Setting of import tolerances for chlorantraniliprole in strawberries and pulses

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant FMC Agro Limited submitted a request to the competent national authority in the UK to set import tolerances for the active substance chlorantraniliprole in strawberries and the whole category pulses (beans, lentils, peas and lupins/lupini beans). The data submitted in support of the request were found to be sufficient to derive an maximum residue level (MRL) proposal for the whole category pulses. The available data are not sufficient to derive an import tolerance for strawberries and no modification of the current EU MRL is required. 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. The reliable end points, appropriate for use in regulatory risk assessment are presented.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, FMC Agro Limited submitted an application to the competent national authority in the UK (Evaluating Member State, EMS) to set import tolerances for the active substance chlorantraniliprole in strawberries and pulses. 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 20 August 2019. The EMS proposed to establish maximum residue levels (MRLs) for the whole category pulses at the level of 0.3 mg/kg and to maintain the MRL for strawberries at the level of 1.00 mg/kg in the event that the current MRL for strawberries would not be supported in the MRL review.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. After the withdrawal of the UK from the Union on 1 February 2020, the application was reallocated to the EMS Ireland. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 3 September 2020, the EMS Ireland submitted a revised evaluation report, which replaced the previously submitted evaluation report.

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 following foliar applications has been investigated in crops belonging to the groups of fruit, leafy and pulses/oilseeds crops and following soil treatment in cereals/grasses crop groups. For the intended use of chlorantraniliprole in strawberries and pulses, belonging to the fruit and pulses/oilseeds crop groups respectively, the metabolic behaviour in primary crops is satisfactorily addressed.

Studies investigating the effect of processing on the nature of chlorantraniliprole (hydrolysis studies) demonstrated that the active substance is stable under representative conditions 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. The chlorantraniliprole degradants IN-F6L99, IN-EQW78 and IN-ECD73 were considered in the framework of the recent MRL review of the active substance chlorantraniliprole. The MRL review concluded that the plant residue definition for monitoring and risk assessment derived in the conclusion of the peer review is applicable to processed commodities; nonetheless, the MRL review recommended that for new uses, the levels of these degradants should be analysed in processed commodities and, if significant levels are found, their inclusion in the risk assessment residue definition should be reconsidered. For the current reasoned opinion, residues levels are expected to be very low in the crops under consideration and further consideration of the nature of residues in processed commodities is not required. As the proposed uses of chlorantraniliprole are on imported crops, 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. The MRL review recommended that for new uses, the levels of the degradants IN-F6L99, IN-EQW78 and IN-ECD73 should be analysed in processed commodities and, if significant levels are found, their inclusion in the risk assessment residue definition should be reconsidered. 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)).
The available residue trials are sufficient to derive an MRL proposal of 0.3 mg/kg for the whole category pulses. For the intended use on strawberries, the available data are not sufficient to derive an import tolerance and no modification of the current EU MRL is required.

Specific studies investigating the magnitude of chlorantraniliprole residues in processed commodities are not required as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI). The degradants IN-F6L99, IN-EQW78 and IN-ECD73 were not included in the residue definition for processed commodities; nonetheless, the MRL review recommended that for new uses, the levels of these degradants should be analysed in processed commodities and, if significant levels are found, their inclusion in the risk assessment residue definition should be reconsidered. For the current reasoned opinion, residue levels in the crops under consideration are expected to be very low and therefore investigation of the magnitude of the degradants IN-F6L99, IN-EQW78 and IN-ECD73 in processed commodities is not required.

Although some of the crops under assessment (pulses) and their by-products are used as feed products, a modification of the existing MRLs for commodities of animal origin was considered unnecessary since the authorised use of chlorantraniliprole on the commodities under consideration has no significant impact on the previous livestock dietary burden assessed by EFSA.

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 3.1 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 from the crops under assessment except for strawberries where the Codex maximum residue limit (CXL) STMR was used since it was derived from a more critical Good Agricultural Practice (GAP), and the STMR values derived in the recent review of the existing MRLs under Article 12 of Regulation 396/2005 (not yet implemented in the European Union (EU) regulation) taking also into account the CXLs values that were adopted into the EU regulation and the existing EU MRL for Brussels sprouts, kohlrabies, beans (without pods), peas (without pods), lentils (fresh) and chicory roots.

The estimated long-term dietary intake accounted for a maximum of 0.8% of the ADI (NL toddler). The contribution of residues in strawberries and in each commodity belonging to the group of pulses (beans, lentils, peas, lupins/lupini beans and other pulses) assessed in the present application, to the overall long-term exposure is very low (0.01% and < 0.01% of the ADI, respectively). EFSA concluded that the authorised use of chlorantraniliprole on strawberries and pulses 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 to D.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0152000 | Strawberries | 1.00 | No MRL proposal | The available data are not sufficient to derive an import tolerance due to a lack of available independent residues trials. In case risk managers consider the trials to be acceptable, the available data would allow for the calculation of an MRL of 1 mg/kg Risk for consumers unlikely |
| 0300000 | Pulses | 0.01* | 0.3 | The submitted data are sufficient to derive an import tolerance (US 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.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for chlorantraniliprole in pulses and to maintain the existing MRL for strawberries. The detailed description of the intended uses of chlorantraniliprole in strawberries and pulses, which are the basis for the current 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)-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 EFSA (2013a). Chlorantraniliprole was approved2 for the use as an insecticide on 1 May 2014. The process of renewal of the first approval has not yet been initiated.

The European Union (EU) MRLs for chlorantraniliprole are established in Annex III of Regulation (EC) No 396/20053. The review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2020), the proposed modifications have not yet been implemented in the EU MRL legislation. EFSA has issued several reasoned opinions on the modification of MRLs for chlorantraniliprole. The proposals from these reasoned opinions have been considered in recent MRL regulations.4 Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.5

In accordance with Article 6 of Regulation (EC) No 396/2005, FMC Agro Limited submitted an application to the competent national authority in the UK (evaluating Member State, EMS) to set import tolerances for the active substance chlorantraniliprole in strawberries and pulses. 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 20 August 2019. The EMS proposed to establish MRLs for pulses at the level of 0.3 mg/kg and to maintain the MRL for strawberries at the level of 1.00 mg/kg in the event that the current MRL for strawberries would not be supported in the MRL review.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. After the withdrawal of the UK from the Union on 1 February 2020, the application was reallocated to the EMS Ireland. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 3 September 2020, the EMS Ireland submitted a revised evaluation report, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS UK and updated by Ireland (United Kingdom, 2019), the draft assessment report (DAR) (and its addendum) (Ireland, 2010, 2013) 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), the reasoned opinion on the MRL review (EFSA, 2020) as well as the conclusions from previous EFSA opinions on chlorantraniliprole (EFSA, 2010, 2011, 2012a,b, 2013b, 2015, 2016, 2018b, 2019b).

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.

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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 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, benzo[b]thiophenepirim, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluazifop-P, isofetamid, metfenacet, pendimethalin and tebuconazole 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.
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. 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, is presented in Appendix B.

The evaluation report submitted by the EMS UK and updated by Ireland (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 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, 2011, 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, 2011, 2013a).

For the intended use of chlorantraniliprole in strawberries and pulses, belonging to the fruit and pulses/oilseeds crop groups respectively, the metabolic behaviour in primary crops is satisfactorily addressed.

1.1.2. Nature of residues in rotational crops

The investigation of chlorantraniliprole residues in rotational crops is not required for an 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 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 ongoing applications for setting MRLs for cyantraniliprole, 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-NSM09 which is the cyano analogue of the chlorantraniliprole degradant IN-ECD73) was discussed. The chlorantraniliprole degradants IN-F6L99, IN-EQW78 and IN-ECD73 were considered in the framework of the recent MRL review of the active substance chlorantraniliprole. The MRL review concluded that...
the plant residue definition for monitoring and risk assessment derived in the conclusion of the peer review is applicable to processed commodities, nonetheless, the MRL review recommended that for new uses, the levels of these degradants should be analysed in processed commodities and, if significant levels are found, their inclusion in the risk assessment residue definition should be reconsidered (EFSA, 2020). For the current reasoned opinion, residues levels are expected to be very low in the crops under consideration and further consideration of the nature of residues in processed commodities is not required.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of chlorantraniliprole residues were assessed during the EU pesticides peer review and the MRL review (EFSA, 2013a, 2020). The DFG S19 multi-residue method based on liquid chromatography-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, dry commodities and hops. An independent laboratory validation (ILV) was available (EFSA, 2013a, 2018b).

QuEChERS multi-residue method is also available using LC-MS/MS with an LOQ of 0.01 mg/kg in high water content, high acid content, high oil content and dry commodities (LOQ 0.005 mg/kg) for the enforcement of chlorantraniliprole in routine analysis (EFSA, 2020). No new methods for enforcement were submitted in the framework of the current application. It is concluded that the method DFG S19 is appropriate for the determination of residues of chlorantraniliprole in the crops under assessment at the validated LOQ of 0.01 mg/kg.

1.1.5. Storage stability of residues in plants

The 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, high starch and dry 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 for products of plant origin:

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

The same residue definitions are applicable to rotational crops and processed products. The MRL review recommended that for new uses, the levels of the degradants IN-F6L99, IN-EQW78 and IN-ECD73 should be analysed in processed commodities and, if significant levels are found, their inclusion in the risk assessment residue definition should be reconsidered (EFSA, 2020).

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 requested import tolerances.

The residue definition set in the USA for the determination of tolerance levels for the commodities under consideration is chlorantraniliprole only and is equivalent to the EU residue definition for products of plant origin.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the import tolerance application, the applicant submitted residue trials performed in strawberry, pea and bean. The residue trials were performed by foliar application with various adjuvants; however, the Good Agricultural Practice (GAP) and label do not specify that an adjuvant should be used. The EMS reported that the adjuvants increase spray droplet retention and will most likely result in a worst-case residues level within the trials and the values are suitable for the risk assessment (United Kingdom, 2019).
The samples of all the residue trials were stored under conditions for which integrity of the residues has been demonstrated. The samples were analysed for the parent compound in accordance with the residue definition for enforcement and risk assessment. According to the assessment of the EMS, the methods of analysis used were sufficiently validated and fit for purpose (United Kingdom, 2019).

**Strawberry**

The applicant submitted eight trials performed in strawberry in the USA and Canada in 2011 (109–119 g a.s./ha, 2 applications, 6- or 7-day interval, 1-day preharvest interval (PHI)) which are compliant with the US GAP maximum application rate per crop (224 g a.s./ha). EFSA requested further information to address the independency of two trials (trials No 6 and No 7) performed at sites less than 10 km and with dates of treatment that differed by 3 days. The EMS provided argumentation that the trials may be considered independent due to rainfall data of the trials; however EFSA considers that the rainfall amount is very low compared to the total irrigation applied to the trials. EFSA considers the trials are not sufficiently independent and may be considered as different experimental conditions within a same trial, and therefore the higher residue value was selected. Strawberries are a major crop and a minimum of 8 trials are required (European Commission, 2017). Therefore, EFSA concluded that one additional trial is required to derive an MRL proposal for strawberries.

**Pulses**

The applicant submitted five trials on dry beans and five trials on dry peas performed in the USA in 2017 (109–114 g a.s./ha, 2 applications, 3-day interval, 1-day PHI), which are compliant with the US GAP for pulses. Dry peas and dry beans are a major crop and thus a minimum of 8 trials are needed (European Commission, 2017). Since it is possible to combine both data sets according to the guidelines (European Commission, 2017), 10 trials are available to derive an import tolerance of 0.3 mg/kg for the whole category pulses by extrapolation.

1.2.2. Magnitude of residues in rotational crops

The investigation of chlorantraniliprole residues in rotational crops is not required for an import tolerance application.

1.2.3. Magnitude of residues in processed commodities

Studies to assess the magnitude of chlorantraniliprole residues during the processing of the crops under assessment have not been submitted and are not required as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI) (European Commission, 1997d).

The degradants IN-F6L99, IN-EQW78 and IN-ECD73 were not included in the residue definition for processed commodities (see Sections 1.1.3 and 1.1.6); nonetheless, the MRL review recommended that for new uses, the levels of these degradants should be analysed in processed commodities and, if significant levels are found, their inclusion in the risk assessment residue definition should be reconsidered (EFSA, 2020). For the current reasoned opinion, residue levels in the crops under consideration are expected to be very low and therefore investigation of the magnitude of the degradants IN-F6L99, IN-EQW78 and IN-ECD73 in processed commodities is not required.

1.2.4. Proposed MRLs

The available data are sufficient to derive an MRL proposal of 0.3 mg/kg for the whole category pulses (beans, lentils, peas and lupins/lupini beans) extrapolated from the residue trials on dry peas and dry beans in the United States. It is noted that the US tolerance corresponds to the US classification Vegetable Legume Group 6 and is currently set at 2 mg/kg.

The available data are not sufficient to derive an MRL proposal for strawberries due to a lack of available independent residues trials. In case risk managers consider the non-independent trials to be acceptable, the available data would allow for the calculation of an MRL for strawberries of 1 mg/kg. It is noted that the current EU MRL for chlorantraniliprole on strawberries is the same as the one recommended by the MRL review (based on CXLs) (EFSA, 2020) and by the applicant (1 mg/kg). The US tolerance for strawberries is currently set at 1 mg/kg.

In Section 3, EFSA assessed whether residues on this crop resulting from the intended use are likely to pose a consumer health risk.
2. **Residues in livestock**

Pulses may be used for feed purposes; therefore, it was necessary to update the previous dietary burden calculation for livestock to estimate whether the authorised use of chlorantraniliprole would have an impact on the residues expected in food of animal origin.

The metabolism of chlorantraniliprole residues in livestock was investigated in the framework of the Article 12 MRL review and, considering the different metabolic patterns observed in ruminants and poultry and the results of the feeding studies, different residue definitions for risk assessment were proposed, namely, sum of chlorantraniliprole, IN-HXH44 and IN-K9T00, expressed as chlorantraniliprole, for ruminants and swine products; and parent chlorantraniliprole only, for poultry tissues and eggs (EFSA, 2020).

The input values for the exposure calculations for livestock are presented in Appendix D.1. The results of the dietary burden calculation are presented in Section B.2. Considering that the authorised use of chlorantraniliprole on the commodities under consideration has no significant impact on the previous dietary burden assessed by EFSA for ruminants, poultry and swine (EFSA, 2020) (only for swine the calculated maximum dietary burden was 1.30 mg/kg dry matter (DM) vs 1.29 mg/kg DM from the previous EFSA assessment), EFSA concluded that a modification of the MRLs proposed in the MRL review for products of animal origin is not required.

3. **Consumer risk assessment**

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev.3.1). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018a, 2019a).

The toxicological reference value for chlorantraniliprole used in the risk assessment (i.e. ADI value of 1.56 mg/kg body weight (bw) per 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 from the crops under assessment except for strawberries where the CXL STMR was used since it was derived from a more critical GAP, and the STMR values derived in the recent review of the existing MRLs under Article 12 of Regulation 396/2005 (not yet implemented in the EU regulation) taking also into account the CXLs values that were adopted into the EU regulation and the existing EU MRL for Brussels sprouts, kohlrabies, beans (without pods), peas (without pods), lentils (fresh) and chicory roots.

The list of input values is presented in Appendix D.2.

The estimated long-term dietary intake accounted for a maximum of 0.8% of the ADI (NL toddler).

The contribution of residues in strawberries and in each commodity belonging to the group of pulses (beans, lentils, peas, lupins/lupini beans and other pulses) assessed in the present application to the overall long-term exposure is very low (0.01% and < 0.01% of the ADI, respectively).

EFSA concluded that the long-term intake of chlorantraniliprole residues resulting from the existing uses and the authorised use on strawberries and pulses 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 an MRL proposal for the whole category pulses. The available data are not sufficient to derive an MRL proposal for strawberries due to a lack of available independent residues trials.

EFSA concluded that the authorised use of chlorantraniliprole on strawberries and pulses 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
- **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
- **DM** dry matter
- **EMS** evaluating Member State
- **FAO** Food and Agriculture Organization of the United Nations
- **GAP** Good Agricultural Practice
- **HR** highest residue
- **IEEDI** international estimated daily intake
- **IESTI** international estimated short-term intake
- **ILV** independent laboratory validation
- **ISO** International Organisation for Standardisation
- **IUPAC** International Union of Pure and Applied Chemistry
- **LC–MS/MS** liquid chromatography with tandem mass spectrometry
- **LOQ** limit of quantification
- **MRL** maximum residue level
- **NEU** northern Europe
- **OECD** Organisation for Economic Co-operation and Development
- **PBI** plant-back interval
| Abbreviation | Description |
|--------------|-------------|
| PF           | processing factor |
| PHI          | preharvest interval |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SC           | suspension concentrate |
| SEU          | southern Europe |
| 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 | NEU, SEU, MS or country | Pest(s) or Group of pests controlled | Preparation Type | Conc. a.s. | Method kind | Start growth stage & season | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|--------------------------------------|------------------|-----------|-------------|-----------------------------|---------------|-----------------------------------|----------------|----------------|-----------------------------|-----------|---------|
| **Strawberry**        | USA F                    | Beet armyworm; Cabbage looper; Corn earworm; Japanese beetle; Light brown apple moth | SC 200 g/L       | Foliar treatment – broadcast spraying | 11–89       | 4             | 7                           | 47-94         | 110 g a.s./ha                   | Maximum application rate per crop: 224 g a.s./ha | Maximum annual application rate: 448 g a.s./ha (Critical GAP per crop: 2 applications at the maximum rate) |
| **Pulses** (bean, lentil, pea, lupin/lupini bean) | USA F | Corn earworm; Beet armyworm; European corn borer; Fall armyworm; Cabbage looper; Soybean looper; Western bean cutworm; Leaf miners (larvae); Silverleaf whiteflies (nymphs) | SC 200 g/L | Foliar treatment – broadcast spraying | 11–89       | 4             | 3                           | 47-94         | 110 g a.s./ha                   | Maximum application rate per crop: 224 g a.s./ha | Maximum annual application rate: 673 g a.s./ha (Critical GAP per crop: 2 applications at the maximum rate) |

MRL: maximum residue level; GAP: Good Agricultural Practice; 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, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
## Appendix B – List of end points

### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

#### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Apples      | 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 (EFSA, 2011, 2013a) |
| Fruit crops                       | Tomatoes    | 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                       | Lettuces    | 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 | Crop(s) | Application(s) | 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 (EFSA, 2011, 2013a) |
| Leafy crops                          | Lettuces    | Soil, 300 g/ha | 0, 30, 120, 365 DAT (pyrazole carbonyl label) and 30 DAT (benzamide carbonyl label) |  |
| 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        | –       | –                                                                              |

### 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 is 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)
- High water, high acid, high oil content commodities, dry commodities and hops [EFSA, 2013a, 2018b]:
  - Multiresidue Method DFG S19 (LC–MS/MS)
  - LOQ 0.01 mg/kg
  - ILV (LC–MS/MS) available
  - QuEChERS (LC–MS/MS) also available for enforcement in routine analysis, LOQ 0.01 mg/kg for high water, high acid, and high oil content commodities; LOQ 0.005 mg/kg for dry commodities [EFSA, 2020]

DAT: days after treatment; 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; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; LOQ: limit of quantification.
### 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                       | –20    | 24 Months       | Chlorantraniliprole                | EFSA (2013a)    |
|                                    |                     | Apple, tomato, lettuce, cauliflower      |        |                 |                                     |                 |
|                                    |                     | High oil content                         | –20    | 24 Months       | Chlorantraniliprole                | EFSA (2013a)    |
|                                    |                     | Cotton seed                              |        |                 |                                     |                 |
|                                    |                     | High protein                             | –20    | 24 Months       | Chlorantraniliprole                | EFSA (2013a)    |
|                                    |                     | Wheat grain                              |        |                 |                                     |                 |
|                                    |                     | High starch                              | –20    | 24 Months       | Chlorantraniliprole                | EFSA (2013a)    |
|                                    |                     | Potato                                   |        |                 |                                     |                 |
|                                    |                     | High acid content                        | –20    | 24 Months       | Chlorantraniliprole                | EFSA (2013a)    |
|                                    |                     | Grape                                    |        |                 |                                     |                 |
|                                    | 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 (dry)        | Straw                                    | –20    | 24 Months       | Chlorantraniliprole                | EFSA (2013a)    |
|                                    |                     | Alfalfa hay                              |        |                 |                                     |                 |
### 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) |
|-----------|-------------------|---------------------------------------------------------------|----------------|-----------------------|---------------|-----------------|-------|
| Strawberries | USA/Canada Outdoor | 0.18; 0.21; 0.23†; 0.24; 0.24; 0.40; 0.68 | Residue trials on strawberries compliant with GAP. The available data are not sufficient to derive an import tolerance due to a lack of available independent residues trials (†) higher residue value of two trials not sufficiently independent regarding geographical location and dates of treatments but performed with different experimental conditions In case risk managers consider both residue values (0.20 and 0.23) from the non-independent trials to be acceptable, the available data would allow for the calculation of an MRL of 1 mg/kg | – | – | – | – |
| Pea (dry) | USA Outdoor | Pea (dry): 0.024; 0.036; 0.054; 0.057; 0.18 Bean (dry): 0.011; 0.013; 0.016; 0.025; 0.051 | Combined residue trials on peas (dry) and beans (dry) compliant with GAP. Extrapolation to the whole category pulses (bean, lentil, pea, lupin/lupini bean) possible | 0.3 | 0.18 | 0.03 | – |

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): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.3. Residues in rotational crops

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

| Study not required (imported crops) |
| ----------------------------------- |

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

| Study not required (imported crops) |
| ----------------------------------- |

B.1.2.4. Processing factors

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

B.2. Residues in livestock

Dietary burden calculation according to OECD (2013).

| Relevant groups (sub groups) | Dietary burden expressed in mg/kg bw per day | Most critical sub group(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | Previous assessment (EFSA, 2020) Max burden mg/kg DM |
|-----------------------------|---------------------------------------------|-----------------------------|-----------------------------|------------------------|---------------------------------------------------|
| Cattle (all diets)          | 0.051 0.088 1.40 2.41                      | Dairy cattle                | Cabbage, heads              | Yes                    | 2.41                                              |
| Cattle (dairy only)         | 0.051 0.088 1.34 2.30                      | Dairy cattle                | Cabbage, heads              | Yes                    | 2.30                                              |
| Sheep (all diets)           | 0.035 0.055 1.05 1.58                      | Lamb                        | Cabbage, heads              | Yes                    | 1.58                                              |
| Sheep (ewe only)            | 0.035 0.053 1.05 1.58                      | Ram/Ewe                     | Cabbage, heads              | Yes                    | 1.58                                              |
| Swine (all diets)           | 0.017 0.030 0.74 1.30                      | Swine (breeding)            | Cabbage, heads              | Yes                    | 1.29                                              |
| Poultry (all diets)         | 0.018 0.035 0.26 0.51                      | Poultry layer               | Cabbage, heads              | Yes                    | 0.51                                              |
| Poultry (layer only)        | 0.018 0.035 0.26 0.51                      | Poultry layer               | Cabbage, heads              | Yes                    | 0.51                                              |

bw: body weight; DM: dry matter.

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

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

bw: body weight; DM: dry matter.

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

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

bw: body weight; DM: dry matter.

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

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

bw: body weight; DM: dry matter.

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

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

bw: body weight; DM: dry matter.

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

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

bw: body weight; DM: dry matter.

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

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

bw: body weight; DM: dry matter.

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

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

bw: body weight; DM: dry matter.

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

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

bw: body weight; DM: dry matter.
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 | 0.8% ADI (NL toddler) |

Contribution of crops assessed:
- Strawberries: 0.01% of ADI
- Pulses (beans, lentils, peas): each < 0.01% of ADI

Assumptions made for the calculations

The calculation is based on the median residue levels (STMR) derived for the commodities of the group of pulses from the residue trials submitted in the current application. For strawberries, the CXL STMR was used since it represents a more critical GAP than the GAP assessed in the current reasoned opinion. The STMR values for other crops were derived from the recent MRL review taking also into account the CXLs that have been already implemented into the EU regulation (EFSA, 2020) and the existing EU MRLs for Brussels sprouts, kohlrabies, beans (without pods), peas (without pods), lentils (fresh) and chicory roots.

Calculations were performed with PRiMo revision 3.1.

ADI: acceptable daily intake; IEDI: international estimated daily intake; PRiMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; STMR: supervised trials median residue; CXL: Codex maximum residue limit.

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|--------|-----------|------------------------|-------------------------|-----------------------|
| 0152000 | Strawberries | 1.00 | No MRL proposal | The available data are not sufficient to derive an import tolerance due to a lack of available independent residues trials. In case risk managers consider the trials to be acceptable, the available data would allow for the calculation of an MRL of 1 mg/kg Risk for consumers unlikely |
| 0300000 | Pulses | 0.01* | 0.3 | The submitted data are sufficient to derive an import tolerance (US GAP) Risk for consumers unlikely |

MRL: maximum residue level.
*: 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.
Chlorantraniliprole (DPX-E-2Y45) (F)

### Refined calculation mode

| Commodity | MS Diet | Exposure (µg/kg bw per day) | % of ADI | Highest contributor | 2nd contributor | 3rd contributor | Calculated exposure (µg/kg bw per day) | % of ADI | Calculated exposure (µg/kg bw per day) | % of ADI |
|-----------|---------|----------------------------|--------|--------------------|----------------|---------------|---------------------------------------|--------|---------------------------------------|--------|
| Lettuces  | DE child| 0.06                       | 0.1%   | Leeks              | Milch: Cattle  | Milch: Cattle | 3.12                                   | 0.1%   | 3.12                                  | 0.1%   |
|           | ES child| 0.06                       | 0.1%   | Leeks              | Milch: Cattle  | Milch: Cattle | 3.12                                   | 0.1%   | 3.12                                  | 0.1%   |
|           | NL child| 0.06                       | 0.1%   | Leeks              | Milch: Cattle  | Milch: Cattle | 3.12                                   | 0.1%   | 3.12                                  | 0.1%   |
|           | NL adult| 0.06                       | 0.1%   | Leeks              | Milch: Cattle  | Milch: Cattle | 3.12                                   | 0.1%   | 3.12                                  | 0.1%   |
|           | VT adult| 0.06                       | 0.1%   | Leeks              | Milch: Cattle  | Milch: Cattle | 3.12                                   | 0.1%   | 3.12                                  | 0.1%   |
|           | WW adult| 0.06                       | 0.1%   | Leeks              | Milch: Cattle  | Milch: Cattle | 3.12                                   | 0.1%   | 3.12                                  | 0.1%   |
|           | WW child| 0.06                       | 0.1%   | Leeks              | Milch: Cattle  | Milch: Cattle | 3.12                                   | 0.1%   | 3.12                                  | 0.1%   |

**Conclusion:**

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

The long-term intake of residues of Chlorantraniliprole (DPX-E-2Y45) (F) is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

| Commodities | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|--------------|-------------------|--------------------|
| Unprocessed commodities | Highest % of ARfD/ADI | RA |
| Processed commodities | Highest % of ARfD/ADI | RA |

**Conclusion:**

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Results for children: No of commodities for which ARfD/ADI is exceeded (IESTI):

Results for adults: No of commodities for which ARfD/ADI is exceeded (IESTI):

Details – acute risk assessment/children

Details – acute risk assessment/adults
### Appendix D – Input values for the exposure calculations

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

| Feed commodity                      | Median dietary burden | Maximum dietary burden |
|-------------------------------------|-----------------------|------------------------|
|                                     | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment    |
| Cabbage, heads leaves               | 0.52                  | STMR (EFSA, 2020)      | 1.2                   | HR (EFSA, 2020) |
| Rice straw                          | 0.01                  | STMR (EFSA, 2020)      | 0.21                  | HR (EFSA, 2020) |
| Carrot culls                        | 0.01                  | STMR (EFSA, 2020)      | 0.04                  | HR (EFSA, 2020) |
| Potato culls                        | 0.01*                 | STMR (EFSA, 2020)      | 0.01*                 | HR (EFSA, 2020) |
| Swede roots                         | 0.01                  | STMR (EFSA, 2020)      | 0.04                  | HR (EFSA, 2020) |
| Turnip roots                        | 0.01                  | STMR (EFSA, 2020)      | 0.04                  | HR (EFSA, 2020) |
| Bean seed (dry)                     | 0.03                  | STMR                   |                       |             |
| Corn, field (Maize) grain           | 0.01*                 | STMR (EFSA, 2020)      | 0.01*                 | STMR (EFSA, 2020) |
| Corn, pop grain                     | 0.01*                 | STMR (EFSA, 2020)      | 0.01*                 | STMR (EFSA, 2020) |
| Cotton undelinted seed              | 0.05                  | STMR (EFSA, 2020)      | 0.05                  | STMR (EFSA, 2020) |
| Cowpea seed                         | 0.03                  | STMR                   |                       |             |
| Lupin seed                          | 0.03                  | STMR                   |                       |             |
| Millet grain                        | 0.01*                 | STMR (EFSA, 2020)      | 0.01*                 | STMR (EFSA, 2020) |
| Pea (Field pea) seed (dry)          | 0.03                  | STMR                   |                       |             |
| Sorghum grain                       | 0.01*                 | STMR (EFSA, 2020)      | 0.01*                 | STMR (EFSA, 2020) |
| Apple pomace, wet                   | 0.18                  | STMR × PF (2.2) (EFSA, 2020) | 0.18                  | STMR × PF (2.2) (EFSA, 2020) |
| Canola (Rape seed) meal             | 0.6                   | STMR × default PF (2)(a) (EFSA, 2020) | 0.6                   | STMR × default PF (2)(a) (EFSA, 2020) |
| Citrus dried pulp                   | 2.1                   | STMR × PF (10)(a) (EFSA, 2020) | 2.1                   | STMR × PF (10)(a) (EFSA, 2020) |
| Coconut meal                        | 0.02                  | STMR × default PF (1.5)(a) (EFSA, 2020) | 0.02                  | STMR × default PF (1.5)(a) (EFSA, 2020) |
| Corn, field milled by-pdts          | 0.01*                 | STMR(b) (EFSA, 2020)   | 0.01*                 | STMR(b) (EFSA, 2020) |
| Corn, field hominy meal             | 0.01*                 | STMR(b) (EFSA, 2020)   | 0.01*                 | STMR(b) (EFSA, 2020) |
| Corn, field gluten feed             | 0.01*                 | STMR(b) (EFSA, 2020)   | 0.01*                 | STMR(b) (EFSA, 2020) |
| Corn, field gluten, meal            | 0.01*                 | STMR(b) (EFSA, 2020)   | 0.01*                 | STMR(b) (EFSA, 2020) |
| Cotton meal                         | 0.04                  | STMR × PF (0.8)(c) (EFSA, 2020) | 0.04                  | STMR × PF (0.8)(c) (EFSA, 2020) |
| Distiller’s grain dried             | 0.03                  | STMR × default PF (3.3)(a) (EFSA, 2020) | 0.03                  | STMR × default PF (3.3)(a) (EFSA, 2020) |
| Flaxseed/ Linseed meal              | 0.49                  | STMR × default PF (2)(a) (EFSA, 2020) | 0.49                  | STMR × default PF (2)(a) (EFSA, 2020) |
| Lupin seed meal                     | 0.033                 | STMR (0.03) × default PF (1.1) (EFSA, 2020) | 0.033                 | STMR (0.03) × default PF (1.1) (EFSA, 2020) |
| Palm (hearts) kernel meal           | 0.01*                 | STMR (EFSA, 2020)      | 0.01*                 | STMR (EFSA, 2020) |
| Peanut meal                         | 0.02                  | STMR × default PF (2)(a) (EFSA, 2020) | 0.02                  | STMR × default PF (2)(a) (EFSA, 2020) |

**Risk assessment residue definition:** Chlorantraniliprole

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Setting of import tolerances for chlorantraniliprole in strawberries and pulses

[www.efsa.europa.eu/efsajournal 23 EFSA Journal 2020;18(11):6300](www.efsa.europa.eu/efsajournal)
### Feed commodity Median dietary burden Maximum dietary burden

| Feed commodity       | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
|----------------------|---------------------|---------|---------------------|---------|
| Potato process waste | 0.2                 | STMR × default PF (20)\(^{(a)}\) (EFSA, 2020) | 0.2     | STMR × default PF (20)\(^{(a)}\) (EFSA, 2020) |
| Potato dried pulp    | 0.38                | STMR × default PF (38)\(^{(a)}\) (EFSA, 2020) | 0.38    | STMR × default PF (38)\(^{(a)}\) (EFSA, 2020) |
| Rape meal            | 0.6                 | STMR × default PF (2)\(^{(a)}\) (EFSA, 2020) | 0.6     | STMR × default PF (2)\(^{(a)}\) (EFSA, 2020) |
| Rice bran/pollard    | 1.15                | STMR × default PF (10)\(^{(a)}\) (EFSA, 2020) | 1.15    | STMR × default PF (10)\(^{(a)}\) (EFSA, 2020) |
| Safflower meal       | 0.49                | STMR × default PF (2)\(^{(a)}\) (EFSA, 2020) | 0.49    | STMR × default PF (2)\(^{(a)}\) (EFSA, 2020) |
| Sugarcane molasses   | 4.64                | STMR × default PF (32)\(^{(a)}\) (EFSA, 2020) | 4.64    | STMR × default PF (32)\(^{(a)}\) (EFSA, 2020) |
| Sunflower meal       | 0.37                | STMR × default PF (2)\(^{(a)}\) (EFSA, 2020) | 0.37    | STMR × default PF (2)\(^{(a)}\) (EFSA, 2020) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
* Indicates that the input value is proposed at the limit of quantification.
(a): In the absence of processing factors supported by data, default the processing factor of was included in the calculation to consider the potential concentration of residues in these commodities (EFSA, 2020).
(b): For corn milled by-products, hominy meal, gluten feed and gluten meal, and palm kernel meal no default processing factor was applied because residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected (EFSA, 2020).
(c): The tentative derived processing factors were included in the calculation to consider the potential concentration of residues in these commodities (EFSA, 2020).

### D.2. Consumer risk assessment

| Commodity | Chronic risk assessment |
|-----------|-------------------------|
|           | Input value (mg/kg)     | Comment            |
| Strawberries | 0.34               | STMR CXL (EFSA, 2020) |
| Beans (dry), lentils, peas (dry), lupin/lupini beans, other pulses | 0.03 | STMR |
| Grapefruits | 0.21              | STMR (EFSA, 2020)   |
| Oranges   | 0.21                 | STMR (EFSA, 2020)   |
| Lemons    | 0.21                 | STMR (EFSA, 2020)   |
| Limes     | 0.21                 | STMR (EFSA, 2020)   |
| Mandarins | 0.21                 | STMR (EFSA, 2020)   |
| Almonds   | 0.01                 | STMR (EFSA, 2020)   |
| Brazil nuts | 0.01              | STMR (EFSA, 2020)   |
| Cashew nuts | 0.01             | STMR (EFSA, 2020)   |
| Chestnuts | 0.01                 | STMR (EFSA, 2020)   |
| Coconuts  | 0.01                 | STMR (EFSA, 2020)   |
| Hazelnuts/cobnuts | 0.01        | STMR (EFSA, 2020)   |
| Macadamia | 0.01                 | STMR (EFSA, 2020)   |
| Pecans    | 0.01                 | STMR (EFSA, 2020)   |
| Pine nut kernels | 0.01         | STMR (EFSA, 2020)   |
| Pistachios | 0.01             | STMR (EFSA, 2020)   |
| Walnuts   | 0.01                 | STMR (EFSA, 2020)   |
| Apples    | 0.08                 | STMR (EFSA, 2020)   |
| Pears     | 0.08                 | STMR (EFSA, 2020)   |
| Commodity                        | Input value (mg/kg) | Comment                        |
|---------------------------------|---------------------|--------------------------------|
| Quinces                         | 0.08                | STMR (EFSA, 2020)              |
| Medlar                          | 0.08                | STMR (EFSA, 2020)              |
| Loquats/Japanese medlars        | 0.08                | STMR (EFSA, 2020)              |
| Apricots                        | 0.20                | STMR CXL (EFSA, 2020)          |
| Cherries (sweet)                | 0.20                | STMR CXL (EFSA, 2020)          |
| Peaches                         | 0.20                | STMR CXL (EFSA, 2020)          |
| Plums                           | 0.20                | STMR CXL (EFSA, 2020)          |
| Table grapes                    | 0.22                | STMR (EFSA, 2020)              |
| Wine grapes                     | 0.22                | STMR (EFSA, 2020)              |
| Strawberries                    | 0.34                | STMR CXL (EFSA, 2020)          |
| Blackberries                    | 0.35                | STMR (EFSA, 2020)              |
| Dewberries                      | 0.35                | STMR (EFSA, 2020)              |
| Raspberries (red and yellow)    | 0.35                | STMR (EFSA, 2020)              |
| Blueberries                     | 0.21                | STMR (EFSA, 2020)              |
| Cranberries                     | 0.34                | STMR CXL (EFSA, 2020)          |
| Currants (red, black and white) | 0.34                | STMR CXL (EFSA, 2020)          |
| Gooseberries (green, red and yellow) | 0.34               | STMR CXL (EFSA, 2020)          |
| Rose hips                       | 0.34                | STMR CXL (EFSA, 2020)          |
| Mulberries (black and white)    | 0.34                | STMR CXL (EFSA, 2020)          |
| Elderberries                    | 0.34                | STMR CXL (EFSA, 2020)          |
| Granate apples/pomegranates     | 0.10                | STMR CXL (EFSA, 2020)          |
| Potatoes                        | 0.01                | STMR (EFSA, 2020)              |
| Cassava roots/manioc            | 0.01                | STMR CXL (EFSA, 2020)          |
| Sweet potatoes                  | 0.01                | STMR CXL (EFSA, 2020)          |
| Yams                            | 0.01                | STMR CXL (EFSA, 2020)          |
| Arrowroots                      | 0.01                | STMR CXL (EFSA, 2020)          |
| Beetroots                       | 0.01                | STMR (EFSA, 2020)              |
| Carrots                         | 0.02                | STMR CXL (EFSA, 2020)          |
| Celeriacs/turnip rooted celeries| 0.01                | STMR (EFSA, 2020)              |
| Horseradishes                   | 0.01                | STMR (EFSA, 2020)              |
| Jerusalem artichokes            | 0.01                | STMR (EFSA, 2020)              |
| Parsnips                        | 0.01                | STMR (EFSA, 2020)              |
| Parsley roots/Hamburg roots parsley | 0.01               | STMR (EFSA, 2020)              |
| Radishes                        | 0.05                | STMR (EFSA, 2020)              |
| Salsifies                       | 0.01                | STMR (EFSA, 2020)              |
| Swedes/rutabagas                | 0.01                | STMR (EFSA, 2020)              |
| Turnips                         | 0.01                | STMR (EFSA, 2020)              |
| Tomatoes                        | 0.07                | STMR CXL (EFSA, 2020)          |
| Sweet peppers/bell peppers      | 0.16                | STMR (tentative) (EFSA, 2020)  |
| Aubergines/egg plants           | 0.07                | STMR (EFSA, 2020)              |
| Okra/lady's fingers             | 0.07                | STMR (EFSA, 2020)              |
| Cucumbers                       | 0.06                | STMR (EFSA, 2020)              |
| Gherkins                        | 0.06                | STMR (EFSA, 2020)              |
| Courgettes                      | 0.06                | STMR (EFSA, 2020)              |
| Melons                          | 0.03                | STMR (0.084) × PeF (0.33) (tentative) (EFSA, 2020) |
| Pumpkins                        | 0.08                | STMR (EFSA, 2020)              |
| Watermelons                     | 0.08                | STMR (tentative) (EFSA, 2020)  |
| Commodity                              | Input value (mg/kg) | Comment                             |
|---------------------------------------|--------------------|-------------------------------------|
| Sweet corn                            | 0.01*              | STMR (EFSA, 2020)                   |
| Broccoli                              | 0.38               | STMR (EFSA, 2020)                   |
| Cauliflowers                          | 0.06               | STMR (EFSA, 2020)                   |
| Brussels sprouts                      | 0.01*              | EU MRL (EFSA, 2020)                 |
| Head cabbages                         | 0.52               | STMR (EFSA, 2020)                   |
| Chinese cabbages/pe-tsai              | 7.30               | STMR CXL (EFSA, 2020)               |
| Kales                                 | 7.30               | STMR CXL (EFSA, 2020)               |
| Kohlrabies                            | 0.01*              | EU MRL (EFSA, 2020)                 |
| Lamb's lettuce/corn salads            | 5.55               | STMR (EFSA, 2020)                   |
| Lettuces                              | 5.55               | STMR (EFSA, 2020)                   |
| Escaroles/broad-leaved endives        | 5.55               | STMR (EFSA, 2020)                   |
| Land cress                            | 5.55               | STMR (EFSA, 2020)                   |
| Roman rocket/rucola                   | 5.55               | STMR (EFSA, 2020)                   |
| Red mustards                          | 5.55               | STMR (EFSA, 2020)                   |
| Baby leaf crops (including brassica species) | 10.50           | STMR CXL (EFSA, 2020)               |
| Spinaches                             | 5.55               | STMR (EFSA, 2020)                   |
| Purslanes                             | 5.55               | STMR (EFSA, 2020)                   |
| Chards/beet leaves                    | 5.55               | STMR (EFSA, 2020)                   |
| Grape leaves and similar species      | 5.80               | STMR (tentative) (EFSA, 2020)       |
| Watercress                            | 7.30               | STMR CXL (EFSA, 2020)               |
| Witloofs/Belgian endives              | 7.30               | STMR CXL (EFSA, 2020)               |
| Chervil                               | 5.55               | STMR (EFSA, 2020)                   |
| Chives                                | 5.55               | STMR (EFSA, 2020)                   |
| Celery leaves                         | 5.55               | STMR (EFSA, 2020)                   |
| Parsley                               | 5.55               | STMR (EFSA, 2020)                   |
| Sage                                  | 5.55               | STMR (EFSA, 2020)                   |
| Rosemary                              | 5.55               | STMR (EFSA, 2020)                   |
| Thyme                                 | 5.55               | STMR (EFSA, 2020)                   |
| Basil and edible flowers              | 5.55               | STMR (EFSA, 2020)                   |
| Laurel/bay leaves                     | 5.55               | STMR (EFSA, 2020)                   |
| Tarragon                              | 5.55               | STMR (EFSA, 2020)                   |
| Beans (with pods)                     | 0.14               | STMR (EFSA, 2020)                   |
| Beans (without pods)                  | 0.01*              | EU MRL (EFSA, 2020)                 |
| Peas (with pods)                      | 0.54               | STMR (EFSA, 2020)                   |
| Peas (without pods)                   | 0.01*              | EU MRL (EFSA, 2020)                 |
| Lentils (fresh)                       | 0.01*              | EU MRL (EFSA, 2020)                 |
| Cardoons                              | 2.60               | STMR (EFSA, 2020)                   |
| Celeries                              | 2.60               | STMR (EFSA, 2020)                   |
| Florence fennels                      | 2.60               | STMR (EFSA, 2020)                   |
| Globe artichokes                      | 0.56               | STMR (EFSA, 2020)                   |
| Rhubarbs                              | 2.60               | STMR (EFSA, 2020)                   |
| Linseeds                              | 0.25               | STMR (EFSA, 2020)                   |
| Peanuts/groundnuts                    | 0.01               | STMR (tentative) (EFSA, 2020)       |
| Poppy seeds                           | 0.25               | STMR (EFSA, 2020)                   |
| Sesame seeds                          | 0.25               | STMR (EFSA, 2020)                   |
| Sunflower seeds                       | 0.19               | STMR (tentative) (EFSA, 2020)       |
| Rapeseeds/canola seeds                | 0.30               | STMR (tentative) (EFSA, 2020)       |
| Commodity                      | Input value (mg/kg) | Chronic risk assessment                  |
|-------------------------------|--------------------|-----------------------------------------|
| Soyabeans                     | 0.01               | STMR CXL (EFSA, 2020)                   |
| Mustard seeds                 | 0.25               | STMR (EFSA, 2020)                       |
| Cotton seeds                  | 0.05               | STMR (EFSA, 2020)                       |
| Pumpkin seeds                 | 0.25               | STMR (EFSA, 2020)                       |
| Safflower seeds               | 0.25               | STMR (EFSA, 2020)                       |
| Borage seeds                  | 0.25               | STMR (EFSA, 2020)                       |
| Gold of pleasure seeds        | 0.25               | STMR (EFSA, 2020)                       |
| Hemp seeds                    | 0.25               | STMR (EFSA, 2020)                       |
| Castor beans                  | 0.25               | STMR (EFSA, 2020)                       |
| Oil palm kernels              | 0.01*              | STMR (EFSA, 2020)                       |
| Oil palm fruits               | 0.23               | STMR (EFSA, 2020)                       |
| Barley                        | 0.01               | STMR CXL (EFSA, 2020)                   |
| Maize/corn                    | 0.01               | STMR CXL (EFSA, 2020)                   |
| Common millet/proso millet    | 0.01               | STMR CXL (EFSA, 2020)                   |
| Oat                           | 0.01               | STMR CXL (EFSA, 2020)                   |
| Rice                          | 0.12               | STMR (EFSA, 2020)                       |
| Rye                           | 0.01               | STMR CXL (EFSA, 2020)                   |
| Sorghum                       | 0.01               | STMR CXL (EFSA, 2020)                   |
| Wheat                         | 0.01               | STMR CXL (EFSA, 2020)                   |
| Coffee beans                  | 0.01*              | STMR (EFSA, 2020)                       |
| HOPS (dried)                  | 10.45              | STMR (EFSA, 2020)                       |
| Horseradish, root spices      | 0.01               | STMR (EFSA, 2020)                       |
| Sugar canes                   | 0.15               | STMR CXL (EFSA, 2020)                   |
| Chicory roots                 | 0.02               | Existing EU MRL                         |
| Poultry meat                  | 0.01               | 0.9 × STMR (0.008) muscle (CXL) + 0.1 × STMR (0.031) fat (CXL) (EFSA, 2020) (a) |
| Poultry fat tissue            | 0.03               | STMR CXL (EFSA, 2020)                   |
| Poultry liver                 | 0.03               | STMR CXL (EFSA, 2020)                   |
| Bird’s eggs                   | 0.1                | STMR CXL (EFSA, 2020)                   |

Risk assessment residue definition 2: sum of chlorantraniliprole, IN-HXH44, IN-K9T00, expressed as chlorantraniliprole

| Commodity                | Input value (mg/kg) | Chronic risk assessment                  |
|--------------------------|--------------------|-----------------------------------------|
| Swine meat               | 0.03               | 0.8 × STMR (0.017) × CF (1.5) muscle (CXL) + 0.2 × STMR (0.049) × CF (1.0) fat (CXL) (EFSA, 2020) (a) |
| Swine fat                | 0.05               | STMR × CF (1.0) (CXL) (EFSA, 2020)       |
| Swine liver              | 0.07               | STMR (0.047) × CF (1.5) (CXL) (EFSA, 2020) |
| Swine kidney             | 0.05               | STMR (0.03) × CF (1.5) (CXL) (EFSA, 2020) |
| Bovine and equine meat   | 0.03               | 0.8 × STMR (0.017) × CF (1.5) muscle (CXL) + 0.2 × STMR (0.049) × CF (1.0) fat (CXL) (EFSA, 2020) (a) |
| Bovine and equine fat    | 0.05               | STMR × CF (1.0) (CXL) (EFSA, 2020)       |
| Bovine and equine liver  | 0.07               | STMR (0.047) × CF (1.5) (CXL) (EFSA, 2020) |
| Bovine and equine kidney | 0.05               | STMR (0.03) × CF (1.5) (CXL) (EFSA, 2020) |
| Sheep and goat meat      | 0.03               | 0.8 × STMR (0.017) × CF (1.5) muscle (CXL) + 0.2 × STMR (0.049) × CF (1.0) fat (CXL) (EFSA, 2020) (a) |
| Sheep and goat fat       | 0.05               | STMR × CF (1.0) (CXL) (EFSA, 2020)       |
| Sheep and goat liver     | 0.07               | STMR (0.047) × CF (1.5) (CXL) (EFSA, 2020) |
| Sheep and goat kidney    | 0.05               | STMR (0.03) × CF (1.5) (CXL) (EFSA, 2020) |
| Cattle and horse milk    | 0.02               | STMR (0.006) × CF (3.0) (CXL) (EFSA, 2020) |
| Sheep and goat milk      | 0.02               | STMR (0.006) × CF (3.0) (CXL) (EFSA, 2020) |
| Sheep and goat milk      | 0.02               | STMR (0.006) × CF (3.0) (CXL) (EFSA, 2020) |

(a) STMR = sum of chlorantraniliprole, IN-HXH44, IN-K9T00, expressed as chlorantraniliprole.
STMR: supervised trials median residue; MRL: maximum residue level; PeF: Peeling factor; CXL: Codex maximum residue limit; CF: conversion factor.
*: Indicates that the input value is proposed at the limit of quantification.
(a): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticides, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|----------------------------------|-------------------------------------------------|---------------------------------|
| Chlorantraniliprole              | 3-bromo-4’-chloro-1-(3-chloro-2-pyridyl)-2’-methyl-6’-(methylcarbamoyl)-1H-pyrazole-5-carboxanilide | ![Structural formula](image1) |
| DPX E-2Y45                       | CNC(=O)c3cc(Cl)cc(C)c3NC(=O)c2cc(Br)nn2c1nccc1Cl PSOVNZNNOMJUBI-UHFFFAOYSA-N | ![Structural formula](image2) |
| IN-F6L99                         | 3-bromo-N-methyl-1H-pyrazole-5-carboxamide      | ![Structural formula](image3) |
|                                 | Brcc1cc(nn1)C(=O)NC                             | ![Structural formula](image4) |
|                                 | LOYJZLKLAMJX-UHFFFAOYAC                        | ![Structural formula](image5) |
| IN-EQW78                         | 2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one | ![Structural formula](image6) |
|                                 | Cc1cc(Cl)cc2c1N-C(c1cc(Br)nn1c1nccc1Cl)N(C)C2=O QTUSYELNSABI-UHFFFAOYSA-N | ![Structural formula](image7) |
| IN-ECD73                         | 2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one | ![Structural formula](image8) |
|                                 | Cc1cc(Cl)cc2c1N-C1C(Cl)-CC-CN1C2=O              | ![Structural formula](image9) |
|                                 | HWZYDXSGZCNEA-UHFFFAOYSA-N                     | ![Structural formula](image10) |
| IN-N5M09                         | 6-chloro-4-methyl-11-oxo-11H-pyrido[2,1-b]quinazoline-2-carbonitrile | ![Structural formula](image11) |
|                                 | Cc1cc(C#N)cc2c1N-C1C(Cl)-CC-CN1C2=O            | ![Structural formula](image12) |
|                                 | MZOZXXSP3GMFBK-UHFFFAOYSA-N                    | ![Structural formula](image13) |
| IN-HXH44                         | 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-(methylcarbamoyl)phenyl]-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide | ![Structural formula](image14) |
|                                 | CNC(=O)c1cc(Cl)cc(CO)c1NC(=O)c1cc(Br)nn1c1nccc1Cl TUGOTPWXTGSGDB-UHFFFAOYSA-N | ![Structural formula](image15) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-----------------------------------------------|----------------------------------|
| IN-K9T00                      | 3-bromo-N-4-chloro-2-(hydroxymethyl)-6-[[hydroxymethyl]carbamoyl]phenyl]-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide | ![Structural formula](image) |
|                              | OCNC(=O)c1cc(Cl)cc(CO)c1NC(=O)c1cc(Br)nn1niccc1Cl | PVGVXUGCQISDM-UHFFFAOYSA-N       |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).