Setting of import tolerances for chlorantraniliprole in oil palms fruits and oil palms kernels

European Food Safety Authority (EFSA), Maria Anastassiadou, Alba Brancato, Luis Carrasco Cabrera, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrants, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Alejandro Rojas, Angela Sacchi, Miguel Santos, Alois Stanek, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant FMC Agro Ltd submitted a request to the competent national authority in the United Kingdom to set import tolerances for the active substance chlorantraniliprole in oil palms fruits and oil palms kernels. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for these products. Adequate analytical methods for enforcement are available to control the residues of chlorantraniliprole in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of chlorantraniliprole according to the reported agricultural practice is unlikely to present a risk to consumer health.

Keywords: chlorantraniliprole, oil palms fruits, oil palms kernels, pesticide, MRL, consumer risk assessment

Requestor: European Commission
Question number: EFSA-Q-2019-00083
Correspondence: pesticides.mrl@efsa.europa.eu
Acknowledgments: EFSA wishes to acknowledge the contribution of Raczyk and Silvia Ruocco to this opinion.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2019. Reasoned Opinion on the setting of import tolerances for chlorantraniliprole in oil palms fruits and oil palms kernels. EFSA Journal 2019;17(11):5877, 23 pp. https://doi.org/10.2903/j.efsa.2019.5877

ISSN: 1831-4732

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, FMC Agro Ltd submitted an application to the competent national authority in the United Kingdom (evaluating Member State, EMS) to set import tolerances for the active substance chlorantraniliprole in oil palms fruits and oil palms kernels. 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 7 February 2019. The EMS proposed to establish maximum residue levels (MRLs) for oil palms fruits and oil palms kernels imported from Malaysia at the level of 0.8 mg/kg and 0.01* mg/kg, respectively.

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 additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of chlorantraniliprole was investigated in the fruit, leafy, pulses/oilseeds crop groups after foliar applications and in cereals/grasses following soil treatment.

Studies investigating the effect of processing on the nature of chlorantraniliprole (hydrolysis studies) were assessed in the framework of the EU pesticides peer review and demonstrated that the active substance is hydrolytically stable under the conditions representative of pasteurisation and sterilisation. However, under boiling conditions, it degraded slightly, forming the degradants 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 total radioactive residue (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 recommends that the relevance and the toxicological profiles of the chlorantraniliprole degradants IN-F6L99, IN-EQW78 and IN-ECD73 identified in standard hydrolysis studies should be assessed, e.g. in the framework of the MRL review or during the process for the renewal of the approval of the active substance chlorantraniliprole.

As the proposed use of chlorantraniliprole is on imported crops and considering that oil palms are a permanent/semi-permanent crop, investigations of residues in rotational crops are not required.

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

EFSA concluded that for the commodities assessed in this application, 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.

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

In support of the authorised use of chlorantraniliprole in Malaysia, the applicant submitted four Good Agricultural Practice (GAP)-compliant residue trials on oil palms, which were performed at four different locations in Malaysia in 2015.

The available residue trials are sufficient to derive MRL proposals of 0.01* mg/kg for oil palms kernels and of 0.8 mg/kg for oil palms fruits.

Processing factors (PF) for the crops under assessment were derived from processing studies provided and are recommended to be included in Annex VI of Regulation (EC) No 396/2005 as follows:

- Oil palms fruits, mesocarp oil (crude palm oil): 2.6
- Oil palms fruits, cake (mesocarp cake): 1.2

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

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 acceptable daily intake (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 3 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) values derived from residue trials on oil palms assessed in the present application, and the STMR value derived in a previous reasoned opinion. For the remaining commodities the existing European Union (EU) MRLs established in Commission Regulation (EU) 2019/50 were used as input values.

The estimated long-term dietary intake accounted for a maximum of 3% of the ADI (NL toddler). The contribution of residues in oil palms fruits and oil palms kernels to the overall long-term exposure is insignificant (0.01% and < 0.01% ADI, respectively).

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

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

| Code(a) | Commodity          | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                      |
|---------|--------------------|-------------------------|-------------------------|------------------------------------------------------------|
| 402020  | Oil palms kernels  | 0.01*                   | 0.01*                   | The submitted data are sufficient to derive an import tolerance (Malaysia GAP). Risk for consumers unlikely |
| 402030  | Oil palms fruits   | 0.01*                   | 0.8                     | The submitted data are sufficient to derive an import tolerance (Malaysia 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.
(F): Fat soluble.
# Table of Contents

Abstract................................................................................................................................................... 1  
Summary................................................................................................................................................. 3  
Assessment.............................................................................................................................................. 6  
1. Residues in plants ........................................................................................................................ 7  
  1.1. Nature of residues and methods of analysis in plants ........................................................... 7  
  1.1.1. Nature of residues in primary crops ............................................................................... 7  
  1.1.2. Nature of residues in rotational crops .......................................................................... 7  
  1.1.3. Nature of residues in processed commodities ............................................................. 7  
  1.1.4. Methods of analysis in plants ...................................................................................... 8  
  1.1.5. Stability of residues in plants ...................................................................................... 8  
  1.1.6. Proposed residue definitions ....................................................................................... 8  
1.2. Magnitude of residues in plants .............................................................................................. 8  
  1.2.1. Magnitude of residues in primary crops................................................................. 8  
  1.2.2. Magnitude of residues in rotational crops ............................................................ 9  
  1.2.3. Magnitude of residues in processed commodities .................................................... 9  
  1.2.4. Proposed MRLs .................................................................................................. 9  
2. Residues in livestock ..................................................................................................................... 9  
3. Consumer risk assessment ............................................................................................................ 9  
4. Conclusion and Recommendations................................................................................................. 10  
References............................................................................................................................................... 10  
Abbreviations ........................................................................................................................................... 11  
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs.............. 13  
Appendix B – List of end points .................................................................................................. 14  
Appendix C – Pesticide Residue Intake Model (PRIMo) ................................................................. 20  
Appendix D – Input values for the exposure calculations ............................................................. 22  
Appendix E – Used compound codes............................................................................................. 23
Assessment

The detailed description of the authorised use of chlorantraniliprole in Malaysia in oil palms, 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-chorol-1-(3-chloro-2-pyridyl)-2-methyl-6-[(methylcarbamoyl)-1H-pyrazole-5-carboxanilide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Chlorantraniliprole was evaluated in the framework of Directive 91/414/EEC1 with Ireland designated as rapporteur Member State (RMS) for several representative uses (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 European Food Safety Authority (EFSA, 2013a). Chlorantraniliprole was approved2 for the use as an insecticide on 1 May 2014.

The EU MRLs for chlorantraniliprole are established in Annex III of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is currently on going. EFSA has issued several reasoned opinions on the modification of MRLs for chlorantraniliprole and the proposals from these reasoned opinions have been considered in several MRL regulations.4 In 2018, the Codex maximum residue limits (CXLs) for peanuts and poultry matrices have been taken over in the EU legislation by the Commission Regulation (EU) 2018/6875.

In accordance with Article 6 of Regulation (EC) No 396/2005, FMC Agro Ltd submitted an application to the competent national authority in the United Kingdom (evaluating Member State, EMS) to set import tolerances for the active substance chlorantraniliprole in oil palms fruits and oil palms kernels. 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 EFSA on 7 February 2019. The EMS proposed to establish MRLs for oil palms fruits and oil palms kernels imported from Malaysia at the level of 0.8 mg/kg and 0.014 mg/kg, respectively.

EFSA based its assessment on the evaluation report submitted by the EMS (United Kingdom, 2019), the draft assessment report (DAR) (Ireland, 2010) prepared under Council Directive 91/414/EEC, the Commission review report on chlorantraniliprole (European Commission, 2018), the conclusion on the peer review of the pesticide risk assessment of the active substance chlorantraniliprole (EFSA, 2013a), as well as the conclusions from previous EFSA opinions on chlorantraniliprole (EFSA, 2010, 2011, 2012a,b, 2013b, 2015, 2016, 2017, 2018).

For this application, the data requirements established in Regulation (EU) No 544/20116 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 546/20117.

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 might need to be reconsidered in the light of the outcome of the MRL review.

---

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 Commission Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
4 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu–pesticides-database/public/?event=pesticide.residue.selection&language=EN
5 Commission Regulation (EU) 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, benzoinderiflupyr, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluazifop-P, isofetamid, methafrenone, pendimethalin and teflubenzuron in or on certain products. C/2018/2627. OJ L 121, 16.5.2018, p. 63–104.
6 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.
7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
A selected list of end points of the studies assessed by EFSA in the framework of this import tolerance application, including the end points of relevant studies previously assessed, are presented in Appendix B. The evaluation report submitted by the EMS (United Kingdom, 2019) 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 the cereals/grasses crop group (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).

Specific metabolism studies for palm fruit/palm kernel are not available. However, considering that plant metabolism was comparable in all crops for which data were available, it is likely that the metabolic behaviour of chlorantraniliprole in the crop/commodities under assessment is comparable. Thus, for the authorised use on oil palms 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 for a permanent/semi-permanent crop such as oil palms.

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 the degradants 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).

In the context of the peer review of the active substance cyantraniliprole (EFSA, 2014) and in recent ongoing applications for setting MRLs for cyantraniliprole,8 the need to further investigate the toxicological properties of a common degradation product (IN-F6L99) and a degradant which is structurally very similar to one of the degradation products found for chlorantraniliprole (IN-N5M09 which is the cyano analogue of the chlorantraniliprole degradant IN-ECD73) was discussed.

EFSA recommends that the relevance and the toxicological profiles of the chlorantraniliprole degradants IN-F6L99, IN-EQW78 and IN-ECD73 identified in standard hydrolysis studies should be assessed, e.g. in the framework of the MRL review or during the process for the renewal of the approval of the active substance chlorantraniliprole.

---

8 EFSA-Q-2018-00324, EFSA-Q-2018-00325 and EFSA-Q-2016-00650.
1.1.4. Methods of analysis in plants

No new methods for enforcement were submitted in the framework of the current application. Analytical methods for the determination of chlorantraniliprole residues in plant commodities were assessed during the EU pesticides peer review (EFSA, 2013a). The DFG S19 multi-residue method based on liquid chromatography and tandem mass spectrometric detection (LC–MS/MS) was sufficiently validated at the limit of quantification (LOQ) of 0.01 mg/kg for the determination of chlorantraniliprole residues in high water-, high acid- and high oil content matrices and in dry/starch commodities. An independent laboratory validation (ILV) was available (EFSA, 2013a).

It is concluded that the method DFG S19 is appropriate for the determination of chlorantraniliprole residues in oil palms fruits and oil palms kernels 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.

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

EFSA concludes that these residue definitions are appropriate for the authorised use on oil palms.

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 Malaysia, the applicant submitted four Good Agricultural Practice (GAP)-compliant residue trials on oil palms, which were performed at four different locations in Malaysia in 2015. The authorised product label in Malaysia allows two applications to each crop cycle and the GAP foresees two harvests per year in oil palm plantations. As such, the GAP (30 g a.s./ha, two applications, 14-day interval, 1-day preharvest interval (PHI)) allows two applications made to each crop cycle with a maximum of four applications per year. The residue trials were performed with two applications with a 14-day (3 trials) or 15-day (1 trial) interval, at growth stages BBCH 61–85 (first application) and BBCH 61–89 (second application), and were judged to be sufficiently representative of the GAP on oil palms.

Sampling was performed at 1-day PHI, in compliance with the authorised use GAP. One trial was designed as a residue decline study and provided information on residues at the PHI intervals of 0, 1, 3, 6, 14 and 19 days after the last application.

In addition, the applicant provided data on four overdosed trials (two applications at a dose rate of 60 g/ha); one of these trials was designed as decline study. The trials were considered as supporting information only and were not used to derive the MRL proposal.

For all trials, results were reported for oil palms fruits and oil palms kernels. The trials were also used to derive processing factors (see Section 1.2.3).

Overall, the number of GAP-compliant residue trials is sufficient to derive MRL proposals for oil palms fruits (code 0402030) and oil palms kernels (code 0402020). For oil palms fruits, the residue levels ranged from 0.19 to 0.38 mg/kg. It is noted that the highest value was observed in the decline study at the PHI interval of 19 days. However, considering also the result of the two decline studies (GAP-compliant and overdosed residue trial), it becomes evident that the residues stay at a rather
constant level with low decline within the period investigated. Thus, the highest result at PHI 19 is considered to be within the normal variability of results in field trials.

For oil palms kernels, quantifiable residues were not found in any of the trials (GAP-compliant and overdosed residue trials).

The residue trial samples of oil palms fruit were stored for a maximum of 2 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 with an LOQ of 0.01 mg/kg and was proven to be fit for purpose (United Kingdom, 2019).

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

Processing studies to assess the magnitude of chlorantraniliprole residues during the processing of oil palms fruits and palms kernels were submitted. Processing of oil palms fruits to mesocarp oil (crude palm oil) leads to a concentration of chlorantraniliprole in the processed product (United Kingdom, 2019).

One of the processing studies investigating the transfer of residues from oil palms kernels to palm kernel oil (crude oil) gave an indication that chlorantraniliprole may concentrate in the kernel oil. However, since the residue concentration in unprocessed oil palms kernels were below the LOQ in all trials, a processing factor could not be derived.

Studies to investigate the magnitude of residues in refined palm oil are not available.

It is noted that the magnitudes of the degradants IN-F6L99, IN-EQW78 and IN-ECD73 were not reported in the submitted processing studies.

The number and quality of the processing studies is sufficient to derive a processing factor of 2.6 for crude palm oil and of 1.2 for mesocarp cake derived from palm fruits, which are recommended to be included in Annex VI of Regulation (EC) No 396/2005.

1.2.4. Proposed MRLs

The submitted data are sufficient to derive risk assessment values and MRL proposals of 0.8 mg/kg for oil palms fruits and 0.01* mg/kg for oil palms kernels in support of the authorised use of chlorantraniliprole on oil palms in Malaysia.

The proposed EU MRLs are in accordance with the MRLs applicable in the exporting country, where MRLs are set only for the processed crude palm fruit oil and crude palm kernel oil (Malaysia MRLs proposed at 1.5 mg/kg and 0.05 mg/kg, respectively), considering the processing factor for crude palm oil (proposed EU MRL_{oil_palms_fruits} × PF (0.8 × 2.6) = 2.08 mg/kg crude palm oil) and the available information for processing of oil palms fruits to crude palm kernel oil (United Kingdom, 2019). The proposed EU and Malaysia MRLs are reported to be based on the same set of residues data.

2. Residues in livestock

Oil palms fruits and oil palms kernels (processed or unprocessed) and their relevant by-products are not included as feed item in the OECD guidance document (OECD, 2013). Thus, an assessment of the impact of the revision of MRLs for palms fruits and palms kernels on expected residues in livestock is not required.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3 of the EFSA PRIMo (EFSA, 2018a). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the 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. acceptable daily intake (ADI) value of 1.56 mg/kg body weight (bw) day) was derived in the framework of the EU pesticides peer review (European Commission, 2018). An acute reference dose (ARfD) was not allocated as not considered necessary.
The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) values derived from residue trials on oil palms assessed in the present application, and the STMR value for hops derived in a previous reasoned opinion (EFSA, 2018b). For the remaining commodities, the existing EU MRLs established in Commission Regulation (EU) 2019/509 were used as input values. The list of input values is presented in Appendix D.

The estimated long-term dietary intake accounted for a maximum of 3% of the ADI (NL toddler). The contribution of residues in oil palms fruits and oil palms kernels to the overall long-term exposure is insignificant (0.01% and < 0.01% ADI, respectively).

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

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for oil palms kernels (code 0402020) and oil palms fruits (code 0402030).

EFSA concluded that the proposed use of chlorantraniliprole on oil palms 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.

References

EFSA (European Food Safety Authority), 2010. Modification of the existing MRL for chlorantraniliprole in carrots. EFSA Journal 2010;8(10):1859, 27 pp. https://doi.org/10.2903/j.efsa.2010.1859

EFSA (European Food Safety Authority), 2011. Reasoned opinion on the modification of the existing MRLs for chlorantraniliprole in various crops and in products of animal origin. EFSA Journal 2011;9(3):2099, 45 pp. https://doi.org/10.2903/j.efsa.2011.2099

EFSA (European Food Safety Authority), 2012a. Reasoned opinion on the modification of the existing MRLs for chlorantraniliprole in various crops. EFSA Journal 2012;10(1):2548, 38 pp. https://doi.org/10.2903/j.efsa.2012.2548

EFSA (European Food Safety Authority), 2012b. Reasoned opinion on the modification of the existing MRLs for chlorantraniliprole in carrots, parsnips, parsley root and celeriac. EFSA Journal 2012;10(11):2988, 24 pp. https://doi.org/10.2903/j.efsa.2012.2988

EFSA (European Food Safety Authority), 2013a. Conclusion on the peer review of the pesticide risk assessment of the active substance chlorantraniliprole. EFSA Journal 2013; 11(6):3143, 107 pp. https://doi.org/10.2903/j.efsa.2013.3143

EFSA (European Food Safety Authority), 2013b. Reasoned opinion on the modification of the existing MRLs for chlorantraniliprole in several root and tuber vegetables and oilseeds. EFSA Journal 2013;11(7):3296, 25 pp. https://doi.org/10.2903/j.efsa.2013.3296

EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole. EFSA Journal 2014;12(9):3814, 249 pp. https://doi.org/10.2903/j.efsa.2014.3814

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of MRLs and the setting of import tolerances for chlorantraniliprole in various crops. EFSA Journal 2015;13(9):4216, 20 pp. https://doi.org/10.2903/j.efsa.2015.4216

EFSA (European Food Safety Authority), 2016. Reasoned opinion on the setting of a temporary maximum residue level for chlorantraniliprole in hops. EFSA Journal 2016;14(11):4638, 16 pp. https://doi.org/10.2903/j.efsa.2016.4638

EFSA (European Food Safety Authority), 2017. Scientific Report of EFSA on the support for preparing an EU position in the 49th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2017;15 (7):4929, 162 pp. https://doi.org/10.2903/j.efsa.2017.4929

EFSA (European Food Safety Authority), 2018a. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMO revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

9 Commission Regulation (EU) 2019/50 of 11 January 2019 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole, clomazone, cyclaniliprole, fenazaquin, fenpicoxamid, fluoxastrobin, lambda-cyhalothrin, meipiquat, onion oil, thiacloprid and valifenalate in or on certain products. C/2019/20. OJ L 10, 14.1.2019, p. 8-59.

10 A more refined chronic intake assessment, including the STMRs for all uses for which MRLs have been assessed in reasoned opinions, would be possible but was considered not necessary, due to the low exposure expressed as percentage of the ADI.
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, 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, 2018b. 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

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/V/95-rev. 6, 22 July 1997.

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

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

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

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

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/V/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, 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, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/V/95-rev. 10.3, 13 June 2017.

European Commission, 2018. Review report for the active substance chlorantraniliprole finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 October 2013 in view of the approval of chlorantraniliprole as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/12081/2013 rev 2, 3 October 2013, revised in 26 January 2018.

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 Ed. FAO Plant Production and Protection Paper 225, 298 pp.

Ireland, 2010. Draft assessment report on the active substance chlorantraniliprole prepared by the rapporteur Member State Ireland in the framework of Directive 91/414/EEC, December 2008. Available online: www.efsa.europa.eu

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. Available online: http://www.oecd.org

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.

United Kingdom, 2019. Evaluation report on the setting of import tolerances in oil palms fruits and oil palms kernels. November 2018, 46 pp. Available online: www.efsa.europa.eu

Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement to risk assessment residue definition
CXL Codex maximum residue limit
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
HR highest residue
IEDI international estimated daily intake
ILV independent laboratory validation
InChIKey International Chemical Identifier Key
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LC-MS/MS liquid chromatography with tandem mass spectrometry
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
$P_{ow}$ partition coefficient between n-octanol and water
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SC suspension concentrate
SEU southern Europe
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
TRR total radioactive residue
UV ultraviolet (detector)
WG water-dispersible granule
### 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<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|------------------------|-----------------------------------|-------------|-----------------|-------------------------------|-----------|---------|
|                       |                         |                        |                                    | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | g a.s./hL min-max | Water L/ha min-max | Rate | Unit |                     |
| Oil Palms             | Import tolerance (Malaysia) | F                       | Bunch moth (<i>Tirathaba mundella</i>) | WG          | 350 g/kg     | Foliar spray | BBCH 11–89                  | 1–2        | 14                  | 10 g a.s./hL (29 g WG product/hL) | 300            | 30                  | g a.s./ha | 1                   | There are 2 harvests per year in oil palm plantations such that 2 applications are made to each crop cycle with a maximum of 4 applications per year |

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: water-dispersible granule.

<sup>(a)</sup>: Outdoor or field use (F), greenhouse application (G) or indoor application (I).

<sup>(b)</sup>: CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.

<sup>(c)</sup>: 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.

<sup>(d)</sup>: 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 DAT<sub>1,2,3</sub> (immature leaves and fruits); 15 and 30 DALA (maturity) | Radiolabelled active substance: mixture of [benzamide carbonyl-<sup>14</sup>C]-chlorantraniliprole and [pyrazole carbonyl-<sup>14</sup>C]-chlorantraniliprole (Ireland, 2010) |
|                                   | Tomato      |       | Foliar, 3 × 100 g/ha; BBCH 61, 73, 81 | 0 DAT<sub>1,2,3</sub> (immature leaves and fruits); 7 and 15 DALA (maturity) |                |
| Leafy crops                       | Lettuce     |       | Foliar, 3 × 100 g/ha; BBCH 13, 19 | 0 DAT<sub>1,2,3</sub>; 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-<sup>14</sup>C]-chlorantraniliprole and [pyrazole carbonyl-<sup>14</sup>C]-chlorantraniliprole (Ireland, 2010) |
| Leafy crops                       | Lettuce     |       | Soil, 300 g/ha | 0, 30, 120, 365 DAT (pyrazole carbonyl label) and 30 DAT (benzamide carbonyl label) |                |
| Cereals (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       | –           | –                                                                              |

### Can a General Residue Definition Be Proposed for Primary Crops?

Yes  EFSA (2013a)

### Rotational Crop and Primary Crop Metabolism Similar?

Yes  EFSA (2013a)

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

Yes  Chlorantraniliprole stable under pasteurisation 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)

Chlorantraniliprole

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

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)

DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; DALA: days after last application; PBI: plant-back interval; TRR: total radioactive residue; 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      | 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, cotton seed meal, raisins | –20    | 12 Months       | Chlorantraniliprole, IN-EQW78, IN-ECD73, IN-F6L99 | EFSA (2013a)    |
|                                   | 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 (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) |
|--------------------|-------------------|----------------------------------------------------------------|------------------------------------------------------|------------------------|---------------|----------------|-------|
| Oil palms fruits   | Malaysia          | 0.19, 0.21, 0.25, 0.38                                          | Residue trials on oil palms compliant with GAP        | 0.8                    | 0.38          | 0.23           | –     |
| Oil palms kernels  | Malaysia          | 4 × < 0.01                                                      | Residue trials on oil palms compliant with GAP        | 0.01*                  | < 0.01        | < 0.01         | –     |

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

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

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

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

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

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

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

|                      | Not triggered | – |
|----------------------|---------------|---|

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

|                      | Not triggered | – |
|----------------------|---------------|---|

B.1.2.3. Processing factors

| Processed commodity                          | Number of valid studies (a) | Processing Factor (PF) Individual values | Median PF | CFp (b) | Comment/ Source |
|----------------------------------------------|-----------------------------|------------------------------------------|-----------|---------|-----------------|
| Oil palms kernels, palm kernel oil (crude oil) | 0                           | –                                        | –         | –       | One study indicated processing of palm kernel to palm kernel oil may result in a concentration of residues. No PF derived since residues in palm kernel were below the LOQ (United Kingdom, 2019) |
| Oil palms fruits, mesocarp oil (crude palm oil) | 6                           | 1.6, 1.9, 1.9, 3.3, 3.4, 3.9       | 2.6       | –       | Three studies at 1N and three studies at 2N (United Kingdom, 2019) |
| Oil palms fruits, cake (mesocarp cake)        | 6                           | 0.38, 0.9, 1.1, 1.2, 1.4, 1.9 | 1.2       | –       | Three studies at 1N and three studies at 2N (United Kingdom, 2019) |

LOQ: limit of quantification.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Not relevant

B.3. Consumer risk assessment

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

ADI

1.56 mg/kg bw per day (European Commission, 2018)

Highest IEDI, according to EFSA PRIMo

3% ADI (NL toddler)

Contribution of crops assessed:

Oil palms fruits: 0.01% of ADI

Oil palms kernels: < 0.01% of ADI

Assumptions made for the calculations

The calculation is based on the median residue levels (STMR) derived for oil palms fruits and oil palms kernels from the residue trials submitted in the framework of this MRL application, and the STMR value for hops derived in a previous reasoned opinion. For the remaining commodities of plant and animal origin the existing EU MRLs set in Commission Regulation (EU) 2019/50 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; HR: highest residue.
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity         | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|------------------|-------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 402020           | Oil palms kernels | 0.01*                   | 0.01*                   | The submitted data are sufficient to derive an import tolerance (Malaysia GAP). Risk for consumers unlikely |
| 402030           | Oil palms fruits  | 0.01*                   | 0.8                     | The submitted data are sufficient to derive an import tolerance (Malaysia GAP). Risk for consumers unlikely |

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

- 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.
- (F): Fat soluble.
## Setting of import tolerances for chlorantraniliprole in oil palms fruit and oil palms kernels

### Appendix C – Pesticide Residue Intake Model (PRIMo)

#### Chlorantraniliprole (F)

| Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment | Details – acute risk assessment/children |
|--------------|-----------------------------------|-----------------------------------------------|--------------------------------|-----------------------------------------|

| Toxicological reference values | EUADI (mg/kg) range from | ADI (mg/kg bw per day) | Net-toxicity |
|------------------------------|---------------------------|------------------------|--------------|
| Source of ADI: | | | | |
| European | | | | |
| Year of evaluation: | | | | |
| European Commission | | | | |
| Year of evaluation: | | | | |

| LOQs (mg/kg) range from | | | | |
| 0.05 | | | | |
| 0.1 | | | | |
| 1.56 | | | | |

#### Normal mode

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

- **Source of ADI:**
  - JMPR methodology (IEDI/TMDI)
  - Year of evaluation: 2018

**Normal mode**

| Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment | Details – acute risk assessment/children |
|--------------|-----------------------------------|-----------------------------------------------|--------------------------------|-----------------------------------------|

**Conclusion:**

The estimated long-term dietary intake (TMDI/IEDI/IDD) was below the ADI.

The long-term intake of residues of Chlorantraniliprole (F) is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Show results for all crops

**Unprocessed commodities**

| Results for children | Results for adults |
|----------------------|--------------------|
| No. of commodities for which ARfD/ADI is exceeded (ESTI): | — |
| Highest % of ARfD/ADI | — |
| Commodities | — |
| MRL/input for RA | — |
| (mg/kg) | — |
| Exposure | — |
| (µg/kg bw) | — |

**Processed commodities**

| Results for children | Results for adults |
|----------------------|--------------------|
| No. of processed commodities for which ARfD/ADI is exceeded (ESTI): | — |
| Highest % of ARfD/ADI | — |
| Processed commodities | — |
| MRL/input for RA | — |
| (mg/kg) | — |
| Exposure | — |
| (µg/kg bw) | — |

**Conclusion:**

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

## D.1. Consumer risk assessment

| Commodity                              | Input value (mg/kg) | Chronic risk assessment | Comment                                      |
|----------------------------------------|---------------------|-------------------------|----------------------------------------------|
| Oil palms kernels (palm nuts)          | 0.01                |                         | STMR                                         |
| Oil palms fruits (palm fruit)          | 0.23                |                         | STMR                                         |
| Hops                                   | 10.45               |                         | STMR (EFSA, 2018b)                           |
| Other commodities of plant and animal origin | MRL                |                         | Commission Regulation (EU) 2019/50            |

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'-choloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'- (methylcarbamoyl)-1H-pyrazole-5-carboxanilide CNC(-O)c3 cc(Cl)cc(C)c3NC(=O)c2 cc(Br)nn2c1nccc1Cl PSOVNZNOMUFI-UMFFFAPYSA-N | ![Structural formula](image) |
| IN-F6L99 | 3-bromo-N-methyl-1H-pyrazole-5-carboxamide BrC1 cc(nn1)C(=O)NC LOYJZLXLMX-UMFFFAPYAC | ![Structural formula](image) |
| IN-EQW78 | 2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one Cc4 cc(Cl)cc3c4N=C(c2 cc(Br)nn2c1nccc1Cl)N(C)C3=O QTUSYELNABSJ-UHFFFAOYAD | ![Structural formula](image) |
| IN-ECD73 | 2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one Cc3 cc(C)=cc2c3N=C1C(Cl)=CC-CN1C2=O HWZDYXZGZCNEA-UHFFFAOYAD | ![Structural formula](image) |
| IN-N5M09 | 6-chloro-4-methyl-11-oxo-11H-pyrido[2,1-b]quinazoline-2-carbonitrile Cc3 cc(C=N)cc2c3N=C1C(Cl)=CC-CN1C2=O | ![Structural formula](image) |

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

<sup>(a)</sup>: ACD/Name 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).