------------------------------|---------------------------|
|                                |                         | Commodity/ group of commodities             | Commodity/ group of commodities         | Commodity/ group of commodities         |                           |
|                                |                         |                                             |                                         |                                         |                           |
| 59.4  | FR toddler             | 39.6 Milk and cream                       | 2.5 Apples                              | 2.6 Apples                              | 1.0                       |
| 58.6  | NL child               | 29.3 Milk and cream                       | 6.3 Apples                              | 4.7 Wheat                               | 2.0                       |
| 54.8  | UK infant              | 38.7 Milk and cream                       | 2.6 Wheat                               | 2.0 Sugar beet (root)                   | 3.3                       |
| 47.6  | DE child               | 14.3 Milk and cream                       | 12.1 Apples                             | 4.1 Wheat                               | 1.6                       |
| 40.6  | WHO Cluster diet B     | 8.5 Wheat                                | 3.2 Milk and cream                      | 3.1 Tomatoes                            | 1.1                       |
| 39.3  | UK Toddler             | 20.7 Milk and cream                       | 4.6 Sugar beet (root)                   | 3.9 Wheat                               | 5.9                       |
| 38.0  | FR infant              | 25.7 Milk and cream                       | 2.5 Apples                              | 0.8 Beans (with pods)                   | 1.6                       |
| 36.9  | DK child               | 12.6 Milk and cream                       | 5.5 Wheat                               | 4.4 Rye                                 | 0.9                       |
| 33.0  | IE adult               | 3.5 Sweet potatoes                       | 2.8 Milk and cream                      | 2.3 Maize                               | 0.8                       |
| 31.7  | ES child               | 12.5 Milk and cream                       | 4.4 Wheat                               | 1.5 Bovine                              | 0.9                       |
| 27.1  | SE general population 90th percentile | 12.4 Milk and cream | 3.2 Wheat | 1.8 Banana | 1.3 |
| 24.8  | WHO cluster diet E     | 3.9 Wheat                                | 3.0 Milk and cream                      | 1.6 Wine grapes                         | 1.1                       |
| 24.1  | WHO cluster diet D     | 6.5 Wheat                                | 5.0 Milk and cream                      | 1.0 Tomatoes                            | 1.0                       |
| 21.9  | WHO regional European diet | 4.8 Milk and cream | 3.0 Wheat | 1.5 Swine | 1.1 |
| 20.8  | WHO Cluster diet F     | 4.0 Milk and cream                       | 3.6 Wheat                               | 1.3 Swine                               | 1.0                       |
| 18.8  | NL general             | 6.6 Milk and cream                       | 2.1 Wheat                               | 1.2 Apples                              | 0.9                       |
| 17.8  | ES adult               | 5.0 Milk and cream                       | 2.3 Wheat                               | 0.8 Swine                               | 0.5                       |
| 16.8  | FR all population      | 4.0 Wine grapes                          | 3.3 Wheat                               | 2.7 Milk and cream                      | 0.4                       |
| 15.4  | UK adult               | 5.4 Milk and cream                       | 2.0 Wheat                               | 1.4 Wine grapes                         | 0.4                       |
| 15.3  | IT kids/toddler        | 6.6 Wheat                                | 1.5 Other cereals                       | 1.4 Tomatoes                            | 0.3                       |
| 15.0  | PT General population  | 3.9 Wheat                                | 2.5 Wine grapes                         | 1.1 Potatoes                            | 1.4                       |
| 13.4  | LT adult               | 4.0 Milk and cream                       | 1.9 Apples                              | 1.1 Swine                               | 0.7                       |
| 12.3  | UK vegetarian          | 3.3 Milk and cream                       | 2.0 Wheat                               | 0.8 Wine grapes                         | 1.3                       |
| 12.1  | FI adult               | 5.7 Milk and cream                       | 1.0 Wheat                               | 0.7 Rye                                 | 0.5                       |
| 11.2  | IT adult               | 4.1 Wheat                                | 1.2 Tomatoes                            | 0.8 Apples                              | 0.2                       |
| 11.0  | UK Adult               | 3.0 Milk and cream                       | 1.7 Wheat                               | 1.1 Wine grapes                         | 1.3                       |
| 6.5   | PL general population  | 2.0 Apples                               | 0.9 Tomatoes                            | 0.7 Potatoes                            | 0.8                       |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Tefluthrin is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

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

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

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

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

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

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

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 exceedance of the ARfD/ADI was identified for any unprocessed commodity.

Acute risk assessment/children – refined calculations

| Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) |
|-----------------------------------|-----------------------------|-----------------------------------|-----------------------------|
| 82.4 Carrots                      | 0.065/-                     | 58.9 Carrots                      | 0.065/-                     |
| 15.4 Carrots                      | 0.065/-                     | 12.3 Carrots                      | 0.065/-                     |
| 68.6 Carrot, juice                | 0.08/-                      |

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

Conclusion:

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

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

For processed commodities, no exceedance of the ARfD/ADI was identified.

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

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

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.
Appendix D – Input values for the exposure calculations

### D.1. Livestock dietary burden calculation

| Feed commodity                      | Median dietary burden | Maximum dietary burden |
|-------------------------------------|-----------------------|------------------------|
|                                     | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment |
| **Tefluthrin**                      |                       |                        |                      |         |
| Swedes                             | 0.02                  | STMR                   | 0.07                 | HR (EFSA, 2015) |
| Turnips                            | 0.02                  | STMR                   | 0.07                 | HR (EFSA, 2015) |
| Sugar beet, dried pulp             | 0.18                  | STMR x default PF (18) | (EFSA, 2015)         |         |
| Sugar beet tops and leaves         | 0.01                  | STMR                   | 0.01                 | HR (EFSA, 2015) |
| Carrots                            | 0.01                  | STMR                   | 0.07                 | HR       |
| Other food/feed commodities        | MRLs listed for the food/feed commodities under Regulation (EC) No 149/2008 (0.05 mg/kg, except potato 0.01* mg/kg)^(a) | |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; MRL: maximum residue level.

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

(a): In the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities. For potato, as the MRL is 0.01* mg/kg the PF of 1 was used.

### D.2. Consumer risk assessment

| Commodity                                | Chronic risk assessment | Acute risk assessment |
|------------------------------------------|-------------------------|-----------------------|
|                                          | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Carrots                                  | 0.01                    | STMR                  | 0.065               | HR       |
| Beetroots, celeriacs, swedes, turnips    | 0.02                    | STMR (EFSA, 2015)     |                      |         |
| Radishes                                 | 0.03                    | STMR (EFSA, 2015)     |                      |         |
| Garlic, onions                           | 0.01                    | STMR (EFSA, 2015)     |                      |         |
| Shallots                                 | 0.01                    | STMR (EFSA, 2015)     |                      |         |
| Herbal infusions from roots, root and rhizome spices | 0.16                    | STMR (EFSA, 2015)     |                      |         |
| Sugar beet root, chicory roots           | 0.01                    | STMR (EFSA, 2015)     |                      |         |
| Other plant and animal commodities       | EU MRLs                 | MRLs listed for the food/feed commodities under Regulation (EC) No 149/2008 | |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
### Appendix E – Used compound codes

| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|-------------------|--------------------------------|--------------------|
| **Tefluthrin**    | 2,3,5,6-tetrafluoro-4-methylbenzyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate or 2,3,5,6-tetrafluoro-4-methylbenzyl (1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate | ![Structural formula](image1.png) |
| **Compound Ia**   | PPP890 (1RS,3RS)-3-[(1Z)-2-chloro-3,3,3-trifluoroprop-1-en-1-yl]-2,2-dimethylcyclopropane-1-carboxylic acid | ![Structural formula](image2.png) |
| **Compound IV**   | RS4170 tetrafluoroterephthalic acid | ![Structural formula](image3.png) |
| **Compound VI**   | R173204 2,3,5,6-tetrafluoro-4-(hydroxymethyl)benzoic acid | ![Structural formula](image4.png) |
| **Compound XI**   | (1RS,2RS,3RS)-3-[(1Z)-2-chloro-3,3,3-trifluoroprop-1-en-1-yl]-2-(hydroxymethyl)-2-methylcyclopropanecarboxylic acid | ![Structural formula](image5.png) |

SMILES: simplified molecular-input line-entry system.