Setting of an import tolerance for chlorantraniliprole in hops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant DuPont de Nemours (Deutschland) GmbH submitted a request to the competent national authority in France to set an import tolerance for the active substance chlorantraniliprole in hops. The data submitted in support of the request were found to be sufficient to derive an maximum residue level (MRL) proposal for hops in support of the authorised use in the USA. Adequate analytical methods for enforcement are available to control the residues of chlorantraniliprole in hops at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the existing uses and the authorised use of chlorantraniliprole according to the reported agricultural practice is unlikely to present a risk to consumer health. The reliable end points, appropriate for use in regulatory risk assessment are presented.

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Keywords: Chlorantraniliprole, hops, dried cones, pesticide, MRL, consumer risk assessment

Requestor: European Commission
Question number: EFSA-Q-2018-00235
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Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Pedersen R, Reich H, Riemenschneider C, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B and Villamar-Bouza L, 2018. Reasoned Opinion on the setting of an import tolerance for chlorantraniliprole in hops. EFSA Journal 2018;16(6):5312, 21 pp. https://doi.org/10.2903/j.efsa.2018.5312

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, DuPont de Nemours (Deutschland) GmbH submitted an application to the competent national authority in France (evaluating Member State (EMS)) to set an import tolerance for the active substance chlorantraniliprole in hops. 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 08 March 2018. The EMS proposed to establish maximum residue level (MRL) for hops imported from the USA at the level of 40 mg/kg.

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

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of chlorantraniliprole in primary crops was investigated in the fruit, leafy and pulses/oilseeds crop groups using foliar applications and in cereals after soil application. Following foliar applications chlorantraniliprole is not metabolised to a great extent and it is also the major component of the residues after soil application and in rotational crops.

Studies investigating the nature of chlorantraniliprole residues (hydrolysis studies) demonstrated that the active substance is stable under pasteurisation and sterilisation conditions, but slightly degrades under boiling/brewing/baking conditions. The formed metabolites were detected at low levels and the magnitude of the parent compound residues was always significantly higher.

The investigation of chlorantraniliprole residues in rotational crops is of no relevance for the import tolerance application.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as chlorantraniliprole for enforcement and for risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for hops the metabolism of chlorantraniliprole in primary crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable. Adequate analytical methods to enforce the residues of chlorantraniliprole in hops are available. The available residue trials are sufficient to derive an MRL proposal of 40 mg/kg for hops.

Specific studies investigating the magnitude of chlorantraniliprole residues in processed commodities are not required since the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI).

The investigation of chlorantraniliprole residues in livestock is of no relevance for the import tolerance application.

The toxicological profile of chlorantraniliprole was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 1.56 mg/kg body weight (bw) per day; an acute reference dose (ARfD) was deemed unnecessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term exposure assessment was performed taking into account the supervised trials median residue (STMR) value derived from residue trials on hops, assessed in this application. For the remaining commodities the existing European Union (EU) MRLs established in Regulation (EU) 2018/687 were selected as input values. The estimated long-term dietary intake accounted for a maximum of 2.2% of the ADI (NL child diet). The contribution of residues in hops to the overall long-term exposure is insignificant (0.004% ADI).

EFSA concluded that the long-term intake of chlorantraniliprole residues resulting from the existing uses and the authorised use on hops is unlikely to present a risk to consumer health.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–C.
### Setting of import tolerance for chlorantraniliprole in hops

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------------|-----------|-------------------------|-------------------------|------------------------|
| 0700000 Hops  | 10\(^{(b)}\) | 40 | The submitted data are sufficient to derive an import tolerance (USA GAP). Risk for consumers unlikely |

**Enforcement residue definition:** Chlorantraniliprole\(^{(F)}\)

MRL: maximum residue level; GAP: Good Agricultural Practice.

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

\(^{(b)}\): Temporary MRL, valid until 31 December 2020, according to Commission Regulation (EU) 2018/687.

\(^{(F)}\): Fat soluble.
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Assessment

The detailed description of the authorised use of chlorantraniliprole in the USA on hops, which is the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Chlorantraniliprole is the ISO common name for 3-bromo-4′-chloro-1-(3-chloro-2-pyridyl)-2′-methyl-6′-(methylcarbamoyl)pyrazole-5-carboxanilide (IUPAC). The chemical structure of the active substance and its main metabolites are reported in Appendix E.

Chlorantraniliprole was evaluated in the framework of Directive 91/414/EEC with Ireland designated as rapporteur Member State (RMS) for the representative uses of field spray applications on tree fruit, grapes, citrus, potato, aubergine, tomato, pepper, lettuce and glasshouse spray applications on aubergine, tomato, pepper, lettuce and cucurbits. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2013a). Chlorantraniliprole was approved for the use as an insecticide on 1 May 2014.

The European Union (EU) MRLs for chlorantraniliprole are established in Annex III of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is currently ongoing. The European Food Safety Authority (EFSA) has issued several reasoned opinions on the modification of MRLs for chlorantraniliprole (EFSA, 2010, 2011, 2012a,b, 2013b, 2015, 2016, 2017) and the proposals from these reasoned opinions have been considered in recent regulations for EU MRL legislation.

In 2017, EFSA assessed several Codex maximum residue limit (CXL) proposals for the 49th Codex Committee on Pesticide Residues (CCPR) session (EFSA, 2017). The CXL proposals for peanuts and poultry matrices have recently been implemented by the Commission Regulation (EU) 2018/687. For hops, the CXL of 40 mg/kg has been established by the Codex Alimentarius Commission (CAC) in 2014 (CAC, 2014).

In accordance with Article 6 of Regulation (EC) No 396/2005, DuPont de Nemours (Deutschland) GmbH submitted an application to the competent national authority in France (evaluating Member State (EMS)) to set an import tolerance for the active substance chlorantraniliprole in hops. 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 8 March 2018. The tolerance for chlorantraniliprole currently set in the USA on hops is 90 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2018), the DAR (and its addendum) (Ireland, 2010) prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance chlorantraniliprole (EFSA, 2013a), as well as the conclusions from recent EFSA opinions on chlorantraniliprole.

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, 2017; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

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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 Implementing Regulation (EU) No 1199/2013 of 25 November 2013 approving the active substance chlorantraniliprole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 315, 26.11.2013, p. 69–73.
3 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
4 For an overview of all MRL decisions on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
5 Commission Regulation (EU) 2018/687 of 4 May 2018 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, benzo[1,2,3-cd]pyrrole, bifenilthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluaflavip-P, isofetamid, metrafenone, pendimethalin and teflubenzuron in or on certain products. OJ L 121, 16.5.2018, p. 63–104.
6 Environmental Protection Agency, Federal Register 5526, Vol. 75, No 22/3 February 2010.
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.
As the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the MRL 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 report submitted by the EMS (France, 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 chlorantraniliprole in primary crops was evaluated in the framework of the EU pesticides peer review in the fruit (apple, tomato), leafy (lettuce), pulses/oilseeds (cotton) crop groups after foliar applications and in cereals/grasses (rice) following soil treatment (EFSA, 2013a).

Following foliar applications, chlorantraniliprole was metabolised to a very limited extent, accounting for more than 80% total radioactive residue (TRR) in all plant samples collected up to 30 days after the last application and 57% TRR in the mature cotton seeds harvested 126 days after the last treatment. The metabolism was more extensive in rice after soil application with a total of 14 metabolites identified, each accounting for less than 6% TRR, but chlorantraniliprole still remained the major component of the residues, representing more than 50% TRR in all rice matrices at harvest (0.08 mg/kg in grain). Following foliar applications chlorantraniliprole is not metabolised to a great extent and is also the major component of the residues after soil application (EFSA, 2013a).

For the authorised use on hops, EFSA concludes that the metabolism of chlorantraniliprole is sufficiently addressed and additional studies are not required.

1.1.2. Nature of residues in rotational crops

The investigation of chlorantraniliprole residues in rotational crops is of no relevance for the import tolerance application.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of chlorantraniliprole residues was investigated in the framework of the EU pesticides peer review in a standard hydrolysis study (EFSA, 2013a). Chlorantraniliprole is hydrolytically stable under the conditions representative of pasteurisation and sterilisation. However, under boiling conditions it degraded slightly, forming metabolites IN-F6L99, IN-EQW78 and IN-ECD73 (11–14% of applied radioactivity). Since the degradation products were detected at low levels and the magnitude of the parent compound was always significantly higher (87–86% of the TRR), the peer review concluded that for processed commodities the same residue definition for enforcement and risk assessment as for raw agricultural commodities (RAC) is applicable (EFSA, 2013a).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of chlorantraniliprole residues in plant commodities were assessed during the EU pesticides peer review (EFSA, 2013a). The DFG S19 multiresidue method based on liquid chromatography and tandem mass detection (LC-MS/MS) was sufficiently validated at the limit of validation (LOQ) of 0.01 mg/kg for the determination of chlorantraniliprole residues in high water-, high acid- and high oil content commodities and in dry/starch commodities. An independent laboratory validation (ILV) was available (EFSA, 2013a).

In the framework of the current application, the applicant submitted a validation data of the above mentioned method for the determination of chlorantraniliprole residues in hops (France, 2018). An ILV was also provided. It is concluded that DFG S19 method is applicable for the determination of chlorantraniliprole residues in hops at the validated LOQ of 0.01 mg/kg.
1.1.5. Stability of residues in plants

The freezer storage stability of chlorantraniliprole in plants was investigated in the EU pesticides peer review in studies which demonstrated that chlorantraniliprole residues are stable for at least 24 months in high water, high oil, high acid, high protein and high starch content commodities when stored frozen at –20°C (EFSA, 2013a).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in primary and rotational crop metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the EU pesticides peer review:

- residue definition for risk assessment: chlorantraniliprole
- residue definition for enforcement: chlorantraniliprole

The same residue definitions are applicable to rotational crops and processed products.

EFSA concludes that these residue definitions are appropriate for the authorised use on hops and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the authorised use of chlorantraniliprole in the United States, the applicant submitted four Good Agricultural Practice (GAP)-compliant residue trials on hops, which were performed in three different locations in the USA in 2011. The authorised GAP in the USA allows no more than 4 applications per crop per season with a maximum annual application rate of 220 g/ha and a maximum rate per application of 110 g/ha. The applicant has designed the trials in a way to reflect the most critical use pattern by treating hops close to harvest twice at an individual application rate of 110 g/ha, with 7-day interval. Two trials were designed as decline trials and provided information on residues in hops at the preharvest interval (PHI) intervals of 0, 1, 3, 7, 10–14 days. Higher residues were observed at the PHI of 1–3 days. Residue data are sufficient to derive an MRL proposal of 40 mg/kg in support of the authorised use of chlorantraniliprole on hops in the USA.

The residue trial samples of hops were stored for a maximum of 8 months at –18°C, thus, residue trials data are valid with regard to the storage stability. The analytical method used to analyse residue trial samples has been sufficiently validated and was proven to be fit for purpose (France, 2018).

1.2.2. Magnitude of residues in rotational crops

The investigation of chlorantraniliprole residues in rotational crops is of no relevance for the import tolerance application.

1.2.3. Magnitude of residues in processed commodities

New studies to assess the magnitude of chlorantraniliprole residues during the processing of hops have not been submitted in the framework of the current assessment and are not necessary as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI) (European Commission, 1997d).

1.2.4. Proposed MRLs

The submitted data are sufficient to derive a MRL proposal and risk assessment values in support of the authorised use of chlorantraniliprole on hops in the United States.

2. Residues in livestock

The investigation of chlorantraniliprole residues in livestock is of no relevance for the import tolerance application.
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 value for chlorantraniliprole used in the risk assessment (i.e. ADI value of 1.56 mg/kg body weight (bw) day) was derived in the framework of the EU pesticides peer review (EFSA, 2013a). An acute reference dose (ARfD) was not allocated as not considered necessary.

The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) value derived from residue trials on hops, assessed in this application. For the remaining commodities the existing EU MRLs established in Regulation (EU) 2018/687 were used as input values. The complete list of input values is presented in Appendix D.

The estimated long-term dietary intake accounted for a maximum of 2.2% of the ADI (NL child diet). The contribution of residues in hops to the overall long-term exposure is insignificant (0.004% ADI).

EFSA concluded that the long-term intake of chlorantraniliprole residues resulting from the existing uses and the authorised use on hops is unlikely to present a risk to consumer health.

4. Conclusion and Recommendations

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

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

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CAS Chemical Abstract Service
CCPR Codex Committee on Pesticide Residues
CXL Codex maximum residue limit
DALA days after last application
DAR draft assessment report
DAT days after treatment
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
gPa gigapascals
IEDI international estimated daily intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS/MS tandem mass spectrometry detector
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NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern Europe
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
TMDI theoretical maximum daily intake
TRR total radioactive residue
WHO World Health Organization
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | Crop (import tolerance) | F | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Method kind | Range of growth stages & season (a) | Max number | Interval between application (min) | g a.s./lL min-max | Water L/ha min-max | Rate | Unit | PHI (days) (d) | Remarks |
|-----------------------|-------------------------|---|------------------------|-----------------------------------|------------|----------|-----------------------------|-------------|-------------------------------|----------------|----------------|------|------|-------------|---------|
| Hops                  | USA                     | F | Western yellow-striped armyworm | SC 200 g/L Broadcast mist blower, hydraulic ground directed boom Aerial application | BBCH 11–89 | 1–4 | 7 days | 467–2,337 (ground), 50–250 gPa, 93–140 (aerial) 10–15 gPa | a) max per appl.: 110 | b) max total rate per crop/season: 219 | g a.s./ha | | 0 | Maximum seasonal application rate: 219 g a.s./ha (110 g a.s./ha corresponds to 0.098 lbs ai/acre or 7.5 fl oz 200 g/L SC/acre) |

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 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 | Crops | Applications | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|-------|--------------|----------------|----------------|
| Fruit crops                       | Apple       | Foliar, 3 × 100 g/ha; BBCH 71, 75, 77 | 0 DAT₁,₂,₃ (immature leaves and fruits); 15 and 30 DALA (maturity) | Radiolabelled active substance: mixture of [benzamide carbonyl-¹⁴C]-chlorantraniliprole and [pyrazole carbonyl-¹⁴C]-chlorantraniliprole (Ireland, 2010) |
|                                  | Tomatoes    | Foliar, 3 × 100 g/ha; BBCH 61, 73; 81 | 0 DAT₁,₂,₃ (immature leaves and fruits); 7 and 15 DALA (maturity) |
| Leafy crops                       | Lettuce     | Foliar, 3 × 100 g/ha; BBCH 13, 19 | 0 DAT₁,₂,₃; 7 and 15 DALA (maturity) |
| Cereals/ grass                    | Rice        | Soil drench, 1 × 300 g/ha; BBCH 11-12 | 14, 28, 56 DAT (immature), 132 DAT (maturity) |
| Pulses/oilseeds                   | Cotton      | Foliar, 1 × 150 g/ha; 41 day seedling | 8, 15, 22, 86 DAT (immature), 126 DAT (maturity) |
|                                  |            | Foliar, 1 × 150 g/ha; 57 day seedling | 8, 21, 48 DAT (foliage) |
|                                  |            | Excised plant: 18 day seedling | 4 day incubated in solution containing 50 mg as/kg |
| Rotational crops (available studies) | Crop groups | Crops | Applications | PBI (DAT) | Comment/Source |
| Root/tuber crops                  | Red beet    | Soil, 300 g/ha | 0, 30, 120, 365 DAT (pyrazole carbonyl label) and 30 DAT (benzamide carbonyl label) | Radiolabelled active substance: mixture of [benzamide carbonyl-¹⁴C]-chlorantraniliprole and [pyrazole carbonyl-¹⁴C]-chlorantraniliprole (Ireland, 2010) |
| Leafy crops                       | Lettuce     |                  |             |               |                |
| Cereal (small grain)              | Wheat       | Soil, 300 g/ha | 0, 30, 120, 365 DAT (pyrazole carbonyl label) and 30 DAT (benzamide carbonyl label) |                |
|                                  |            | Soil, 900 g/ha | 0, 365 DAT (pyrazole carbonyl label) |                |
| Other                             | –          |                  |             |               |                |
## Processed Commodities (hydrolysis study)

| Conditions                                      | Stable?          | Comment/Source                                                                 |
|-------------------------------------------------|------------------|--------------------------------------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4)             | Yes              | EFSA (2013a)                                                                   |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes/Partially    | Slightly degraded to IN-F6L99, IN-ECD73 and IN-EQW78 (11%–14% TRR) under baking/brewing/boiling conditions (EFSA, 2013a) |
| Sterilisation (20 min, 120°C, pH 6)             | Yes              | EFSA (2013a)                                                                   |
| Other processing conditions                     | –                | –                                                                              |

DAT: x days after the treatment; DALA: days after last application; BBCH: growth stages of mono- and dicotyledonous plants; PBI: plant-back interval.

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

| Answer | Comment/Source |
|--------|----------------|
| Yes    | (EFSA, 2013a)  |

### Rotational Crop and Primary Crop Metabolism Similar?

| Answer | Comment/Source |
|--------|----------------|
| Yes    | (EFSA, 2013a)  |

### Residue Pattern in Processed Commodities Similar to Residue Pattern in Raw Commodities?

| Answer | Comment/Source                                                                                                                                                                                                 |
|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yes    | Chlorantraniliprole stable under pasteurization and sterilisation conditions but slightly degraded to IN-F6L99, IN-ECD73 and IN-EQW78 under baking/brewing/boiling conditions (11% and 14% TRR). Processing studies indicate low residues of these metabolites in only few processed commodities the magnitude of parent chlorantraniliprole being always significantly higher than the magnitude of degradates (EFSA, 2013a). |

### Plant Residue Definition for Monitoring (RD-Mo)

| Residue | Comment |
|---------|---------|
| Chlorantraniliprole | |

### Plant Residue Definition for Risk Assessment (RD-RA)

| Residue | Comment |
|---------|---------|
| Chlorantraniliprole | |

### Methods of Analysis for Monitoring of Residues (Analytical Technique, Crop Groups, LOQs)

- Matrices with high water content (tomatoes), high oil content (almond), high acid content (oranges) and dry matrices (wheat grain): LC-MS/MS (DFG S 19), 0.01 mg/kg
  - ILV available.
  - (EFSA, 2013a)
- Hops: LC-MS/MS (DFG S 19), 0.01 mg/kg
  - ILV available (France, 2018).

TRR: total radioactive residues; LOQ: limit of quantification; LC–MS/MS: liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation.
### 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, lettuce, cauliflower            | −20    | 24 Months        | Chlorantraniliprole                      | EFSA (2013a)   |
|                                   | High oil content          | Cotton seed                                    | −20    | 24 Months        | Chlorantraniliprole                      | EFSA (2013a)   |
|                                   | Dry/High starch content   | Wheat grain, potato                            | −20    | 24 Months        | Chlorantraniliprole                      | EFSA (2013a)   |
|                                   | High acid content         | Grape                                          | −20    | 24 Months        | Chlorantraniliprole                      | EFSA (2013a)   |
|                                   | Processed products        | Apple juice, tomato ketchup, cottonseed oil,  | −20    | 12 Months        | Chlorantraniliprole, IN-EQW78, IN-ECD73, | EFSA (2013a)   |
|                                   |                           | cotton seed meal, raisins                      |        |                  | IN-F6L99                                |                |
|                                   | Others                    | Straw                                          | −20    | 24 Months        | Chlorantraniliprole                      | EFSA (2013a)   |
|                                   |                           | Alfalfa hay                                    | −20    | 24 Months        | Chlorantraniliprole                      | EFSA (2013a)   |
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|------------------------|--------------------------|--------------------------|
| Hops      | USA                         | 7.5<sup>(d)</sup>; 8.4<sup>(d)</sup>; 12.5; 17.5             | Residue trials on hops compliant with the GAP | **40**                 | 17.5                     | 10.45                    |

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): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Residues higher at a longer PHI interval of 1–3 days.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Not triggered |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered |

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

Not relevant since no ARfD has been considered necessary.

| ADI | 1.56 mg/kg bw per day (EFSA, 2013) |
| Highest IEDI, according to EFSA PRIMo | 2.2 % ADI (NL child diet) |
| Contribution of crops assessed: Hops: 0.004 % of ADI (NL child diet/UK adult diet) |
| Assumptions made for the calculations | The calculation is based on the median residue levels (STMR) derived for hops from the residue trials submitted in the framework of this MRL application. For the remaining commodities of plant and animal origin the existing EU MRLs set in Regulation (EU) 2018/687 were used as input values. |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; MRL: maximum residue level.

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
| --- | --- | --- | --- | --- |
| 0700000 | Hops | 10(b) | 40 | The submitted data are sufficient to derive an import tolerance (USA GAP). Risk for consumers unlikely |

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Temporary MRL, valid until 31 December 2020, according to Commission Regulation (EU) 2018/687.
(F): Fat soluble.
Appendix C – Pesticide Residue Intake Model (PRIMo)

Chlorantraniliprole

| Status of the active substance: | Code no. |
|---------------------------------|----------|
|                                | 0.01     |

| Toxological end points |
|------------------------|
| ADI (mg/kg bw per day) | 1.56     |
| ARfD (mg/kg bw) | n.n. |

| Source of ADI | Source of ARfD |
|---------------|----------------|
| EFSA          | EFSA           |

| Year of evaluation |
|--------------------|
| 2013               |

| No of diets exceeding ADI | Highest calculated TMDI (range) in % of ADI |
|---------------------------|--------------------------------------------|
|                           | Minimum – Maximum                          |
|                            | MS Diet                                    |
|                            | Commodity/group of commodities             |
|                            | 1st contributor to          | 2nd contributor to          | 3rd contributor to          | pTMRLs at LOQ |
|                            | MS diet | Commodity/group of commodities | MS diet | Commodity/group of commodities | MS diet | Commodity/group of commodities |
| 2.2                        | NL child | 0.5 | Spinach | 0.3 | Scarlet (broad-leaf endive) | 0.2 | Willow | 0.0 |
| 1.7                        | WHO Cluster diet B | 0.5 | Lettuce | 0.1 | Tomatoes | 0.1 | Wine grapes | 0.0 |
| 1.6                        | FR toddler | 0.9 | Spinach | 0.1 | Milk and cream | 0.1 | Oranges | 0.0 |
| 1.5                        | DE child | 0.4 | Apples | 0.3 | Spinach | 0.2 | Oranges | 0.0 |
| 1.3                        | IT adult | 0.5 | Lettuce | 0.2 | Other lettuce and other salad plants | 0.1 | Spinach | 0.0 |
| 1.3                        | IE adult | 0.3 | Other leafy brassica | 0.2 | Spinach | 0.1 | Lettuce | 0.0 |
| 1.2                        | ES adult | 0.7 | Lettuce | 0.1 | Beet leaves (chard) | 0.1 | Spinach | 0.0 |
| 1.2                        | NL general | 0.2 | Willow | 0.2 | Spinach | 0.2 | Lettuce | 0.0 |
| 1.1                        | ES child | 0.5 | Lettuce | 0.1 | Spinach | 0.1 | Beet leaves (chard) | 0.0 |
| 1.1                        | WHO regional European diet | 0.5 | Lettuce | 0.0 | Head cabbage | 0.0 | Scarlet (broad-leaf endive) | 0.0 |
| 1.1                        | FR all population | 0.3 | Wine grapes | 0.2 | Other lettuce and other salad plants | 0.2 | Willow | 0.0 |
| 1.1                        | FR infant | 0.6 | Spinach | 0.1 | Willow | 0.1 | Milk and cream | 0.0 |
| 1.1                        | IT kids/toddler | 0.4 | Lettuce | 0.1 | Other lettuce and other salad plants | 0.1 | Beet leaves (chard) | 0.0 |
| 1.0                        | WHO cluster diet D | 0.2 | Chinese cabbage | 0.1 | Kale | 0.1 | Kale | 0.0 |
| 0.9                        | WHO Cluster diet E | 0.1 | Lettuce | 0.1 | Wine grapes | 0.1 | Rape seed | 0.0 |
| 0.9                        | ES general population 90th percentile | 0.3 | Chinese cabbage | 0.1 | Spinach | 0.1 | Head cabbage | 0.0 |
| 0.5                        | UK vegetarian | 0.2 | Lettuce | 0.1 | Wine grapes | 0.0 | Spinach | 0.0 |
| 0.5                        | DK child | 0.2 | Lettuce | 0.1 | Apples | 0.0 | Milk and cream | 0.0 |
| 0.5                        | UK Toddler | 0.1 | Oranges | 0.1 | Milk and cream | 0.1 | Apples | 0.0 |
| 0.4                        | UK infant | 0.1 | Milk and cream | 0.1 | Oranges | 0.1 | Apples | 0.0 |
| 0.4                        | PT General population | 0.2 | Wine grapes | 0.0 | Sunflower seed | 0.0 | Tomatoes | 0.0 |
| 0.4                        | UK Adult | 0.2 | Lettuce | 0.1 | Wine grapes | 0.0 | Oranges | 0.0 |
| 0.3                        | FR adult | 0.1 | Lettuce | 0.0 | Chinese cabbage | 0.0 | Oranges | 0.0 |
| 0.3                        | LT adult | 0.1 | Lettuce | 0.1 | Apples | 0.1 | Head cabbage | 0.0 |
| 0.3                        | PL general population | 0.1 | Apples | 0.0 | Head cabbage | 0.0 | Tomatoes | 0.0 |
| 0.3                        | DK adult | 0.1 | Wine grapes | 0.0 | Apples | 0.0 | Chinese cabbage | 0.0 |

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

Setting of import tolerance for chlorantraniliprole in hops

www.efsa.europa.eu/efsajournal 18 EFSA Journal 2018;16(6):5312
### Acute risk assessment/children – refined calculations

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

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

* The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
* pTMRL: provisional temporary MRL.
** pTMRL: provisional temporary MRL for unprocessed commodity.

**Conclusion:**

As no ARfD was considered necessary, it is concluded that the short-term intake of Chlorantraniliprole residues is unlikely to present a public health concern.
## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

| Commodity                                      | Chronic risk assessment | Input value (mg/kg) | Comment                          |
|------------------------------------------------|-------------------------|---------------------|----------------------------------|
| Hops                                           |                         | 10.45               | STMR                             |
| Other commodities of plant and animal origin   |                         | MRL                 | Regulation (EU) 2018/687         |

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

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|------------------|-------------------------------------------------|---------------------------------|
| Chlorantraniliprole (DPX E-2Y45) | 3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methylcarbamoyl)-1H-pyrazole-5-carboxanilide<br>CNC(-O)c3cc(Cl)cc(C)c3NC(-O)c2cc(Br)<br>nn2c1ncccc1Cl<br>PSOVNZZNOMJUBI-UHFFFAOYSA-N | ![Structural formula](image1) |
| IN-F6L99 | 3-bromo-N-methyl-1H-pyrazole-5-carboxamide<br>Brc1cc(nn1)C(=O)NC<br>LOYJZLKXTLAMJX-UHFFFAOYAC | ![Structural formula](image2) |
| IN-EQW78 | 2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one<br>Cc4cc(C)c3c4N=C(c2cc(Br)nn2c1ncccc1Cl)N(C)C3=O<br>QTUSYELSAOBSI-UHFFFAOYAD | ![Structural formula](image3) |
| IN-ECD73 | 2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one<br>Cc3cc(C)c2c3N=C1C(Cl)=CC=CN1C2=O<br>HWZDYZSGZCNEA-UHFFFAOYAQ | ![Structural formula](image4) |

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