Modification of the existing maximum residue level for clothianidin in potatoes

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer CropScience AG submitted a request to the competent national authority in Germany to modify the existing maximum residue level (MRL) for the active substance clothianidin to accommodate the use on potatoes imported from Canada. The data submitted in support of the request were found to be sufficient to derive a MRL proposal. Adequate analytical methods for enforcement are available to control clothianidin residues on the commodity under consideration. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of clothianidin according to the notified agricultural practice in Canada is unlikely to present a risk to consumer health.

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Keywords: clothianidin, potato, pesticide, thiamethoxam, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience AG submitted an application to the competent national authority in Germany (evaluating Member State (EMS)) to set an import tolerance for the active substance clothianidin in potatoes imported from Canada. 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 26 April 2018. The EMS proposed to set an import tolerance for potatoes imported from Canada at the level of 0.3 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the maximum residue level (MRL) regulation. Based on the conclusions in the framework of Directive 91/414/EEC, the data evaluated under the MRL review and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of clothianidin in primary crops was investigated in three different crop groups (fruit crops, root/tuber crops and cereals/grasses) and in rotational crops (root/tuber crops, leafy crops and cereals) during the European Union (EU) pesticides peer review. Studies investigating the effect of processing on the nature of clothianidin (hydrolysis studies) submitted in the current application demonstrated that the active substance remained stable under the standard hydrolysis conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

Based on the metabolic pattern identified in metabolism studies, the residue definitions for enforcement and risk assessment was proposed as clothianidin for primary crops, including the crop under assessment in this application, and rotational crops. The new hydrolysis studies confirmed that the residue definitions are applicable to processed products as well. Sufficiently validated analytical methods are available to quantify residues in potatoes according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg (limit of quantification (LOQ)).

The available residue trials are sufficient to derive a MRL proposal of 0.3 mg/kg for potatoes accommodating the notified seed treatment use in Canada.

Tentative processing factors for clothianidin on cooked potatoes, chips and granules were derived from a processing study on potatoes. Because of the limited number of results, they are not recommended for inclusion in Annex VI of Regulation (EC) No 396/2005.

As the crop under consideration and its by-products are used as feed products, a potential carry-over into food of animal origin was assessed. The most recent livestock dietary burden calculations performed in the framework of the MRL review were revised using the OECD livestock feeding tables and updated considering the use on potatoes under assessment. The new calculation methodology and the highest residue derived for potatoes had an impact on the livestock dietary burden compared with the previous calculations. Nevertheless, a change of the existing MRLs in products of animal origin is not required, since the existing EU MRLs for animal products are Codex MRLs (CXLs) implemented in the EU legislation. The CXLs were estimated based on burden calculations which were higher than the revised EU dietary burdens.

The toxicological profile of clothianidin was assessed in the framework of Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.097 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.1 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). Clothianidin is a relevant metabolite formed from the use of thiamethoxam, which is also approved as a pesticide. Therefore, the consumer risk assessment was conducted taking into account maximum intake of clothianidin from either the direct use of clothianidin or the use of the pesticide thiamethoxam, assuming that both compounds are not applied to the same crop in the same crop cycle. The short-term risk assessment was conducted for potato only.

EFSA concluded that the notified use of clothianidin on potatoes imported from Canada will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.
## Modification of the existing MRL for clothianidin in potatoes

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------------|-----------|------------------------|-------------------------|-----------------------|
| 0211000 | Potatoes | 0.03 | 0.3 | Import tolerance is sufficiently supported by data. The MRL proposal corresponds to the MRL value in place in Canada. The risk for consumers is unlikely |

**Enforcement residue definition:** Clothianidin

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MRL: maximum residue level. 

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

The detailed description of the use of clothianidin on potatoes notified to be authorised in Canada, which is the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Clothianidin is the ISO common name for (E)-1-(2-chloro-1,3-thiazol-5-ylimethyl)-3-methyl-2-nitroguanidine (IUPAC). It is noted that clothianidin is a relevant metabolite of thiamethoxam, another insecticide belonging to the group of neonicotinoids. The chemical structures of both active substances are reported in Appendix E.

Clothianidin was evaluated in the framework of Directive 91/414/EEC1 with Belgium designated as rapporteur Member State (RMS) for the representative uses as a seed treatment on maize and on sugar and fodder beet. The draft assessment report (DAR) prepared by the RMS was not peer reviewed by the European Food Safety Authority (EFSA). Therefore no EFSA conclusion is available. Clothianidin was approved2 for the use as an insecticide on 1 August 2006. In the EU, the use of clothianidin has been recently restricted to uses in permanent greenhouses or for the treatment of seeds intended to be used only in permanent greenhouses, provided the resulting crop stays within a permanent greenhouse during its entire life cycle.3 Member States have to amend or withdraw existing authorisations for plant protection products containing clothianidin as an active substance according to the proportion of the new regulation at the latest by 19 September 2018. These restrictions are not relevant as the MRL application is concerning an imported crop.

The EU MRLs for clothianidin are established in Annex II of Regulation (EC) No 396/20054. The review of existing MRLs for clothianidin and thiamethoxam according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014) and the proposed modifications have been implemented in the MRL legislation.5 A number of additional Codex maximum residue limits (CXLs) established by Codex Alimentarius Commission (CAC) for clothianidin have been implemented in the EU legislation by Regulation (EU) 2017/6716.

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience AG submitted an application to the competent national authority in Germany (EMS) to set an import tolerance for the active substance clothianidin in potatoes. 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 EFSA on 26 April 2018. EFSA identified a data gap in the assessment of the hydrolysis studies which was addressed in a revised evaluation report submitted by the EMS on 9 August 2018 and taken into consideration by EFSA for finalisation of this reasoned opinion.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2018), the draft assessment report (Belgium, 2003) prepared under Directive 91/414/EEC, the Commission review report on clothianidin and its addenda (European Commission, 2005, 2013, 2018) as well as the conclusions from previous EFSA opinion on the MRL review of clothianidin and thiamethoxam (EFSA, 2014).

For this application, the data requirements established in Regulation (EU) No 544/20117 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/20118.

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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 2006/41/EC of 7 July 2006 amending Council Directive 91/414/EEC to include clothianidin and pethoxamid as active substances. OJ L 187, 8.7.2006, p. 24–27.
3 Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin. OJ L 132, 30.5.2018, p. 35–39.
4 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.
5 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
6 Commission Regulation (EU) 2017/671 of 7 April 2017 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products. C/2017/2240. OJ L 97, 8.4.2017, p. 9–23.
7 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
8 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.
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, are presented in Appendix B.

The revised evaluation report submitted by the EMS (Germany, 2018) 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.

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 clothianidin in plants was investigated following seed treatment in root/tuber crops and cereals/grasses and following soil and foliar applications in fruit crops. These studies were assessed in the framework of the EU pesticides peer review and the MRL review (Belgium, 2003; EFSA, 2014). EFSA concluded that parent clothianidin represented the major component of the residues in the tested crops.

For the reported use, the metabolic behaviour in primary crops is considered as sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Not relevant, as the application is for imported crop. Details of the confined rotational crop studies assessed in the framework of the EU pesticides peer review and the MRL review (Belgium, 2003; EFSA, 2014) are presented in Appendix B for information.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of clothianidin was investigated in the framework of the current MRL application (Germany, 2018). The hydrolysis studies demonstrated that clothianidin remained stable under the standard hydrolysis conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of clothianidin residues in commodities of plant origin were evaluated under the EU pesticides peer review and the MRL review (Belgium, 2003; EFSA, 2014). Clothianidin can be enforced with a high-performance liquid chromatography with ultraviolet detection (HPLC-UV) method in high water content, high oil content and in dry matrices at the limit of quantification (LOQ) of 0.01 mg/kg and in high acid content matrices at the LOQ of 0.02 mg/kg. The multi-residue high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) (QuEChERS) method with an LOQ of 0.01 mg/kg was also found to be appropriate for enforcement purposes (EFSA, 2014).

For the determination of clothianidin residues in the crop under assessment, adequate analytical enforcement methods are available.

1.1.5. Stability of residues in plants

The storage stability of clothianidin in plants under frozen conditions was investigated in the framework of the EU pesticides peer review and the MRL review (Belgium, 2003; EFSA, 2014). It was demonstrated that in the crop group relevant for this application, residues were stable during frozen storage for at least 24 months.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in the metabolism studies, the MRL review proposed the residue definitions for enforcement and risk assessment as clothianidin for primary and rotational crops (EFSA, 2014). The new hydrolysis studies submitted confirmed that the residue definitions are applicable to processed products as well. The residue definition for enforcement is set in Regulation (EC) No 396/2005. Since clothianidin is a major metabolite of thiamethoxam, also clothianidin residues resulting from the use of thiamethoxam need to be taken into account in the risk assessment.
Taking into account the use assessed in this application, the proposed residue definitions are applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Among the submitted residue trials on potatoes, the EMS identified five independent Good Agricultural Practice (GAP)-compliant (± 25% tolerance) residue trials conducted in Canada and the USA. To complete the data set, 16 overdosed trials conducted in the USA were provided. Since not independent, EFSA disregarded two results from the overdosed trial data set. Values from both the GAP-compliant and overdosed trials were proportionally scaled to the nominal treatment rate of the Canadian GAP in order to estimate the MRL and the input values for the risk assessment reflecting the GAP under assessment.

According to the assessment of the EMS, the analytical methods used were sufficiently validated, and the trial samples were stored under conditions for which integrity was demonstrated.

1.2.2. Magnitude of residues in rotational crops

Not relevant as the application is concerning an imported crop.

1.2.3. Magnitude of residues in processed commodities

The EMS reported a processing study on potatoes investigating the effect of washing, peeling, cooking, and the production of chips and flakes. For these studies, potatoes were sampled at maturity after seed treatment at exaggerate dose rate (7.6 times the nominal application rate of the Canadian GAP). The processing factors derived from this study should be considered as tentative because of the limited number of results. However, the information was considered useful for refinement of the dietary burden calculations (see Section 2).

1.2.4. Proposed MRLs

The available data are sufficient to derive a MRL proposal of 0.3 mg/kg, which corresponds to the MRL value set in the country of origin, Canada.

2. Residues in livestock

Potatoes and by-products of potato industry can be used as feed items in livestock. The most recent calculation of the livestock dietary burdens was performed in the framework of the MRL review considering the residues of clothianidin where residues of clothianidin resulting from authorised uses of clothianidin or thiamethoxam were taken into account (EFSA, 2014). These calculations were revised considering the use of clothianidin in Canadian potatoes assessed in this application. The calculations were performed based on the OECD livestock feeding tables (OECD, 2013) and the animal model calculator amended by EFSA in 2017. It is noted that compared to the dietary burden calculations performed in the framework of the MRL review, the calculation methodology has changed, i.e. additional feed items such as carrots, by-products of potatoes, sugar beets and cereals were included in the calculation. For most by-products, the defaults processing factors (PFs) were used to estimate the residue levels, except for potato process waste, where the indicative peeling factor of 1.43 was used to refine the calculation. The input values are summarised in Appendix D.1. The results of the calculations are presented in Appendix B.3.

The new calculation methodology (OECD, 2013) and the estimated highest residue derived from imported potatoes had an impact on the livestock dietary burden compared with the previous calculations. The new calculation lead to an increased dietary burden for all species; the trigger value of 0.1 mg/kg DM was exceeded for all species, including poultry. Potato culls were the most critical feed product contributing to the ruminant/pigs and poultry exposure. Nevertheless, the existing MRLs of clothianidin set for products of animal origin (except the MRLs set at the LOQ) are Codex MRLs (CXLs), which were based on livestock dietary exposures significantly higher (6.1 for ruminants and 1.64 mg/kg dry matter (DM) for poultry, from the uses of thiamethoxam; FAO, 2014) than the burdens calculated in this framework. Thus, EFSA concludes that the use on potatoes assessment in this MRL application will not trigger a revision of the current MRLs set for products of animal origin.
3. **Consumer risk assessment**

The toxicological profile of clothianidin was assessed in the framework of Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.097 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.1 mg/kg bw (European Commission, 2005).

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).

Since clothianidin is also a relevant metabolite resulting from the use of thiamethoxam, for the risk assessment both sources (use of clothianidin and thiamethoxam) need to be considered, assuming that both compounds are not applied to the same crop in the same crop cycle.

For clothianidin, the estimated short-term intake for potatoes was 35% of the ARfD and the total calculated long-term intake accounted for 2% of the ADI; the maximum contribution of potatoes to the overall long-term intake was estimated to be 0.12% of the ADI.

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

In the framework of the MRL review of clothianidin and thiamethoxam, EFSA performed a combined risk assessment considering that clothianidin and thiamethoxam residues share a similar toxicological effect. It was assumed that consumers will be exposed to residues of both substances by summing up the exposure calculated individually, taking into account the different toxicological endpoints of the two substances (EFSA, 2014). Since the STMR value for potatoes included in the calculation of the MRL review was equal to the STMR value derived in this MRL application (0.02 mg/kg), an update of the combined long-term risk assessment is not required. Short-term risk assessment was performed only for the reported use of clothianidin in potatoes.

4. **Conclusion and Recommendations**

The data submitted in support of this import tolerance application were found to be sufficient to derive a MRL proposal to accommodate the reported use on potatoes imported from Canada. EFSA concluded that the use of clothianidin on potatoes under assessment will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendation is summarised in Appendix B.4.

**References**

Belgium, 2003. Draft assessment report on the active substance clothianidin prepared by the rapporteur Member State Belgium in the framework of Council Directive 91/414/EEC, May 2003.

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

EFSA (European Food Safety Authority), 2014. Review of the existing maximum residue levels for clothianidin and thiamethoxam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(12):3918, 120 pp. https://doi.org/10.2903/j.efsa.2014.3918

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

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

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

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

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

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

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals.7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.
European Commission, 2005. Review report for the active substance clothianidin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 27 January 2006 in view of the inclusion of clothianidin in Annex I of Council Directive 91/414/EEC. SANCO/10533/05-Final, 18 January 2005.
European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2013. Addendum to the review report for the active substance clothianidin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 March 2013 in view of the review of clothianidin as regards the risk to bees in accordance with Article 21 of Regulation (EC) No 1107/2009. SANCO/10589/2013 rev 2, 15 March 2013.
European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.
European Commission, 2018. Addendum to the Review report for the active substance clothianidin Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 March 2013 in view of the review of clothianidin as regards the risk to bees in accordance with Article 21 of Regulation (EC) No 1107/2009. Clothianidin. SANCO/10589/2013 rev 8, 27 April 2018. 5 pp.
FAO (Food and Agriculture Organization of the United Nations), 2010. Clothianidin. In: Pesticide residues in food – 2010. Evaluations, Part I, Residues. FAO Plant Production and Protection Paper 206.
FAO (Food and Agriculture Organization of the United Nations), 2014. Clothianidin; Thiamethoxam. In: Pesticide residues in food – 2014. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 221.
FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.
Germany, 2018. Evaluation report on the setting of an import tolerance for clothianidin in potato. February 2018, revised August 2018, 45 pp.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues.
OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.

**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
- CAC Codex Alimentarius Commission
- CV coefficient of variation (relative standard deviation)
- CXL Codex maximum residue limit
- DALA days after last application
- 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
- FAO Food and Agriculture Organization of the United Nations
- FS flowable concentrate for seed treatment
- GAP Good Agricultural Practice
- HPLC–MS/MS high-performance liquid chromatography with tandem mass spectrometry
- HPLC-UVD high-performance liquid chromatography with ultra-violet detector
- HR highest residue
- IEDI international estimated daily intake
| Acronym | Description |
|---------|-------------|
| IESTI   | international estimated short-term intake |
| ILV     | independent laboratory validation |
| InChiKey| International Chemical Identifier Keys |
| ISO     | International Organisation for Standardisation |
| IUPAC   | International Union of Pure and Applied Chemistry |
| LOQ     | limit of quantification |
| MRL     | maximum residue level |
| MS      | Member States |
| 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 |
| QuEChERS| Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA      | risk assessment |
| RAC     | raw agricultural commodity |
| 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 |
| WHO     | World Health Organization |
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|----------------------|-------------------------------------|-----------------------------------|-------------|-------------|-------------------------------|--------------|---------|
| **Potato**           | Canada                              | F                                 | Wireworms, aphids, Colorado potato beetles, potato leafhoppers, flea beetles | FS          | 600 g/L Seed treatment BBCH 00 | g a.s. | NA | NA | 252 equivalent to 12.5 g/ha g/100 kg seed pieces | 90 | Seed piece treatment Sowing rate of 2018 kg seed-pieces/ha |

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State or country; a.s.: active substance; FS: flowable concentrate for seed treatment.

(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.
# 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 | Comment/source |
|-----------------------------------|-------------|---------|----------------|----------|----------------|
| Fruit crops                       | Apple       | Foliar, 2 × 0.15 kg/ha | 14 DALA | Radiolabelled active substance: [Nitroimino-14C]-clothianidin (EFSA, 2014) |
| | Tomato      | Foliar, 2 × 0.16 kg/ha | 3 DALA | Radiolabelled active substance: [Nitroimino-14C]-clothianidin (EFSA, 2014) |
| | Soil, 1 × 15 mg/plant | 97 DAT | | |
| Root crops                        | Sugar beet  | Seed treatment, 1 × 0.19 kg/ha | 48, 55, 144 DAT | Radiolabelled active substance: [Nitroimino-14C]-clothianidin (EFSA, 2014) |
| Cereals/grass                     | Maize       | Seed treatment, 1 × 1.06 mg/seed | 60 (forage), 145 (maturity) days after sowing | Radiolabelled active substance: [Nitroimino-14C]-clothianidin (EFSA, 2014) |
| | Seed treatment, 1 × 2.52 mg/seed | 63 (forage), 160 (maturity) days after sowing | | Radiolabelled active substance: [Thiazolyl-2-14C]-clothianidin (EFSA, 2014) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Turnip      | 0.33 kg/ha bare soil | 29, 153, 314 | Radiolabelled active substance: [Nitroimino-14C]-clothianidin (EFSA, 2014) |
| Leafy crops                        | Swiss chard | 29, 153, 314 | | |
| Cereal (small grain)                | Wheat       | 29, 153, 314 | | |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)     | Yes        | Radiolabelled active substance: [Thiazolyl-2-14C]-clothianidin (Germany, 2018) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | |
| Sterilisation (20 min, 120°C, pH 6) | Yes | |
Can a general residue definition be proposed for primary crops?
Yes EFSA (2014)

Rotational crop and primary crop metabolism similar?
Yes EFSA (2014)

Residue pattern in processed commodities similar to residue pattern in raw commodities?
Not applicable

Plant residue definition for monitoring (RD-Mo)
Clothianidin

Plant residue definition for risk assessment (RD-RA)
Clothianidin(a)

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
Matrices with high water (apple) content, high oil (sunflower seed) content, high acid (orange) content and dry (maize grain) matrices: HPLC-UV, LOQ 0.01 mg/kg or 0.02 mg/kg (high acid matrix); Confirmatory method and ILV available. (EFSA, 2014)

(a): Since clothianidin is a major metabolite of thiamethoxam, also clothianidin residues resulting from the use of thiamethoxam need to be taken into account in the risk assessment (EFSA, 2014).

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

| Plant products (available studies) | Category          | Commodity                        | T (°C) | Stability period | Compounds covered | Comment/source |
|-----------------------------------|-------------------|----------------------------------|--------|------------------|-------------------|----------------|
|                                    | High water content| Apple, tomato, potato, sugar beet root | −18    | 24 Months        | Parent            | EFSA (2014)     |
|                                    | High oil content  | Rape seed                        | −18    | 24 Months        | Parent            | EFSA (2014)     |
|                                    | Dry/High starch   | Maize grain                       | −18    | 24 Months        | Parent            | EFSA (2014)     |

DALA: days after last application; DAT: days after treatment; PBI: plant-back interval; HPLC-UV: high-performance liquid chromatography with ultraviolet detection; LOQ: limit of quantification; ILV: independent laboratory validation.

(a): Since clothianidin is a major metabolite of thiamethoxam, also clothianidin residues resulting from the use of thiamethoxam need to be taken into account in the risk assessment (EFSA, 2014).
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|------------------|---------------------------------------------------------------|-----------------|------------------------|--------------|----------------|-------|
| Potatoes  | Canada           | 2 × < 0.020; 0.046; 0.093; 0.230 Overdosed results: < 0.010; 0.011; 2 × 0.018; 0.021; 0.024; 0.025; 0.028; 0.040; 0.052; 0.059; 0.075; 0.081; 0.086 Scaled data set: 2 × < 0.010; 2 × 0.011; 0.014; 0.015; 0.016; 0.017; 2 × < 0.020; 0.022; 0.032; 0.039; 0.043; 2 × 0.045; 0.050; 0.092; 0.240 | Residue trials on potatoes from Canada and USA. Samples collected at maturity (PHI 79–143 days). Results from GAP-compliant (± 25% tolerance) and overdosed trials proportionally scaled to nominal application rate, except values < LOQ. Scaling factors: 0.98–1.04 (GAP-compliant), 0.55–0.66 (overdosed) MRL\_OECD: 0.25 (unrounded) | 0.3 | 0.24 | 0.02 | 1 |

*MRL*: maximum residue level; *PHI*: preharvest interval; *GAP*: Good Agricultural Practice; *LOQ*: limit of quantification; *OECD*: Organisation for Economic Co-operation and Development.

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

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

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

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

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

|                          | Not relevant | Application for setting an import tolerance |
|--------------------------|--------------|---------------------------------------------|
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not relevant | Application for setting an import tolerance |

B.1.2.3. Processing factors

| Processed commodity          | Number of valid studies\(^{(a)}\) | Processing factor (PF) | Comment/source |
|------------------------------|-----------------------------------|------------------------|----------------|
|                              |                                   | Individual values      | Median PF      |                |
|                              |                                   | <\(^{(b)}\) 0.77; 1.43 | 1.43           | Tentative, best estimate\(^{(c)}\) |
| Potato, wet peel             | 2                                 | 1.03                   | Tentative      |
| Potato, (peeled) cooked      | 1                                 | 1.50\(^{(b)}\); 2.64  | 2.64           | Tentative, best estimate\(^{(c)}\) |
| Potato, chips                | 2                                 | 2.10\(^{(b)}\); 6.38  | 6.38           | Tentative, best estimate\(^{(c)}\) |
| Potato, granules/flakes      | 2                                 |                        |                |                |

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

\(^{(b)}\): Study conducted with potatoes sampled 124 days after a single in-furrow application of clothianidin (FAO, 2010).

\(^{(c)}\): Only tentative PFs are derived since a limited dataset is available. The highest value of two studies was selected as best estimate, since the type of application was not comparable (in-furrow treatment and seed treatment) and may influence the result of the processing study.

B.2. Residues in livestock

| Relevant groups (sub-groups) | Dietary burden expressed in\(^{(a)}\) mg/kg bw per day | mg/kg DM | Most critical subgroup\(^{(b)}\) | Most critical commodity\(^{(c)}\) | Trigger exceeded (Yes/No) mg/kg DM |
|-----------------------------|--------------------------------------------------------|----------|---------------------------------|---------------------------------|-----------------------------------|
| Cattle (all diets)          | 0.010                                                  | 0.025    | 0.26                            | 0.64                            | Dairy cattle                      |
|                             |                                                        |          |                                 | Potato culls                    | Yes                               |
| Cattle (dairy only)         | 0.010                                                  | 0.025    | 0.26                            | 0.64                            | Dairy cattle                      |
|                             |                                                        |          |                                 | Potato culls                    | Yes                               |
| Sheep (all diets)           | 0.015                                                  | 0.026    | 0.44                            | 0.77                            | Ram/Ewe                          |
|                             |                                                        |          |                                 | Potato culls                    | Yes                               |
| Sheep (ewe only)            | 0.015                                                  | 0.026    | 0.44                            | 0.77                            | Ram/Ewe                          |
|                             |                                                        |          |                                 | Potato culls                    | Yes                               |
| Swine (all diets)           | 0.008                                                  | 0.023    | 0.26                            | 0.78                            | Swine (breeding)                  |
|                             |                                                        |          |                                 | Potato culls                    | Yes                               |
| Poultry (all diets)         | 0.015                                                  | 0.022    | 0.21                            | 0.31                            | Poultry broiler                   |
|                             |                                                        |          |                                 | Potato culls                    | Yes                               |
| Poultry (layer only)        | 0.012                                                  | 0.020    | 0.17                            | 0.30                            | Poultry layer                     |
|                             |                                                        |          |                                 | Potato culls                    | Yes                               |

bw: body weight; DM: dry matter.

\(^{(a)}\): Based on clothianidin residues arising from the use of clothianidin or thiamethoxam.

\(^{(b)}\): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

\(^{(c)}\): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.
B.3. Consumer risk assessment

| ARfD | 0.1 mg/kg bw (European Commission, 2005) |
|------|----------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Potatoes: 35.4% of ARfD |
| Assumptions made for the calculations | The calculation was conducted with the HR of 0.24 mg/kg derived from the residue trials with clothianidin in potatoes considered in the MRL application. |

| ADI | 0.097 mg/kg bw per day (European Commission, 2005) |
|-----|--------------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 2.1% of ADI (German child diet) |
| Contribution of potatoes: 0.12% of ADI | |
| Assumptions made for the calculations | The total dietary intake calculation of the MRL review was conducted with the maximum STMR arising from either the direct use of clothianidin or clothianidin residues resulting from the use of the pesticide thiamethoxam; in addition, STMR values for avocados, mangos, hops, mammalian livers, edible offal and milks derived for the CXLs taken over in EU legislation were included (FAO, 2014). For potatoes, the STMR value included in the calculation of the MRL review is equal to the STMR value derived in this MRL application (0.02 mg/kg). The contributions of commodities where no GAP was reported or Codex MRLs not recommended in the framework of the MRL review were not included in the calculation. It was assumed that both compounds are not applied to the same crop in the same crop cycle. |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; HR: highest residue; ADI: acceptable daily intake; IEDI: international estimated daily intake; STMR: supervised trials median residue; GAP: Good Agricultural Practice.

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0211000 | Potatoes  | 0.03                   | 0.3                     | Import tolerance is sufficiently supported by data. The MRL proposal corresponds to the MRL value in place in Canada. The risk for consumers is unlikely. |

MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
Appendix C – Pesticide Residue Intake Model (PRIMo)

**Clothianidin**

| Status of the active substance: | Approved |
|--------------------------------|----------|
| Code no.                       | P000016  |

**Toxicological end points**

| LOQ (mg/kg bw) | Proposed LOQ |
|----------------|--------------|
| 0.1            | 0.1          |

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|------------------------|-----------------|
| 0.697                  | 0.1             |

**Source of ADI:** COM, Source of ARfD: COM

Year of evaluation: 2005

No of diets exceeding ADI: ---

**Chronic risk assessment – refined calculations**

| TMDI (range) in % of ADI | MS Diet | Commodity/group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity/group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity/group of commodities | pTMRLs at LOQ (in % of ADI) |
|--------------------------|---------|--------------------------------|----------------------------------------|--------------------------------|----------------------------------------|--------------------------------|-----------------------------|
| 2.1                      | DE child| 1.2                           | Apple                                  | 0.2                            | Table grapes                          | 0.1                            | Milk and milk products: Cattle |
| 1.6                      | NL child| 0.7                           | Apple                                  | 0.2                            | Milk and milk products: Cattle        | 0.1                            | Potatoes                    |
| 1.3                      | WHO Cluster diet B | 0.2                         | Wine grapes                            | 0.2                            | Wheat                                 | 0.1                            | Apple                       |
| 1.1                      | UK Toddler| 0.5                       | Sugar beet (root)                      | 0.2                            | Apple                                 | 0.1                            | Beans (with pods)            |
| 0.9                      | PT General population| 0.3                   | Wine grapes                            | 0.1                            | Rice                                  | 0.1                            | Potatoes                    |
| 0.9                      | FR toddler| 0.3                       | Apple                                  | 0.1                            | Potatoes                              | 0.1                            | Rice                        |
| 0.9                      | IE adult| 0.2                           | Wine grapes                            | 0.1                            | Apple                                 | 0.1                            | Beans (with pods)            |
| 0.8                      | WHO cluster diet E | 0.2                       | Wine grapes                            | 0.1                            | Apple                                 | 0.1                            | Wheat                       |
| 0.8                      | FR all population| 0.5                       | Wine grapes                            | 0.1                            | Wheat                                 | 0.0                            | Apple                       |
| 0.8                      | FR infant| 0.3                           | Apple                                  | 0.2                            | Milk and milk products: Cattle        | 0.1                            | Potatoes                    |
| 0.8                      | UK Infant| 0.2                           | Sugar beet (root)                      | 0.2                            | Apple                                 | 0.1                            | Rice                        |
| 0.7                      | DK child| 0.2                           | Apple                                  | 0.1                            | Wheat                                 | 0.1                            | Milk and milk products: Cattle |
| 0.7                      | ES child| 0.1                           | Apple                                  | 0.1                            | Wheat                                 | 0.1                            | Potatoes                    |
| 0.7                      | WHO cluster diet D | 0.1                       | Wheat                                  | 0.1                            | Rice                                  | 0.1                            | Potatoes                    |
| 0.6                      | SE general population 90th percentile| 0.1             | Apple                                  | 0.1                            | Potatoes                              | 0.1                            | Milk and milk products: Cattle |
| 0.6                      | WHO regional European diet | 0.1             | Potato                                | 0.1                            | Apple                                 | 0.1                            | Wheat                       |
| 0.6                      | WHO Cluster diet F | 0.1                       | Wheat                                  | 0.1                            | Apple                                 | 0.1                            | Potato                      |
| 0.6                      | NL General| 0.1                           | Apple                                  | 0.1                            | Wine grapes                           | 0.1                            | Potato                      |
| 0.5                      | ES adult| 0.1                           | Apple                                  | 0.1                            | Wine grapes                           | 0.0                            | Wheat                       |
| 0.5                      | UK vegetarian| 0.1             | Wine grapes                            | 0.1                            | Sugar beet (root)                     | 0.1                            | Apple                       |
| 0.5                      | UK Adult| 0.1                           | Wine grapes                            | 0.1                            | Sugar beet (root)                     | 0.1                            | Apple                       |
| 0.5                      | LT adult| 0.2                           | Apple                                  | 0.1                            | Potato                                | 0.0                            | Rice                        |
| 0.5                      | DK adult| 0.2                           | Apple                                  | 0.1                            | Potato                                | 0.0                            | Wheat                       |
| 0.4                      | FR kids/toddler| 0.1            | Wheat                                  | 0.1                            | Apple                                 | 0.0                            | Potato                      |
| 0.4                      | FR general population| 0.2          | Apple                                  | 0.1                            | Potato                                | 0.0                            | Table grapes                |
| 0.4                      | FR adult| 0.1                           | Wheat                                  | 0.1                            | Apple                                 | 0.0                            | Potatoes                    |
| 0.2                      | FR adult| 0.0                           | Apple                                  | 0.0                            | Wine grapes                           | 0.0                            | Potatoes                    |

**Conclusion:**

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

MRPLs updated as per Reg. (EU) 2017/871 plus the crop under consideration (potato).
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.

### Acute risk assessment/children – refined calculations

| Highest % of ARfD/ADI | Commodity       | pTMRL/threshold MRL (mg/kg) |
|-----------------------|----------------|----------------------------|
| 36.9                  | Potatoes       | 0.24/-                     |

**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.**

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

| Highest % of ARfD/ADI | Commodity       | pTMRL/threshold MRL (mg/kg) |
|-----------------------|----------------|----------------------------|
| 23.0                  | Grape juice    | 0.7/-                      |
| 29.4                  | Apple juice    | 0.7/-                      |
| 1.4                   | Pear juice     | 0.7/-                      |
| 4.1                   | Potato puree (flakes) | 0.7/-                   |
| 2.7                   | Peach juice    | 0.7/-                      |

| Highest % of ARfD/ADI | Commodity       | pTMRL/threshold MRL (mg/kg) |
|-----------------------|----------------|----------------------------|
| 2.7                   | Wine           | 0.7/-                      |
| 2.6                   | Apple juice    | 0.7/-                      |
| 0.5                   | Quince jelly   | 0.7/-                      |
| 0.3                   | Peach preserved | 0.7/-                      |
| 0.3                   | Rakains        | 0.7/-                      |

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

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

### Conclusion:

For Clothianidin, 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.
### Appendix D – Input values for the exposure calculations

#### D.1. Livestock dietary burden calculations

| Feed commodity                        | Median dietary burden | Maximum dietary burden |
|---------------------------------------|-----------------------|------------------------|
|                                       | Input value (mg/kg)   | Comment(a),(b)         |
|                                       |                       |                        |
| **Risk assessment residue definition:** clothianidin |                      |                        |
| Barley, Oat, Rye, Wheat straw         | 0.05 STMR (EFSA, 2014) | 0.05 HR (EFSA, 2014)  |
| Sugar beet, tops                      | 0.02 STMR (EFSA, 2014) | 0.02 HR (EFSA, 2014)  |
| Cabbage head, leaves                  | 0.02 STMR (EFSA, 2014) | 0.02 HR (EFSA, 2014)  |
| Kale                                  | 0.05 HR (EFSA, 2014)  | 0.09 HR (EFSA, 2014)  |
| Carrots                               | 0.02 STMR (EFSA, 2014) | 0.03 HR (EFSA, 2014)  |
| Potato culls                          | 0.02 STMR (EFSA, 2014) | 0.24 HR               |
| Swede roots                           | 0.02 STMR (EFSA, 2014) | 0.02 HR (EFSA, 2014)  |
| Barley, Oat, Rye, Wheat grains        | 0.02 STMR (EFSA, 2014) | 0.02 STMR (EFSA, 2014) |
| Sorghum grains                        | 0.01 STMR (EFSA, 2014) | 0.01 STMR (EFSA, 2014) |
| Apple, pomace                         | 0.15 STMR (EFSA, 2014) × (PF) | 0.15 STMR (EFSA, 2014) (PF) |
| Beet sugar, dried pulp                | 0.36 STMR (EFSA, 2014) × (PF) | 0.36 STMR (EFSA, 2014) × (PF) |
| Beet sugar, ensiled pulp              | 0.06 STMR (EFSA, 2014) × (PF) | 0.06 STMR (EFSA, 2014) × (PF) |
| Beet sugar, molasses                  | 0.56 STMR (EFSA, 2014) × (PF) | 0.56 STMR (EFSA, 2014) × (PF) |
| Brewer’s grain, dried                 | 0.07 STMR (EFSA, 2014) × (PF) | 0.07 STMR (EFSA, 2014) × (PF) |
| Citrus, dried pulp                    | 0.20 STMR (EFSA, 2014) × (PF) | 0.20 STMR (EFSA, 2014) × (PF) |
| Distiller’s grain, meal               | 0.07 STMR (EFSA, 2014) × (PF) | 0.07 STMR (EFSA, 2014) × (PF) |
| Potato, process waste                 | 0.03 STMR (EFSA, 2014) × PF (1.43) | 0.03 STMR (EFSA, 2014) × PF(1.43) |
| Potato, dried pulp                    | 0.76 STMR (EFSA, 2014) × (PF) | 0.76 STMR (EFSA, 2014) × (PF) |
| Wheat gluten meal                     | 0.04 STMR (EFSA, 2014) × (PF) | 0.04 STMR (EFSA, 2014) × (PF) |
| Wheat, milled by-prods                | 0.14 STMR (EFSA, 2014) × (PF) | 0.14 STMR (EFSA, 2014) × (PF) |

**STMR:** supervised trials median residue; **HR:** highest residue; **PF:** processing factor.
(a): Based on clothianidin residues arising from the use of clothianidin or thiamethoxam.
(b): For fruit pomace, sugar beet, potato dried pulp and cereal by-products, in the absence of processing factors (PFs) supported by data, default PFs were included in the calculation to consider the potential concentration of residues in these commodities.
### D.2. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               |
| Citrus fruits              | 0.02 (a)                | STMR (EFSA, 2014)     |
| Tree nuts                  | 0.01 (a)                | STMR (CXL) (EFSA, 2014) |
| Pome fruits                | 0.10 (b)                | STMR (CXL) (EFSA, 2014) |
| Apricots, peaches          | 0.03 (b)                | STMR (EFSA, 2014)     |
| Cherries                   | 0.02 (a)                | STMR (EFSA, 2014)     |
| Table, wine grapes         | 0.12 (a)                | STMR (CXL) (EFSA, 2014) |
| Strawberries               | 0.02 (a)                | STMR (EFSA, 2014)     |
| Table olives               | 0.03 (a)                | STMR (EFSA, 2014)     |
| Avocados                   | 0.01 (a)                | STMR (EFSA, 2014)     |
| Bananas                    | 0.02 (b)                | STMR (CXL) (EFSA, 2014) |
| Mangos                     | 0.02 (a)                | STMR (EFSA, 2014)     |
| Papayas                    | 0.01 (a)                | STMR (EFSA, 2014)     |
| Pineapples                 | 0.01 (a)                | STMR (EFSA, 2014)     |
| Potatoes                   | 0.02 (b)                | STMR (EFSA, 2014)     |
| Carrots                    | 0.02 (a)                | STMR (EFSA, 2014)     |
| Swedes/rutabagas           | 0.02 (a)                | STMR (EFSA, 2014)     |
| Tomatoes                   | 0.02 (a)                | STMR (EFSA, 2014)     |
| Sweet/bell peppers         | 0.02 (a)                | STMR (EFSA, 2014)     |
| Aubergines/eggplants       | 0.02 (a)                | STMR (EFSA, 2014)     |
| Cucumbers, Courgettes      | 0.02 (a)                | STMR (EFSA, 2014)     |
| Melons, Watermelons        | 0.02 (a)                | STMR (EFSA, 2014)     |
| Sweet corns                | 0.01 (a)                | STMR (CXL) (EFSA, 2014) |
| Flowering brassica         | 0.02 (a)                | STMR (EFSA, 2014)     |
| Head brassica              | 0.02 (a)                | STMR (EFSA, 2014)     |
| Leafy brassica             | 0.05 (b)                | STMR (EFSA, 2014)     |
| Kohlrabies                 | 0.01 (a)                | STMR (EFSA, 2014)     |
| Lettuces, escaroles        | 0.03 (a)                | STMR (EFSA, 2014)     |
| Herbs and edible flowers   | 0.12 (b)                | STMR (EFSA, 2014)     |
| Beans, peas with pods      | 0.08 (a)                | STMR (EFSA, 2014)     |
| Beans, peas w/out pods     | 0.01 (a)                | STMR (CXL) (EFSA, 2014) |
| Lentils                    | 0.01 (a)                | STMR (CXL) (EFSA, 2014) |
| Celeries                   | 0.01 (a)                | STMR (EFSA, 2014)     |
| Globe artichokes           | 0.02 (a)                | STMR (CXL) (EFSA, 2014) |
| Pulses                     | 0.02 (a)                | STMR (CXL) (EFSA, 2014) |
| Oilseeds, except g. of p.  | 0.02 (a)                | STMR (EFSA, 2014)     |
| Gold of pleasure           | 0.02 (a)                | STMR (EFSA, 2014)     |
| Olives for oil production  | 0.03 (a)                | STMR (EFSA, 2014)     |
| Barley, Oat, Rye, Wheat    | 0.02 (a)                | STMR (EFSA, 2014)     |
| Maize/corn                 | 0.02 (a)                | STMR CXL (EFSA, 2014) |
| Sorghum                    | 0.01 (a)                | STMR (EFSA, 2014)     |
| Rice                       | 0.15 (b)                | STMR (CXL) (EFSA, 2014) |
| Teas                       | 0.12 (a)                | STMR (CXL) (EFSA, 2014) |
| Coffee beans               | 0.02 (a)                | STMR (CXL) (EFSA, 2014) |
| Cocoa beans                | 0.02 (a)                | STMR (CXL) (EFSA, 2014) |
| Hops                       | 0.026 (a)               | STMR (EFSA, 2014)     |
| Sugar beet roots           | 0.02 (a)                | STMR (EFSA, 2014)     |
|                           |                        | 0.24 (b) HR           |
| Commodity            | Chronic risk assessment | Acute risk assessment |
|----------------------|-------------------------|-----------------------|
|                      | Input value (mg/kg)     | Comment               |
| Sugar canes          | 0.03\(^{(b)}\)          | STMR (CXL) (EFSA, 2014) |
| Chicory roots        | 0.01\(^{(b)}\)          | STMR (EFSA, 2014)     |
| Meat                 | 0.02 \(^{(b)}\)         | STMR (CXL) (EFSA, 2014) |
| Fat                  | 0.02 \(^{(b)}\)         | STMR (CXL) (EFSA, 2014) |
| Liver                | 0.06 \(^{(c)}\)         | STMR (FAO, 2014)      |
| Kidney               | 0.02 \(^{(b)}\)         | STMR (CXL) (EFSA, 2014) |
| Edible offal         | 0.06 \(^{(c)}\)         | STMR (FAO, 2014)      |
| Poultry, meat        | 0.01 \(^{(b)}\)         | STMR (CXL) (EFSA, 2014) |
| Poultry, fat         | 0.01 \(^{(b)}\)         | STMR (CXL) (EFSA, 2014) |
| Poultry, liver       | 0.02 \(^{(c)}\)         | STMR (CXL) (EFSA, 2014) |
| Poultry, kidney      | 0.01 \(^{(b)}\)         | STMR (CXL) (EFSA, 2014) |
| Poultry, edible offal| 0.02 \(^{(c)}\)         | STMR (CXL) (EFSA, 2014) |
| Milks                | 0.006 \(^{(c)}\)        | STMR (FAO, 2014)      |
| Bird’s eggs          | 0.01 \(^{(b)}\)         | STMR (CXL) (EFSA, 2014) |

STMR: supervised trials median residue; HR: highest residue; CXL: Codex maximum residue limit.

\(^{(a)}\): Residues of clothianidin arising from the use of thiamethoxam.

\(^{(b)}\): Residues of clothianidin arising from the direct use of clothianidin.

\(^{(c)}\): Input values for risk assessment of clothianidin in mammalian (swine, bovine, sheep, goat, equine, other farmed terrestrial animals) tissues and milks were derived based on the results of the cattle feeding study conducted with thiamethoxam.
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|---------------------------------|-----------------------------------------------|-------------------------------|
| clothianidin                    | (E)-1-(2-chlorothiazol-5-ylmethyl)-3-methyl-2-nitroguanidine Clc1ncc(C=N/N+]/([O-])=O)s1 PGOOBECODWQEAB-PQKPOUEINA-N | ![Structural formula for clothianidin](image) |
| thiamethoxam                    | (EZ)-3-(2-chlorothiazol-5-ylmethyl)-5-methyl-1,3,5-oxadiazinan-4-ylidene(nitro)amine Clc1ncc(C=OOCN(C)C/2=N[N+]/([O-])=O)s1 NWWZPOKUAAIXI-UHFFFAOYSA-N | ![Structural formula for thiamethoxam](image) |

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

<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).