Modification of the existing maximum residue levels for thiacloprid in corn gromwell seeds and radish

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Nature’s Crops International submitted a request to the competent national authority in the United Kingdom to modify the existing maximum residue level (MRL) for the active substance thiacloprid in corn gromwell seeds. Furthermore, the competent national authority in Belgium compiled an application to modify the existing MRL for the active substance thiacloprid in radish. The renewal process for thiacloprid is currently ongoing; in 2015, the Committee for Risk Assessment concluded that the classification as Cat. 1B for adverse effects on development according to CLP criteria is warranted (H360FD). Considering that there is strong evidence that this active substance meets the cut-off criteria for non-approval defined in Article 4 of Regulation (EC) No 1107/2009, further risk management considerations have to be taken into account before a decision on the amendment of the existing MRLs is taken. The data submitted were compliant with the currently applicable legal requirement to derive MRL proposals for corn gromwell seeds and radish. The estimated exposure resulting from the residues of thiacloprid in corn gromwell seeds and radishes is not expected to exceed the toxicological reference values.

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Keywords: thiacloprid, corn gromwell seeds, radish, pesticide, MRL, consumer risk assessment

Requestor: European Commission
Question numbers: EFSA-Q-2017-00423; EFSA-Q-2017-00685
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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Nature’s Crops International submitted an application to the competent national authority in the United Kingdom to modify the existing maximum residue level (MRL) for the active substance thiacloprid in corn gromwell seeds. The United Kingdom 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 16 May 2017. To accommodate for the intended use of thiacloprid, the UK proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.3 mg/kg. Furthermore, the competent national authority in Belgium compiled an application to modify the existing MRL for the active substance thiacloprid in radish. Belgium 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 2 October 2017. To accommodate for the intended use of thiacloprid, Belgium proposed to raise the existing MRL from 0.05 mg/kg to 0.7 mg/kg.

It is highlighted to risk managers that there is strong evidence that thiacloprid meets the cut-off criteria for non-approval based on the harmonised classification for fertility and development with reproduction category 1B H360FD (RAC, 2015).

The peer review for the renewal of the approval of thiacloprid in accordance with Regulation (EC) No 1107/2009 is not yet finalised. Therefore, the conclusions reported in this reasoned opinion should be taken as provisional and should be reconsidered in the light of the outcome of the peer review. Considering that thiacloprid may meet the cut-off criteria for non-approval, the active substance is currently assessed under the provisions of negligible exposure to satisfy points 3.6.3 and 3.6.4 of Annex II of Regulation 1107/2009, i.e. residues of thiacloprid on food and feed should not exceed the default value set at the limit of quantification.

A risk management decision needs to be taken, whether it is appropriate to raise the existing MRLs for the intended uses of thiacloprid in radishes and in corn gromwell seeds.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. The data submitted were found to be compliant with the currently applicable requirements and guidance documents. The following conclusions were derived:

- The metabolism of thiacloprid in primary crops was sufficiently investigated.
- Studies investigating the effect of processing on the nature of thiacloprid (hydrolysis studies) demonstrated that the active substance is stable.
- In rotational crops, the major residues identified were four primary metabolites (M02, M30, M34 and M37). All metabolites were considered of no toxicological concern. Based on the available information, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).
- For risk assessment, thiacloprid was found to be the appropriate residue definition for plant products; the same residue definition should be applied for risk assessment. This residue definition is applicable to primary crops, rotational crops and processed products.
- Sufficiently validated analytical methods based on high-performance liquid chromatography (HPLC) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues (LOQ) at or above 0.01 mg/kg in radish and 0.02 mg/kg in corn gromwell seeds.
- Specific processing studies for corn gromwell seeds and radish were not provided and are not required since the crops are low contributors to the total exposure.
- The toxicological profile of thiacloprid was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.03 mg/kg bw. It is to be noted that toxicological reference values may be revised during the ongoing peer review.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO).
Overall, EFSA derived the conclusions summarised in the table below.

| Code\(^{(a)}\) | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|--------------|----------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0401120      | Borage seeds (Corn gromwell seeds) | 0.02\(^*\)             | Further risk management considerations needed | Further risk management consideration required taking into account the evidence that the active substance thiacloprid meets the cut-off criteria for non-approval. The submitted data are sufficient to derive a MRL proposal of 0.3 mg/kg by extrapolation from oilseed rape. The calculated exposure (short-term and long-term) did not exceed the toxicological reference values |
| 0213080      | Radishes                   | 0.05                    | Further risk management considerations needed | Further risk management consideration required taking into account that the active substance thiacloprid meets the cut-off criteria for non-approval. The submitted data are sufficient to derive a MRL proposal of 0.7 mg/kg for the intended indoor use. The calculated exposure (short-term and long-term) did not exceed the toxicological reference values |

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

MRL: maximum residue level.

\(^{*}\): Indicates that the MRL is set at the limit of analytical quantification (LOQ).
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Assessment

The detailed description of the intended uses of thiacloprid in corn gromwell seeds and radish, which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Thiacloprid is the ISO common name for (Z)-3-(6-chloro-3-pyridylmethyl)-1,3-thiazolidin-2-ylidenecyanamide (IUPAC). The chemical structure of the active substance is reported in Appendix D. Thiacloprid belongs to the group of neonicotinoids, which are used as insecticides.

Thiacloprid was evaluated in the framework of Directive 91/414/EEC1 by United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2004/99/EC2 which entered into force on 1 January 2005. In accordance with Regulation (EU) No 540/20113 thiacloprid is approved as an insecticide under Regulation (EC) No 1107/20094, repealing Council Directive 91/414/EEC. The representative uses supporting the Annex I inclusion were uses on various pome fruits, stone fruits, fruiting vegetables, cucurbits and ornamentals. The draft assessment report (DAR) (United Kingdom, 2000) was not peer reviewed by the European Food Safety Authority (EFSA); therefore, no EFSA conclusion is available. The renewal process is currently ongoing (United Kingdom, 2017). It is highlighted to risk managers that thiacloprid meets the cut-off criteria for non-approval based on the harmonised classification for fertility and development with reproduction category 1B H360FD (RAC, 2015). Thiacloprid is therefore being assessed under the provisions of negligible exposure (United Kingdom, 2017) to satisfy points 3.6.3 and 3.6.4 of Annex II of Regulation 1107/2009, i.e. residues of thiacloprid on food and feed should not exceed the default value set at the limit of quantification (LOQ).

The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014) and the MRLs established in Annex II of Regulation (EC) No 396/20055 have been modified, taking into account the recommendations of EFSA. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for thiacloprid. The proposals from these reasoned opinions have been considered in recent regulations6 for European Union (EU) MRL legislation.

EFSA based its assessment on the evaluation reports submitted by the evaluating Member States (EMSs) (United Kingdom, 2016; Belgium, 2017), the DAR (United Kingdom, 2000) prepared under Council Directive 91/414/EEC, the Commission review report on thiacloprid (European Commission, 2004), as well as the conclusions from previous EFSA opinions on thiacloprid (EFSA, 2014, 2015, 2016a).

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, 1997a–g, 2000, 2010a,b, 2015; 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 546/20117.

As the EU pesticides peer review for the renewal of the approval of thiacloprid in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion should be taken as provisional and should be reconsidered in the light of the outcome of the peer review.

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, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation reports submitted by the EMS (United Kingdom, 2016; Belgium, 2017) 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 2004/99/EC of 1 October 2004 amending Council Directive 91/414/EEC to include acetamiprid and thiacloprid as active substances. OJ L 309, 6.10.2004, p. 6–8.
3 Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
5 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.
6 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eur-pesticides-database/public/?event=pesticide.residue.selection&language=EN
7 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 thiacloprid in primary crops for foliar and soil applications belonging to the group ‘fruit and fruiting vegetables’ (apple, tomato) and on ‘pulses and oilseeds’ (cotton) was assessed during the peer review (United Kingdom, 2000). An additional study on cereals (wheat) for foliar application was evaluated by UK after Annex I inclusion.

In tomato, apple, wheat grain and straw, thiacloprid parent compound was the main component. The majority of the applied radiolabelled active substance on apples (80% of total radioactive residue (TRR)) remained on leaves; translocation from leaves or roots to fruit did not occur. The translocation study performed on tomatoes showed that phloem and xylem translocation did not occur. In cotton plants, a similar metabolic behaviour was observed. Residues of parent thiacloprid were low in cotton seeds (0.6% of TRR); the main metabolite was 6-chloronicotinic acid (M03) accounting for 45.8% of the TRR (United Kingdom, 2000).

During the MRL review (EFSA, 2014), 6-chloronicotinic acid was not considered of toxicological relevance and additional toxicological studies were not required. During the MRL review of acetamiprid (EFSA, 2016b), the same metabolite was encountered and its toxicity was concluded to be covered by the toxicity of the parent acetamiprid. This was confirmed by the peer review of acetamiprid (EFSA, 2016b). The toxicological reference values of acetamiprid (0.025 mg/kg body weight (bw) and 0.025 mg/kg bw per day) are of a comparable order of magnitude as to those of thiacloprid (0.03 mg/kg bw and 0.01 mg/kg bw per day); based on these data, 6-chloronicotinic acid is not expected to exhibit greater toxicity than thiacloprid.

1.1.2. Nature of residues in rotational crops

Corn gromwell seeds and radish may be grown in rotation with other plants. The soil degradation studies performed in the framework of the peer review showed that the DT_90 value of thiacloprid is below the trigger value of 100 days (United Kingdom, 2000). However, thiacloprid metabolites (M02, M30, M34, M37) were shown to be persistent in soil but were not considered of toxicological concern and a specific residue definition for rotational crops was not deemed necessary (EFSA, 2014).

1.1.3. Nature of residues in processed commodities

Processing studies simulating hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (100 min at 120°C, pH 6), showed that the recovery of radiolabelled thiacloprid was approximately 97% for all solutions. Therefore, processing under these conditions is not expected to have a significant impact on the nature of residues in matrices of plant origin (United Kingdom, 2000).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of thiacloprid in plant commodities were assessed in the framework of the peer review and the Article 12 MRL review (United Kingdom, 2000; EFSA, 2014).

An analytical method using high performance liquid chromatography with ultra-violet detection (HPLC-UV) was validated for the determination of parent thiacloprid in high water content (apple) and high oil content (cotton seed) matrices with an LOQ of 0.02 mg/kg. An independent laboratory validation (ILV) was provided for this method. The confirmatory method used a cyano phase column. A second method for high oil content commodities, validated in rape seed, was provided in the framework of the current application (United Kingdom, 2016) which allowed the quantification at or above the LOQ of 0.02 mg/kg.

A multiresidue Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method in combination with high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) was described by CEN (2008a,b) for the analysis of thiaclopyrid in high water, acidic and dry commodities with an LOQ of 0.01 mg/kg.
EFSA concluded that adequate analytical methods are available to monitor residues of thiacloprid in high water content commodities to which radish belongs with a LOQ of 0.01 mg/kg and in high oil content commodities to which corn gromwell seed belongs with a LOQ of 0.02 mg/kg (EFSA, 2014).

1.1.5. Stability of residues in plants

Storage stability was investigated in the DAR where storage stability of thiacloprid was demonstrated for high water content commodities (apple, tomato and melon peel) at –18°C for a period of 18 months.

In the present application, storage stability was investigated for high oil content commodities (oilseed rape). Rape seed was fortified at 0.20 mg/kg of thiacloprid. Residues were determined by HPLC-MS/MS with an analytical method at a LOQ of 0.02 mg/kg. The samples were stored for a period of 24 months at or below –18°C, demonstrating stability.

All supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated and it is therefore concluded that the residue data are valid with regard to the storage stability.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified, the behaviour in rotational and processed products and the availability of the analytical methods for enforcement, the residue definition ‘thiacloprid (only parent compound)’ proposed for risk assessment and enforcement during the MRL review (EFSA, 2014), remains appropriate and no modification is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

**Corn gromwell seeds**

Corn gromwell seed is a crop listed in Part B of Annex I to Regulation (EC) No 396/2005 under the crop code 0401120 (borage seeds). Specific residue trials on corn gromwell seeds were not submitted. The EMS UK proposed to extrapolate residue trials on oilseed rape to borage seed.

Eight residue trials conducted on oilseed rape were submitted in support of the northern Europe (NEU) good agricultural practice (GAP) for corn gromwell seeds, which is considered a minor crop and for which four trials are sufficient to derive a MRL proposal. The application was submitted in February 2016 when version 10.1 of the extrapolation guidance document (SANCO 7525/95 rev. 10.1, (European Commission, 2015)) was in place. According to the UK, extrapolation of residue trials from ‘any representatives of the group oilseeds, except peanuts/groundnuts’ can be used to support the ‘whole group oilseeds, except peanuts/groundnuts’ allowing treatments ‘after forming of the edible part’, ‘before forming of the edible part’ and ‘seed treatments’. Therefore, oilseed rape residue trials are appropriate to support the intended GAP on corn gromwell seed and propose a MRL of 0.3 mg/kg.

**Radish**

Radish is a minor crop in the northern EU zone. Therefore, the four individual residue supervised trials submitted are sufficient to support the GAP and allow proposing a MRL of 0.7 mg/kg for thiacloprid in radish.

1.2.2. Magnitude of residues in rotational crops

Rotational crop field trials are not available. A confined metabolism study on rotational crops was evaluated during the peer review in lettuce (leafy crop), turnip (root crop) and wheat (cereal crop) planted after bare soil application with radiolabelled thiacloprid at 0.424 kg a.s./ha. The TRR was similar in crops with 30 and 170 days plant-back interval (PBI) and a small decrease at 354 days PBI. Thiacloprid was not detected and the residue concentrations of individual metabolites (M02, M30, M34, M37) were at or below 0.1 mg/kg with the exception of wheat straw.

The intended application rates on radish and corn gromwell are 0.24 kg a.s./ha (two applications of 0.120 kg a.s./ha) and 0.144 kg a.s./ha (two applications in winter of 0.072 kg a.s./ha and only one application in spring), respectively.
Considering that the application rate of the rotational crop studies described was 2.9N compared to the corn gromwell proposed GAP, and 1.8N compared to the radish proposed GAP and thiacloprid metabolites were not considered of toxicological concern (see Section 1.1.2), the residues in rotational crops are not expected to be of concern for the uses under assessment when thiacloprid is applied in compliance with the GAP.

1.2.3. Magnitude of residues in processed commodities

In view of the stability of thiacloprid in processing simulation studies and that radish is a minor contributor in the human diet, no further processing studies are required for this commodity.

Specific studies investigating the effect of processing on oilseed rape have been evaluated by the UK (United Kingdom, 2016). The magnitude of residues of thiacloprid in unprocessed rape seed and different processed products (i.e. screw-pressed solvent extracted oil, crude oil, 8 neutralised crude oil, refined oil, pomace, 9 extracted meal 10) was determined. Reliable processing factors can be derived only for pomace and extracted meal as the method validation and procedural recoveries are not available for other products. The studies demonstrated that there is some concentration of the residue in the extracted meal and possibly in the press cake following the drying process. Considering the different oil content of rape seed and corn gromwell, an extrapolation of the processing factors for rape seed to corn gromwell is not recommended.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for corn gromwell seeds and radish (see Appendix B.4). In Section 3, EFSA assessed whether residues on corn gromwell seeds and radish resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as corn gromwell seeds and radishes are not included in OECD calculator of residues in livestock (OECD, 2013).

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRImo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD)) were derived in the framework of the EU pesticides peer review on thiacloprid (European Commission, 2004).

The short-term exposure assessment for radishes was performed in accordance with the internationally agreed methodology combining the consumption of radishes with the highest residue (HR) derived from supervised field trials. For borage seeds/corn gromwell seed, lacking specific consumption data in the EFSA PRImo rev. 2, the EMS proposed to use the consumption data of an alternative minor oilseed crop to calculate the short-term exposure, using the supervised trial median residue (STMR) (case 3 of IESTI equation) (FAO, 2016). The short-term exposure did not exceed the ARfD for both crops.

In the framework of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level (EFSA, 2014). EFSA updated the calculation with the relevant STMR values derived from the residue trials submitted in support of these MRL applications on borage seeds (where corn gromwell seed belongs to the same group) and radish. In addition, for Jerusalem artichokes (EFSA, 2015) and honey (EFSA, 2016a) STMR values derived in the previous EFSA opinion published after the MRL review were used as an input value. The estimated long-term dietary intake was in the range of 6–30% of the ADI. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.3.

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8 Combine screw-pressed oil and oil derived by solvent extraction with n-hexane.
9 Derived after pressing of rape seed.
10 Derived from pomace, after extraction with n-hexane.
EFSA concluded that the long-term intake of residues resulting from the existing uses of thiacloprid and the intended new uses of thiacloprid on corn gromwell seeds and radish does not exceed the ARfD. It is however highlighted that there is strong evidence thiacloprid meets the cut-off criteria for non-approval (United Kingdom, 2017); the substance is currently assessed in the ongoing peer review under the provisions of negligible exposure to satisfy points 3.6.3 and 3.6.4 of Annex II of Regulation (EC) No 1107/2009.

The input values used in the exposure calculations are summarised in Appendix D.1.

4. Conclusion and Recommendations

It is highlighted that there is strong evidence that thiacloprid meets the cut-off criteria for non-approval.

The data submitted in support of this MRL application were found to be compliant with the data requirements and relevant guidance documents.

However, further risk management considerations need to be taken into account before a decision on amendment of the existing MRLs is taken.

The endpoints of the assessment can be found in Appendix B.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement to risk assessment residue definition
DAR draft assessment report
DAT days after treatment
DT90 period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HPLC high performance liquid chromatography
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
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS/MS tandem mass spectrometry detector
NEU northern Europe
OD oil dispersion
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
| Abbreviation | Description                                |
|--------------|--------------------------------------------|
| 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           |
| TRR          | total radioactive residue                   |
| UV           | ultraviolet (detector)                     |
### 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 |
|-----------------------|--------------------------|------------|-----------------------------------|-------------|------------|--------------------------------|
|                       |                          |            |                                   | Type(b)     | Conc. a.s. | Method kind                     | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate | Unit | PHI (days)(d) | Remarks                  |
| Corn gormwell – winter sown crop | NEU | F | Aphids | OD | 240 g/L | Horizontal boom sprayer | BBCH 30-59 | 2 | – | 200–400 | 72 g a.s./ha | 30 | 0.3 L/ha of product |
| Corn gormwell – spring sown crop | NEU | F | Aphids | OD | 240 g/L | Horizontal boom sprayer | BBCH 30-59 | 1 | – | 200–400 | 72 g a.s./ha | 30 | 0.3 L/ha of product |
| Radish                | NEU | G | Aphids | SC | 480 g/L | Spraying until BBCH 48 | 1–2 | 14 days | 120 g a.s./ha | 7 | |

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: good agricultural practice; MRL: maximum residue level; a.s.: active substance; OD: oil dispersion; SC: suspension concentrate.

(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: e.g. oil dispersion (OD), suspension concentrate (SC).

(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 pre-harvest 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                                                           |             | Apple       | Foliar spraying, 2 × 0.27 kg a.s./ha            | 14             | 14C-methylene label; glasshouse/protected/indoor application                     |
|                                                                       |             | Tomato      | Foliar spraying, 2 × 0.26 kg a.s./ha            | 3, 14          | 14C-methylene label; glasshouse/protected/indoor application                     |
|                                                                       |             | Tomato      | Soil, 2 × 0.13 kg a.s./ha                       | 3, 14          | 14C-methylene label; glasshouse/protected/indoor application                     |
|                                                                       |             |             |                                                |                |                                                                                          |
| Cereals/grass                                                        |             | Wheat       | Foliar spraying, 2 × 0.05 kg a.s./ha             | 21             | 14C-methylene label; grain, straw                                                   |
|                                                                       |             |             |                                                |                |                                                                                          |
| Pulses/oilseeds                                                      |             | Cotton      | Foliar spraying, 3 × 0.19 kg a.s./ha             | 120            | 14C-methylene label; glasshouse/protected/indoor application                     |
|                                                                       |             |             |                                                |                | Leaves, gin trash, seeds                                                          |

| Rotational crops (available studies)                                  | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source                                                                 |
|-----------------------------------------------------------------------|-------------|---------|----------------|-----------|--------------------------------------------------------------------------------|
| Root/tuber crops                                                      | Turnip      | 0.42    |                | 30, 170, 354 | United Kingdom (2000)                                                          |
| Leafy crops                                                           | Lettuce     | 0.42    |                | 30, 170, 354 | United Kingdom (2000)                                                          |
| Cereal (small grain)                                                  | Wheat       | 0.42    |                | 30, 170, 354 | United Kingdom (2000)                                                          |

| Processed commodities (hydrolysis study)                              | Conditions  | Stable? | Comment/Source |
|-----------------------------------------------------------------------|-------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)                                   | Yes         |         | United Kingdom (2000) |
| Baking, brewing and boiling (60 min, 100°C, pH 5)                     | Yes         |         | United Kingdom (2000) |
| Sterilisation (20 min, 120°C, pH 6)                                   | Yes         |         | United Kingdom (2000) |

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; LC-MS/MS: liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation.
Can a general residue definition be proposed for primary crops? yes
Rotational crop and primary crop metabolism similar? yes
Residue pattern in processed commodities similar to residue pattern in raw commodities? yes
Plant residue definition for monitoring (RD-Mo)

| Plant products (available studies) | Category        | Commodity                        | T (°C) | Stability period | Compounds covered | Comment/Source           |
|-----------------------------------|-----------------|----------------------------------|--------|------------------|-------------------|--------------------------|
|                                   | High water content | Apple, tomato and melon peel | –18    | 18 months        | Thiacloprid       | United Kingdom (2000)    |
|                                   | High oil content  | Oilseed rape                     | –18    | 24 months        | Thiacloprid       | United Kingdom (2016)    |

Plant residue definition for risk assessment (RD-RA) Thiacloprid

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

Matrices with high water content, high acid content and dry matrices: LM-MS/MS, LOQ 0.01 mg/kg
Matrices with high oil content: HPLC-UV, LOQ 0.02 mg/kg
Confirmatory method available.
ILV available.
(EFSA, 2014)

B.1.1.2. Stability of residues in plants

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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<sup>(c)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR (mg/kg) | CF<sup>(c)</sup> |
|----------------------|-----------------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|-------------------------------------|--------------------------|---------------|-----------------|
| Corn gromwell seeds  | NEU                         | 0.02, 0.05, 2 × 0.06, 2 × 0.08, 0.09, 0.12                      | Residue trials on oilseed rape compliant with GAP. Extrapolation to corn gromwell seeds possible | 0.30                                | 0.12                     | 0.07          | 1               |
| Radish               | Indoor                      | 0.02, 0.05, 0.20, 0.27                                          | Residue trials on radish compliant with GAP. Number of trials is sufficient since radishes are considered a minor crop | 0.70                                | 0.27                     | 0.13          | 1               |

MRL: maximum residue level; GAP: good agricultural practice.

(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): 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? | no |
|-----------------------------------------------------------------------------------------------|----|
| Parent thiacloprid degrades fast. Metabolites formed of no toxicological concern. (EFSA, 2014) |    |
| No relevant residues expected on corn gromwell seeds and radish. |

| Residues in rotational and succeeding crops expected based on field rotational crop study? | no |
|-----------------------------------------------------------------------------------------------|----|
| Not applicable |    |

B.1.2.3. Processing factors

No processing factors proposed.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

| ARfd | 0.03 mg/kg bw (European Commission, 2004) |
|------|------------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Radishes: 19.7 % of ARfd Corn gromwell/borage: no consumption data on PRIMo rev.2. Alternatively, another minor crop: safflower: 0.9 % of ARfD. |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities. |

| ADI | 0.01 mg/kg bw per day (European Commission, 2004) |
|-----|-----------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 30.1% ADI (WHO cluster diet B) Contribution of crops assessed: Radish: 0.087% of ADI Corn gromwell/borage: no consumption data on PRIMo rev.2; neither safflower. |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for the crops under consideration and for all the other uses assessed in previous reasoned opinions (EFSA 2014, 2015, 2016a). |
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|-----------|------------------------|-------------------------|------------------------|
| 0401120           | Borage seeds (Corn gromwell seeds) | 0.02<sup>*</sup> | | Further risk management considerations needed |
| 0213080           | Radishes | 0.05 | | Further risk management consideration required taking into account that the active substance thiacloprid meets the cut-off criteria for non-approval. The submitted data are sufficient to derive a MRL proposal of 0.7 mg/kg for the intended indoor use. The calculated exposure (short-term and long-term) did not exceed the toxicological reference values |

**Enforcement residue definition:** Thiacloprid

MRL: maximum residue level.

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

<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.
Appendix C – Pesticide Residue Intake Model (PRIMo)

**Thiacloprid**

**Status of the active substance:**

| Code no. | LOQ (mg/kg bw) | proposed LOQ |
|----------|----------------|--------------|
| LOQ (mg/kg bw) | 0.01 | 0.03 |

**Toxicological end points**

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|-------------------------|------------------|
| 0.01                    | 0.03             |

**Source of ADI:**

| Source of ADI | Year of evaluation |
|---------------|--------------------|
| EC            | 2004               |

**Source of ARfD:**

| Year of evaluation |
|--------------------|
| 2004               |

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).

The pTMRLs have been submitted to EFSA in September 2006.

**Theoretical Maximum Daily Intakes (TMDI)**

| Commodity/group of commodities | TMDI (range) in % of ADI | MS Diet |
|-------------------------------|--------------------------|---------|
|                               | minimum - maximum        |         |
| Milk and cream                | 4.3                      | 30%     |
| Milk and cream                | 6.3                      | 28%     |
| Apples                        | 2.0                      | 26%     |
| Sugar beet (root)             | 4.6                      | 24%     |
| Sugar beet (root)             | 2.5                      | 21%     |
| Apples                        | 2.0                      | 18%     |
| Apples                        | 2.2                      | 17%     |
| Milk and cream                | 1.3                      | 15%     |
| Milk and cream                | 1.5                      | 14%     |
| Milk and cream                | 1.5                      | 13%     |
| Milk and cream                | 1.4                      | 13%     |
| Milk and cream                | 1.4                      | 12%     |
| Milk and cream                | 1.2                      | 12%     |
| Milk and cream                | 1.5                      | 11%     |
| Milk and cream                | 1.1                      | 11%     |
| Milk and cream                | 1.2                      | 10%     |
| Milk and cream                | 2.0                      | 10%     |
| Milk and cream                | 1.2                      | 10%     |
| Milk and cream                | 1.0                      | 9%      |
| Milk and cream                | 0.9                      | 9%      |
| Milk and cream                | 1.4                      | 8%      |
| Milk and cream                | 0.8                      | 8%      |
| Milk and cream                | 0.8                      | 7%      |
| Milk and cream                | 0.8                      | 7%      |
| Milk and cream                | 0.9                      | 6%      |
| Milk and cream                | 0.8                      | 6%      |
| Milk and cream                | 0.8                      | 6%      |
| Milk and cream                | 0.9                      | 5%      |
| Milk and cream                | 0.8                      | 5%      |
| Milk and cream                | 0.8                      | 5%      |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs, were below the ADI.

A long-term intake of residues of Thiacloprid is unlikely to present a public health concern.

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### Acute risk assessment/children – refined calculations

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.

| Unprocessed commodities | No. of commodities for which ARfD/ADI is exceeded (ESTI 1): ***) | No. of commodities for which ARfD/ADI is exceeded (ESTI 2): ***) | No. of commodities for which ARfD/ADI is exceeded (ESTI 1): **) | No. of commodities for which ARfD/ADI is exceeded (ESTI 2): **) |
|-------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| Highest % of ARfD/ADI   | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) |
| 19.7                    | Radishes    | 0.27/-                         | 14.1                    | Radishes    | 0.27/-                         | 10.0                    | Radishes    | 0.27/-                         | 7.1                    | Radishes    | 0.27/-                         |
| 0.9                     | Safflower   | 0.07/-                         | 0.9                     | Safflower   | 0.07/-                         | 0.5                     | Safflower   | 0.07/-                         | 0.5                   | Safflower   | 0.07/-                         |

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

| No. of critical MRLs (ESTI 1) | --- |
| No. of critical MRLs (ESTI 2) | --- |

| Processed commodities | No. of commodities for which ARfD/ADI is exceeded: **(*) | No. of commodities for which ARfD/ADI is exceeded: **||*) |
|-----------------------|-------------------------------------------------|-------------------------------------------------|
| Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) |
| 239.8                 | Raspberries juice | 62.5 | 6.8 | Apple juice | 0.3/- |
| 53.4                  | Elderberry juice | 1/-   | 3.3 | Peach preserved with syrup | 0.5/- |
| 51.0                  | Apple juice | 0.3/- | 3.2 | Tomato (preserved) | 0.5/- |
| 33.7                  | Currant juice | 1/-   | 2.7 | Quince jelly | 0.5/- |
| 29.8                  | Peach juice | 0.5/- | 1.5 | Bread/pizza | 0.1/- |

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

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

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

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

** Conclusion:

For Thiacloprid, 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, the ARfD/ADI was exceeded in one or several cases.

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### Appendix D – Input values for the exposure calculations

#### D.1. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Corn gromwell              | 0.07                    | STMR                  | 0.07                | STMR    |
| Radish                     | 0.13                    | STMR                  | 0.27                | HR      |
| Honey                      | 0.06                    | STMR (EFSA, 2016a)    |                      |         |
| Jerusalem artichokes       | 0.01                    | STMR (EFSA, 2015)     |                      |         |
| Other plant and animal     | STMR                    | Based on MRL review   |                      |         |
| commodities               |                         | (EFSA, 2014)          |                      |         |

STMR: supervised trials median residue; HR: highest residue.
| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|------------------|-------------------------------------------------|----------------------------------|
| Thiacloprid      | (Z)-3-(6-chloro-3-pyridylmethyl)-1,3-thiazolidin-2-ylidene cyanamide  \  Clc2nc(CN1CCS/C1=N\#N)cc2 \  HOKKPVRIMVDYPB-UVDQMKNSA-N | ![Structural formula](image1.png) |
| 6-chloronicotinic acid (M03) | 6-chloronicotinic acid  \  (Z)-6-chloropyridine-3-carboxylic acid  \  OC(-O)c1cncc(Cl)c1 | ![Structural formula](image2.png) |
| YRC 2894-amide (M02) | (Z)-N\{3-[(6-chloropyridin-3-yl)methyl]-1,3-thiazolidin-2-ylidene\}urea  \  NC(-O)N=C2(SCCN2Cc1cncc(Cl)c1  \  LEZHOZPJYAQQNU-UVDQMKNSA-N | ![Structural formula](image3.png) |
| YRC 2894-sulfonic acid (M30) | 2{-[carbamoylcarbamoyl][(6-chloropyridin-3-yl)methyl]amino}ethane-1-sulfonic acid  \  Clc1ccc(CN(CCS(-O)(-O)O)C(-O)NC(N)=O)cn1  \  UCZRQNICFJGZAI-UHFFFAOYSA-N | ![Structural formula](image4.png) |
| YRC 2894-sulfonic acid amide (M34) | 2{-[carbamoyl][(6-chloropyridin-3-yl)methyl]amino}ethane-1-sulfonic acid  \  Clc1ccc(CN(CCS(-O)(-O)O)C(N)=O)cn1  \  NTWIWWZFSUKDGZ-UHFFFAOYSA-N | ![Structural formula](image5.png) |
| 4-OH YRC 2894 amide (M37) | (Z)-N\{(4RS)-3-[(6-chloropyridin-3-yl)methyl]-4-hydroxy-1,3-thiazolidin-2-ylidene\}urea  \  OC2CS(C(-N)(C(N)=O)N2Cc1cncc(Cl)c1  \  GHAMYLJSMMEOHA-UVDQMKNSA-N | ![Structural formula](image6.png) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system.  
<sup>(a)</sup>: ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).  
<sup>(b)</sup>: ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).