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Setting of an import tolerance for flutolanil in peanuts

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Nichino America Inc submitted a request to the competent national authority in the Netherlands to set an import tolerance for the active substance flutolanil in peanuts. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposal for peanuts. Adequate analytical methods for enforcement are available to control the residues of flutolanil in plant matrices at the validated limited of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of flutolanil according to the reported agricultural practice is unlikely to present a risk to consumer health.

Keywords: flutolanil, import tolerance, peanuts, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Nichino America Inc submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to set an import tolerance for the active substance flutolanil in peanuts. 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 11 September 2020. The EMS proposed to establish an MRL for peanuts imported from the United States of America (USA) at the level of 0.02 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 19 April 2021, the EMS submitted the requested information in a revised evaluation report (Netherlands, 2020), 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 the review of the existing MRLs for flutolanil in accordance with Regulation (EC) No 396/2005 and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of flutolanil was investigated in primary crops belonging to the groups of root crops (seed treatment and soil treatment), cereals (foliar treatment) and pulses/oilseeds (foliar treatment). In the tested crops, parent and metabolites M-2 and M-4 (and their conjugates) were found as main residues.

As the authorised use of flutolanil is on imported crops, investigations of residues in rotational crops are not required.

Studies investigating the effect of processing on the nature of flutolanil (hydrolysis studies) were not available in the framework of the European peer review carried out under Directive 91/414/EEC. Such studies are not required in the framework of this application because exposure does not exceed 10% of the acceptable daily intake (ADI) and residues of flutolanil in peanuts are below 0.1 mg/kg according to the risk assessment residue definition.

Based on the metabolic pattern identified in metabolism studies and on the toxicological significance of metabolites M-2 and M-4, the residue definition for enforcement in plant products was proposed by the MRL review and EU pesticides peer review as 'flutolanil'. For risk assessment, the residue definition is 'sum of flutolanil, metabolites M-2 and M-4 and their conjugates, expressed as flutolanil'. This residue definitions are also applicable to processed commodities.

EFSA concluded that for the crop assessed in this application (peanuts), metabolism of flutolanil in primary crops, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Multiresidue analytical methods based on QuEChERS method in combination with HPLC-MS/MS are available to quantify flutolanil residues with a limit of quantification (LOQ) of 0.01 mg/kg in acidic, dry, high water content and high oil content commodities. The methods enable quantification of residues at or above 0.01 mg/kg (LOQ) in the crops assessed.

The 13 available residue trials are sufficient to derive an MRL of 0.02 mg/kg for peanuts, in line with the proposed import tolerance.

The authorised use of flutolanil is on imported crops, thus residues in rotational crops were not further considered. Furthermore, it can be concluded that any risk of potential uptake of flutolanil residues in the peanuts grown on the same fields in succeeding years would be captured in the primary crops trials.

Processing factors (PF) for the crops under assessment were derived from processing studies provided within this application. Although three independent trials were performed, two trials were considered to derive PFs because in one of the trials, flutolanil residues were below the LOQ in the raw agricultural commodity and in the processed commodities. When the two individual PF values differed by more than 50%, the highest value, instead of the median value, was considered to derive a tentative PF. However, it is noted that one additional trial should be required to derive robust PFs and the calculated factors cannot be recommended to be included in Annex VI of Regulation (EC) No 396/2005.

Peanut meal, a processing by-product from peanuts oil production, may be used for feed purposes. Therefore, the livestock dietary burden calculation performed in the MRL review was updated in the framework on this application. The exposure exceeded the trigger values for all animal species. A significant increase of the dietary burden is observed compared to the calculations performed in the MRL review of flutolanil. A detailed analysis of the results clearly indicated that this increase is not due

to contribution of peanut meal but to the use of OECD (Organisation for Economic Co-operation and Development) methodology for the exposure calculation and consideration of new feed items which were not considered in previous assessments.

The nature of flutolanil residues in livestock has been investigated during the MRL review and the following residue definition for enforcement and risk assessment was derived on a tentative basis: sum of flutolanil and all metabolites containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil. This is also the residue definition used by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to set Codex MRLs (CXLs) on commodities of animal origin. Updated calculations of the MRLs for all animal tissues and products confirmed that modifications of the current MRLs in animal commodities which are set on the basis of the CXLs are not triggered.

The toxicological profile of flutolanil 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 0.09 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. The metabolites included in the residue definition are of a similar toxicity as the parent compound.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). Considering the toxicological profile of the active substance as assessed in the framework of the EU pesticides peer review, a short-term dietary risk assessment was not required. The estimated long-term dietary intake was in the range of 0.14–4.3% of the ADI. The contribution of residues in peanuts to the overall long-term exposure is insignificant (0.01% of the ADI, NL child diet).

EFSA concluded that residues of flutolanil in peanuts from the authorised use in the USA will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

The peer review for the renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: flutolanil				
401020	Peanuts/groundnuts	0.01*	0.02	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.

US: United States; 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.

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Assessment

The European Food Safety Authority (EFSA) received an application to set an import tolerance for flutolanil in peanuts. The detailed description of existing use of flutolanil authorised in the USA on peanuts, which is the basis for the current MRL application, is reported in Appendix A.

Flutolanil is the ISO common name for α,α,α-trifluoro-3'-isopropoxy-o-toluanilide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Flutolanil was evaluated in the framework of Directive 91/414/EEC[1] with Finland being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was the outdoor seed treatment of potatoes prior to planting at a rate of 92 g a.s./ton of tubers in northern and southern Europe. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2008). Flutolanil was approved[2] for the use as fungicide on 1 March 2009. The process of renewal of the first approval is currently ongoing.

The EU MRLs for flutolanil are established in Annex II of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2013) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued one opinion on the evaluation of confirmatory data following the Article 12 MRL review for flutolanil (EFSA, 2019b). The proposals from these reasoned opinions have not been implemented in MRL regulation yet[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, Nichino America Inc submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to set an import tolerance for the active substance flutolanil in peanuts. 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 11 September 2020. The EMS proposed to establish an MRL for peanuts imported from USA at the level of 0.02 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 19 April 2021, the EMS submitted the requested information in a revised evaluation report (Netherlands, 2020), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Netherlands, 2020), the draft assessment report (DAR) (and its addendum) (Finland, 2005, 2008) prepared under Council Directive 91/414/EEC, the Commission review report on flutolanil (European Commission, 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance flutolanil (EFSA, 2008), as well as the conclusions from previous EFSA opinions on flutolanil (EFSA, 2013, 2019b).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] 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 546/2011[7].

As the EU pesticides peer review for the renewal of the approval of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer 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 Directive 2008/108/EC of 26 November 2008 amending Council Directive 91/414/EEC to include flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as active substances. OJ L 317, 27.11.2008, p. 6–13.

[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) 2016/567 of 6 April 2016 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 chlorantraniliprole, cyflumetofen, cyprodinil, dimethomorph, dithiocarbamates, fenamidone, fluopyram, flutolanil, imazamox, metrafenone, myclobutanil, propiconazole, sedaxane and spirodiclofen in or on certain products. C/2016/1879. OJ L 100, 15.4.2016, p. 1–60.

[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 MRL application including the end points of relevant studies assessed previously is presented in Appendix B.

The evaluation report submitted by the EMS (Netherlands, 2020) 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 flutolanil in primary crops belonging to the group of root crops (potatoes), cereals (rice) and pulses/oilseeds (peanuts) has been investigated in the framework of the EU pesticides peer review (EFSA, 2008); the same studies were considered in the MRL review (EFSA, 2013).

In the studies available at the time of the EU pesticides peer review and MRL review, only ^{14}C-aniline flutolanil was used as test material. As the available data indicated that the amide bridge between the two aromatic rings did not break, no further studies were required (EFSA, 2013). In the tested crops, parent and metabolites M-2 and M-4 (and their conjugates) were found as main residues.

Regarding the intended use (peanuts), the metabolic behaviour in primary crops is addressed by the metabolism study performed on peanuts.

It should be noted that in the framework of the ongoing renewal assessment of the active substance, additional metabolism studies on primary crops were performed with flutolanil radiolabelled on the aniline ring but also on the trifluoromethyl/phenyl ring. These studies indicate the potential cleavage of flutolanil in primary crops, which can release two other metabolites: M-101 and M-102 (Netherlands, 2020). These studies and their impact on the endpoints on nature of residues in plants are assessed in the framework of the renewal of the active substance.

1.1.2. Nature of residues in rotational crops

The metabolism of flutolanil in rotational crops has been investigated in the framework of the EU pesticides peer review (EFSA, 2008) and in its evaluation report (Netherlands, 2020), the EMS noted that an additional metabolism study on rotational crops was performed in the framework of the ongoing renewal assessment of the active substance. This study and its impact on the endpoints on nature of residues in rotational crops will be assessed in the framework of the renewal of the approval of the active substance.

The purpose of the present application is import tolerance. Considering that investigations of residues in rotational crops are not required for imported crops, further discussions on the nature of residues in rotational crops are not triggered.

1.1.3. Nature of residues in processed commodities

Hydrolysis studies are not required in the framework of this application because exposure does not exceed 10% of the acceptable daily intake (ADI) and residues of flutolanil in peanuts are below 0.1 mg/kg according to the risk assessment residue definition (European Commission, 1997d).

However, in its evaluation report (Netherlands, 2020), the EMS noted that a new hydrolysis study was provided in the framework of the ongoing renewal of the active substance, which give an indication that flutolanil is stable under all high temperature hydrolysis conditions simulating pasteurisation, baking, brewing and boiling and sterilisation. This study and its impact on the endpoints on nature of residues in processed commodities will be assessed in the framework of the renewal of the active substance.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of flutolanil residues in high water content commodities were assessed during the original inclusion of flutolanil in Annex I of Directive 91/414/EEC (EFSA, 2008). In the MRL review, a multi-residue QuEChERS method in combination with high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) was also considered for the

enforcement of flutolanil residues in acidic, dry and high oil content commodities. Overall, it was concluded that flutolanil could be enforced in food of plant origin with a limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2013).

It is noted that analytical methods for enforcement of flutolanil are currently under reassessment for the renewal of flutolanil under Regulation (EC) No 1107/2009. In that framework, the analytical methods are assessed according to SANCO/825/00 rev. 8.1, which may lead to data gaps. Within the current application, the applicant provided a validation in an independent laboratory (ILV) for a monitoring residues method for flutolanil in high oil commodities. The validation of this new ILV was fully reported by the EMS (Netherlands, 2020) and is acceptable.

The current methods allow quantifying residues at or above the LOQ of 0.01 mg/kg for flutolanil (without conjugates) in crops belonging to the group of high oil content commodities (relevant for the crop under consideration (peanut)).

1.1.5. Storage stability of residues in plants

The storage stability of flutolanil in dry commodities (wheat grain) and high oil content commodities (rapeseed) was investigated in the framework of the EU pesticides peer review (EFSA, 2008). The stability of flutolanil was demonstrated for 18 months at –18°C in those matrices.

Furthermore, a new study on the stability of flutolanil residues (flutolanil, M-2, M-4, M-101 and M-102) in frozen samples of peanuts (crop classified as matrix with high oil content) was submitted with the current application (Netherlands, 2020). The stability of flutolanil and its metabolites M-2, M-4, M-101 and M-102 was demonstrated (for each compound independently) in peanut shelled nutmeat for 18 months when stored frozen at ≤ –10°C. Within the same study, the storage stability of flutolanil residues was also investigated in hay and in peanut processed commodities. The stability of flutolanil and its metabolites M-2, M-4, M-101 and M-102 was demonstrated (for each compound independently) in all processed commodities (meal, crude oil and peanut butter) for 12 months. It is noted that samples for storage were fortified with free (unconjugated) metabolites. However, this study is considered adequate to also address the storage stability of the conjugated form of the metabolites, because the conjugated M-2 and M-4 are only expected to release free M-2 and M-4 during storage.

Consequently, the storage stability of all compounds included in the current residue definition for risk assessment was sufficiently investigated in peanuts and its processed products (meal, crude oil and peanut butter). Furthermore, the storage stability of additional compounds (M-101 and M-102) was also addressed.

Besides, the storage stability of flutolanil, stability of M-2 and M-4 was also demonstrated for up to 24 months at –18°C in plant matrices representing the high water content group during the assessment of confirmatory data of the MRL review (EFSA, 2019b).

1.1.6. Proposed residue definitions

Although several new metabolism studies are assessed under the ongoing renewal of the approval of the active substance, the residue definitions derived during the MRL review (EFSA, 2013) are still applicable in the current application:

- residue definition for risk assessment: sum of flutolanil, metabolites M-2 and M-4 and their conjugates, expressed as flutolanil
- residue definition for enforcement: flutolanil

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

These residue definitions are appropriate to the use assessed in this application.

It was noted that additional metabolism studies on crops (primary and rotational) and additional hydrolysis studies, performed with trifluoromethyl/phenyl ring radiolabel and aniline ring radiolabel, are assessed in the framework of the ongoing renewal assessment of the active substance. These studies and their impact on residue definitions in plants will be assessed in the framework of EFSA conclusion on the renewal of the active substance also considering a new toxicological assessment of metabolites M-2, M-4, M-101 and M-102. Considering the results of additional metabolism studies, where new metabolites were identified, the applicant has also provided residue data of metabolites M-101 and M-102 in peanuts, should in the future such data be required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted 13 residue trials compliant with the critical Good Agricultural Practice (GAP) authorised in the USA (Foliar application: 2 × 1,065 g a.s./ha; preharvest interval (PHI) 40 days), all performed on peanuts in 2016. Considering the variability of the different geographical places (different areas of the USA, covering a wide range of climate conditions), these trials are considered independent.

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated. One sample was stored for up to 584 days, while the storage stability study covers up to 18 months (560 days), but this is deemed acceptable considering the minor extra time (24 days) and the overall stability of all compounds during storage for up to 18 months.

The trial samples were all analysed for the parent compound and for metabolites M-2, M-4, M-101 and M-102 (and their conjugates) as well as for trifluoracetic acid (TFA). The analytical methods used in the residue trials were sufficiently validated (Netherlands, 2020).

Flutolanil was quantified in one trial of 13, at the level of 0.016 mg/kg. Upon EFSA's request, the EMS clarified in an updated version of the evaluation report that the results for flutolanil residues are in line with the current residue definition for enforcement, i.e. flutolanil without conjugates. A re-interpretation of chromatograms that did not include a hydrolysis step indicated that the levels of flutolanil residues detected in peanut nutmeat were not significantly influenced by the hydrolysis step (Netherlands, 2020). Therefore, the data from this trial can be used for the MRL proposal.

The total residues according to the current residue definition for risk assessment were calculated considering the sum of flutolanil, M-2 and M-4, expressed as flutolanil[8], noting that M-2 (including conjugates) was always below the LOQ, while M-4 (including conjugates) was quantified up to 0.08 mg/kg.

EFSA notes that the applicant submitted residue data for metabolites M-101, M-102 and TFA (Netherlands, 2020), but these were not considered further in the current assessment. It is noted that TFA was not quantified in any trial samples. However, metabolites M-101 and M-102 were quantified in the ranges of < 0.01–0.048 mg/kg and 0.04–0.32 mg/kg, respectively.

1.2.2. Magnitude of residues in rotational crops

Investigations of residues in rotational crops are generally not required for imported crops.

Nevertheless, the potential uptake of flutolanil residues in the peanuts grown in the same fields in succeeding years was discussed by the EMS (Netherlands, 2020). As the primary crops residue trials analysed for all potential metabolites (flutolanil, M-2, M-4, M-101, M-102, trifluoracetic acid and the conjugates of flutolanil, M-2, M-4, M-101 and M-102) after a PHI of 40 days (see also Section 1.2.1), it is expected that the primary crop field trials would capture any additional residues that may have arisen from soil uptake.

Therefore, further data on the magnitude of residues in rotational crops are not needed and it is concluded that residues in rotational crops are adequately addressed.

1.2.3. Magnitude of residues in processed commodities

One new processing study investigating the magnitude of residues in different processed commodities of peanuts (meal, crude oil, RBD oil (refined, bleached, and deodorised oil), dry roasted peanuts and peanut butter) was submitted within this application (Netherlands, 2020).

The samples of raw and processed commodities were all analysed for flutolanil and for metabolites M-2, M-4, M-101 and M-102 (and their conjugates) as well as for trifluoracetic acid (TFA). The analytical methods used in the residue trials were sufficiently validated (Netherlands, 2020).

Three independent trials were performed but, one of these trials could not be used to derive processing factors (PF) since flutolanil residues were below LOQ in the raw agricultural commodity and in the processed commodities. Therefore, only two trials were considered to derive PFs. When the two individual PF values differed by more than 50%, the highest value, instead of the median value, was considered to derive a tentative PF (Netherlands, 2020). However, it is noted that one additional trial

[8] Metabolites M-2 and M-4 were expressed as flutolanil based on the molecular weight difference. The molecular factor for metabolites M-2 and M-4 is 0.95 and 1.15, respectively.

should be required to derive robust PFs, and therefore, the calculated factors cannot be recommended for inclusion in Annex VI of Regulation (EC) No 396/2005.

From an enforcement point of view, a reduction of flutolanil residues is observed in dry roasted peanuts and in peanut butter while a slight concentration of residues is expected in peanut meal (PF = 1.2), in crude oil (PF = 4.34) and refined, bleached and deodorised oil (PF = 2.06). These findings are consistent with the fact that flutolanil is a slightly lipophilic compound (partition coefficient between n-octanol and water, log P_{ow} = 3.17).

Conversion factors (CF) for risk assessment could also be derived for each processed commodity, considering the current residue definitions in processed commodities, for enforcement (flutolanil) and for risk assessment (sum of flutolanil, metabolites M-2 and M-4 and their conjugates, expressed as flutolanil).

It is noted that the available data would also allow to derive PF for metabolites M-101 and M-102 (Netherlands, 2020).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for peanuts (see Appendix B.1.2.1). An MRL of 0.02 mg/kg (instead of existing 0.01 mg/kg) is derived for flutolanil (without conjugates) in line with the current residue definition for enforcement in support of the authorised use of flutolanil on peanuts in the USA.

In Section 3, EFSA assessed whether residues on peanuts and its by-products resulting from the critical authorised use in the USA are likely to pose a consumer health risk.

2. Residues in livestock

Peanut meal, a processing by-product from peanut oil production, may be used for feed purposes. Hence, it was necessary to update the previous dietary burden calculation for livestock to estimate whether the intended use of flutolanil would have an impact on the residues expected in food of animal origin.

The input values for the exposure calculations for livestock are presented in Appendix D.1. The PF and CF derived from the processing studies submitted within this MRL application were used to estimate the residue concentration in peanut meal. The results of the dietary burden calculation are presented in Section B.2. The exposure exceeded the trigger values for all animal species considered. It is noted that a significant increase of the dietary burden is observed compared to the calculations performed in the MRL review of flutolanil (EFSA, 2013). This increase is clearly attributed to the use of the Dietary burden calculator according to the Organisation for Economic Co-operation and Development (OECD) (OECD, 2013), which was not used at the time of the MRL review and consideration of new feed items which were not considered in previous assessments.

2.1. Nature of residues and methods of analysis in livestock

Metabolism studies in livestock (lactating goat and laying hens) have been assessed previously in the framework of the EU pesticides peer review (EFSA, 2008); the same studies were considered in the MRL review (EFSA, 2013).

In the studies available at the time of the peer review and MRL review, only ^{14}C-aniline flutolanil was used as test material. Furthermore, several deficiencies were pointed out on the goat study and a data gap was identified. On the basis of available studies, the following tentative residue definition for risk assessment and enforcement was derived by the EU pesticides peer review and the MRL review: sum of flutolanil and all metabolites containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil. This is also the residue definition used by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to set Codex MRLs (CXLs) on commodities of animal origin.

The data gap identified in available metabolism studies by the EU pesticides peer review and the MRL review was fulfilled during the evaluation of confirmatory data following Article 12 MRL review (EFSA, 2019b). However, in line with the Commission Working Document SANTE/10235/2016, it was decided that the assessment of the new submitted study should be performed in the renewal of the active substance. In the framework of the ongoing renewal assessment of the active substance, additional livestock metabolism studies were also performed on lactating goats and laying hens. These studies and their impact on the endpoints on nature of residues in animals will be assessed in the

framework of EFSA conclusion on the renewal of the active substance. In the meantime, the residue definitions derived during the MRL review (EFSA, 2013) are still applicable in the current application.

Methods of analysis for the common moiety residue definition in products of animal origin have been assessed during the MRL review and its confirmatory data assessment. The validation of the analytical method proposed for the enforcement and of its ILV had some deficiencies (EFSA, 2013) and the data gap identified by EFSA in the MRL review was only partially addressed during the evaluation of confirmatory data following Article 12 MRL review (EFSA, 2019b). No additional studies on methods for enforcement of residues in commodities of animal origin were provided in the framework of this MRL application. This point is still pending a risk management decision.

The storage stability of flutolanil and its metabolites (M-2, M-4, M-07) in commodities of animal origin was investigated and assessed in the framework of the confirmatory data following MRL review (EFSA, 2019b). EFSA concluded that the data gap identified in the MRL review was sufficiently addressed (EFSA, 2019b).

2.2. Magnitude of residues in livestock

The impact of peanut meal as a potential feed item was assessed in an updated calculation of the animal dietary burden, which resulted in a significant increase of exposure for all animal species compared to the exposure calculated in the previous assessment (EFSA, 2013). This increase, however, is not due to contribution of peanut meal but because the exposure was calculated according to the new methodology (OECD, 2013) which considers various new feed by-products which were not considered before.

Nevertheless, EFSA assessed whether the current MRL values for animal commodities (taken from Codex MRLs) are still applicable when considering the updated calculations. The results of the calculations are presented in Section B.2.2.

It is noted that livestock feeding studies were not available during the peer review under Directive 91/414/EEC (EFSA, 2008) but the livestock feeding studies on lactating dairy cows and on laying hens reported by the 2002 JMPR (FAO, 2002) were considered in the framework of the MRL review (EFSA, 2013) and are therefore reused in the present assessment.

Based on the updated calculations, MRLs in muscle and fat of all species are expected to remain below the LOQ of 0.05 mg/kg. Higher residues, compared to estimates done by the MRL review, are expected in liver and kidney of ruminants (up to a potential MRL 0.2 mg/kg in sheep liver and 0.08 mg/kg in sheep kidney). However, this is covered by the MRLs that are currently in place for liver, kidney and edible offals of all ruminants (0.5 mg/kg), which reflect the CXLs, derived by the JMPR (FAO, 2013) on the basis of higher livestock dietary burdens. In poultry liver, milk and eggs, residues are still not expected to exceed the LOQ, even when considering the updated dietary burden values.

It is concluded that modifications of the current MRLs in animal commodities are not triggered by the current assessment.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference value (TRV) for flutolanil used in the risk assessment (i.e. ADI) was derived in the framework of the EU pesticides peer review (European Commission, 2008). The derivation of an acute reference dose (ARfD) was considered not necessary. The metabolites included in the current risk assessment residue definition were considered to be of a similar toxicity as the parent compound. It should be noted that in the framework of the ongoing renewal assessment of the active substance, a reassessment of the toxicological properties of flutolanil and its metabolites is being carried out. However, the current application should be assessed with the endpoints of the initial EU peer review (EFSA, 2008) and MRL review (EFSA, 2013).

Considering the toxicological profile of the active substance as assessed in the framework of the EU pesticides peer review, a short-term dietary risk assessment was not required (EFSA, 2008).

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed (using PRIMo rev.2), taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2013). An update of this calculation (still using PRIMo rev.2) was performed by EFSA

during the assessment of confirmatory data following Article 12 MRL review (EFSA, 2019b), including the STMRs derived in the confirmatory data assessment and the Codex MRLs that have been taken over in the EU MRL legislation after the MRL review. These previous calculations are now updated with the STMR value derived from the residue trials submitted in support of this MRL application for peanuts and considering the revision 3.1 of the EFSA PRIMo. The contributions of commodities where no GAP or safe Codex MRL (CXL) was reported to EFSA were not included in the calculations.

The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake was in the range of 0.14–4.3% of the ADI. The contribution of residues expected in the commodity assessed in this application to the overall long-term exposure is insignificant (0.01% ADI, NL child diet) and presented in more detail in Appendix B.3.

EFSA concluded that the long-term intake of residues of flutolanil resulting from the existing uses and the authorised use of flutolanil on peanut in the USA 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 peanuts.

EFSA concluded that the authorised US use of flutolanil on peanuts will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

The peer review for the renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
CIRCA	(EU) Communication & Information Resource Centre Administrator
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EC	emulsifiable concentrate
EDI	estimated daily intake
EMS	evaluating Member State

FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GS	growth stage
HPLC	high-performance liquid chromatography
HPLC-MS	high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	preharvest interval
P_{ow}	partition coefficient between n-octanol and water
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
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
TRR	total radioactive residue
UV	ultraviolet (detector)
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number max	Interval between application (min–max)	g a.s./hL (min–max)	Water L/ha (min–max)	Rate			
Peanuts/ groundnuts	USA	F	Basidiomycete pathogens (e.g. *Rhizoctonia solani* and *Sclerotium rolfsii*)	SC	455 g/L	Foliar treatment – general (see also comment field)	45–60 days after planting	2	21–30	716–1,417	47–93	666–1,065	g a.s/ha	40	Maximum seasonal dose is 2.13 kg a.s./ha. May be applied in a tank mix with an adjuvant.
Peanuts/ groundnuts	USA	F	Basidiomycete pathogens (e.g. *Rhizoctonia solani* and *Sclerotium rolfsii*)	SC	455 g/L	Foliar treatment – general (see also comment field)	45–60 days after planting	4	10–14	358–1,132	47–93	333–532	g a.s/ha	40	Maximum seasonal dose is 2.13 kg a.s./ha. May be applied in a tank mix with an adjuvant.

NEU: northern European Union; SEU: southern European Union; MS: Member State; USA: United States of America; 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**
	Root crops	Potatoes	Seed treatment: 120 g/ton	131	Radiolabelled active substance: U-^{14}C-aniline/ (Finland, 2005)
			Seed treatment: 360 g/ton	52	Radiolabelled active substance: U-^{14}C-aniline/ (Finland, 2005)
			Soil - In-furrow treatment at sowing: 4.5 kg a.s./ha	131	Radiolabelled active substance: U-^{14}C-aniline/ (Finland, 2005)
	Cereals/grass	Rice	Foliar (indoor): 2 × 0.56 kg a.s./ha	30	Radiolabelled active substance: U-^{14}C-aniline/ (Finland, 2005)
	Pulses/oilseeds	Peanuts	Foliar: 2.24 kg a.s./ha	84	Radiolabelled active substance: U-^{14}C-aniline/ (Finland, 2005)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish	Bare soil: 2.69 kg a.s./ha	30, 90, 148 and 366	Radiolabelled active substance: U-^{14}C-aniline/ (Finland, 2005)
	Leafy crops	Lettuce	Bare soil: 2.69 kg a.s./ha	30, 90, 148 and 366	Radiolabelled active substance: U-^{14}C-aniline/ (Finland, 2005)
	Cereal (small grain)	Oat/Sorghum	Bare soil: 2.69 kg a.s./ha	30, 90, 148 and 366	Radiolabelled active substance: U-^{14}C-aniline/ (Finland, 2005)
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Not triggered		A new hydrolysis study is available in the framework of the ongoing renewal of the active substance.
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Not triggered		
	Sterilisation (20 min, 120°C, pH 6)		Not triggered		
	Other processing conditions		–		–

Can a general residue definition be proposed for primary crops?	Yes	Based on studies performed with aniline ring radiolabelled flutolanil only (EFSA, 2013)[a]
Rotational crop and primary crop metabolism similar?	Yes	Based on studies performed with aniline ring radiolabelled flutolanil only (EFSA, 2013)[a]
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not triggered	Hydrolysis studies are not required because exposure does not exceed 10% of the ADI and residue level of flutolanil in peanuts does not exceed 0.1 mg/kg according to the risk assessment residue definition[b]
Plant residue definition for monitoring (RD-Mo)	Flutolanil	
Plant residue definition for risk assessment (RD-RA)	Sum of flutolanil, metabolites M-2 and M-4 and their conjugates, expressed as flutolanil[a]	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: QuEChERS method in combination with HPLC–MS/MS, LOQ 0.01 mg/kg (EFSA, 2013). ILV available for a monitoring residues method for flutolanil in high oil commodities (Netherlands, 2020).	

DAT: days after treatment; a.s.: active substance; ADI: acceptable daily intake; ILV: independent laboratory validation; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry.

(a): Additional metabolism studies (primary crops, rotational crops) performed with trifluoromethyl/phenyl ring radiolabel and aniline ring radiolabel are assessed in the framework of the ongoing renewal assessment of the active substance. These studies and their impact on the endpoints on nature of residues in plants will be assessed in the framework of the renewal of the active substance.

(b): A new hydrolysis study is available in the framework of the ongoing renewal assessment of the active substance. This study and its impact on the endpoints on nature of residues in processed commodities will be assessed in the framework of the renewal of the active substance.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	High water content	Potato	–18	24	Months	Flutolanil	EFSA (2019b)
	High water content	Spinach	–18	24	Months	Flutolanil	EFSA (2019b)
	High water content	Potato	–18	24	Months	M-2[a]	EFSA (2019b)
	High water content	Spinach	–18	24	Months	M-2[a]	EFSA (2019b)
	High water content	Potato	–18	24	Months	M-4	EFSA (2019b)
	High water content	Spinach	–18	24	Months	M-4	EFSA (2019b)
	High oil content	Rapeseed	–18	18	Months	Flutolanil	EFSA (2008)
	High oil content	Peanuts (shelled nutmeat)	–10	18	Months	Flutolanil	Netherlands (2020)
	High oil content	Peanuts (shelled nutmeat)	–10	18	Months	M-2	Netherlands (2020)
	High oil content		–10	18	Months	M-4	Netherlands (2020)

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
		Peanuts (shelled nutmeat)					
	High oil content	Peanuts (shelled nutmeat)	–10	18	Months	M-101	Netherlands (2020)
	High oil content	Peanuts (shelled nutmeat)	–10	18	Months	M-102	Netherlands (2020)
	Dry/High starch	Wheat grain	–18	18	Months	Flutolanil	EFSA (2008)
	Others	Wheat straw	–18	18	Months	Flutolanil	EFSA (2008)
	Processed products	Peanuts, meal	–10	12	Months	Flutolanil	Netherlands (2020)
	Processed products	Peanuts, meal	–10	12	Months	M-2	Netherlands (2020)
	Processed products	Peanuts, meal	–10	12	Months	M-4	Netherlands (2020)
	Processed products	Peanuts, meal	–10	12	Months	M-101	Netherlands (2020)
	Processed products	Peanuts, meal	–10	12	Months	M-102	Netherlands (2020)
	Processed products	Peanuts, crude oil	–10	12	Months	Flutolanil	Netherlands (2020)
	Processed products	Peanuts, crude oil	–10	12	Months	M-2	Netherlands (2020)
	Processed products	Peanuts, crude oil	–10	12	Months	M-4	Netherlands (2020)
	Processed products	Peanuts, crude oil	–10	12	Months	M-101	Netherlands (2020)
	Processed products	Peanuts, crude oil	–10	12	Months	M-102	Netherlands (2020)
	Processed products	Peanut butter	–10	12	Months	Flutolanil	Netherlands (2020)
	Processed products	Peanut butter	–10	12	Months	M-2	Netherlands (2020)
	Processed products	Peanut butter	–10	12	Months	M-4	Netherlands (2020)
	Processed products	Peanut butter	–10	12	Months	M-101	Netherlands (2020)
	Processed products	Peanut butter	–10	12	Months	M-102	Netherlands (2020)

(a): Slightly decreased mean recoveries (exceeding 30%) were observed at intermediate testing points of 9 and 12 months in both spinach and potato matrices and at the end of the study for two individual values in potato matrix (EFSA, 2019b).

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]
Peanuts	USA	**Mo:** 12 × < 0.01; 0.016 **RA:** 2 × < 0.031; 0.032; 0.033; 0.034; 0.045; 2 × 0.047; 0.061; 0.062; 0.065; 2 × 0.099	Residue trials on peanuts compliant with GAP. MRL_{OECD} = 0.017	0.02	**Mo:** 0.016 **RA:** 0.099	**Mo:** < 0.01 **RA:** 0.047	6[e]

(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.
(e): The CF is indicative as it is derived on the basis of the unique trial where a result above the LOQ was found for flutolanil (0.099/0.016).

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	At PBI 30 days, significant TRR is found in cereal straw (0.80 mg eq/kg), radish tops (0.36 mg eq./kg) and roots (0.17 mg eq./kg), and lettuce (0.18 mg eq./kg).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Residues in rotational crops are not relevant for the present application for important tolerance. The only issue of concern is the possible soil uptake in the peanuts grown on the same fields in succeeding years. However, this potential uptake is expected to be captured by the primary crops residue trials performed with a PHI of 40 days.

PBI: plant-back intervals; TRR: total radioactive residue; PHI: pre–harvest interval.

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[c]	Comment/Source
		Individual values	Median PF[b]		
Peanuts, meal	2	< 0.33; 1.20	1.20 (tentative)[d]	21.3	Individual factors differ by more than 50%; thus, the highest processing factor instead of the median value is considered on tentative basis (Netherlands, 2020).
Peanuts, crude oil	2	1.48; 4.34	4.34 (tentative)[d]	1.4	Individual factors differ by more than 50%; thus, the highest processing factor instead of the median value is considered on tentative basis (Netherlands, 2020).
Peanuts, RBD oil	2	0.62; 2.06	2.06 (tentative)[d]	1.7	Individual factors differ by more than 50%; thus, the highest processing factor instead of the median value is considered on tentative basis (Netherlands, 2020).
Peanuts, dry roasted	2	0.49; 0.53	0.51 (tentative)[d]	6.7	The median processing factor value is considered (Netherlands, 2020).
Peanuts, peanut butter	2	0.38; 0.43	0.40 (tentative)[d]	7.2	The median processing factor value is considered (Netherlands, 2020).

RBD: Refined, blanched, deodorised.
(a): Studies with residues in the raw agricultural commodity (RAC) at or close to the limit of quantification (LOQ) were disregarded (unless concentration may occur).
(b): Median PF: Median of the individual processing factors for each processing residues trial. When individual factors differed by more than 50%, the highest processing factor instead of the median value was considered on a tentative basis.
(c): CF: Conversion factor for risk assessment in the processed commodity (CF = Residue level in processed fraction (expressed according to RD-RA)/residue level in processed fraction according to RD-Mo). The current residue definition for risk assessment in processed commodities was considered (sum of flutolanil, metabolites M-2 and M-4 and their conjugates, expressed as flutolanil).
(d): The derived PF is tentative because based on two individual factors only.

B.2. Residues in livestock

Dietary burden calculation according to OECD, 2013.

Relevant groups	Dietary burden expressed in				Most critical diet[a]	Most critical commodity[b]		Trigger exceeded (Yes/No)	Previous assessment (EFSA, 2013)
	mg/kg bw per day		mg/kg DM					0.10	Max burden
	Median	Maximum	Median	Maximum				mg/kg DM	mg/kg DM
Cattle (all diets)	0.125	0.134	4.29	4.55	Dairy cattle	Potato	Process waste	Yes	0.9209
Cattle (dairy only)	0.125	0.134	3.24	3.50	Dairy cattle	Potato	Process waste	Yes	0.4667
Sheep (all diets)	0.143	0.152	4.29	4.55	Ram/Ewe	Potato	Process waste	Yes	n.a.
Sheep (ewe only)	0.143	0.152	4.29	4.55	Ram/Ewe	Potato	Process waste	Yes	n.a.
Swine (all diets)	0.052	0.062	2.26	2.68	Swine (breeding)	Potato	Process waste	Yes	0.9240
Poultry (all diets)	0.041	0.047	0.58	0.66	Poultry broiler	Potato	Dried pulp	Yes	0.3088
Poultry (layer only)	0.030	0.036	0.44	0.52	Poultry layer	Potato	Dried pulp	Yes	0.3088

bw: body weight; DM: dry matter; n.a.: not available.
(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'.

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	Animal	Dose (mg/kg bw/d)	Duration (days)	Comment/Source
	Laying hen	0.035	4	Label position U-^{14}C-aniline ring (EFSA, 2008)
		1	4	Label position U-^{14}C-aniline ring (EFSA, 2008)
	Lactating ruminants	0.61	4	Study performed on goat. Label position U-^{14}C-aniline ring (EFSA, 2008)
	Fish	–	–	–

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 4 days	EFSA (2013)
	Eggs: 1 day	Residues < 0.007 mg eq/kg after 24 hours (EFSA, 2013)
Metabolism in rat and ruminant similar	Yes	Tentative[(a)]
Can a general residue definition be proposed for animals?	Yes	Tentative[(a)]
Animal residue definition for monitoring (RD-Mo)	Sum of flutolanil and all metabolites containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil (tentative)[(a)]	
Animal residue definition for risk assessment (RD-RA)	Sum of flutolanil and all metabolites containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil (tentative)[(a)]	
Fat soluble residues	No	EFSA (2013)
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	Common moiety method not fully validated. Confirmatory data missing; ILV not fully validated. Milk, eggs, muscle, fat, liver: GC–MS, LOQ 0.05 mg/kg (EFSA, 2019b).	

bw: body weight; d: day; ILV: independent laboratory validation; GC–MS: gas chromatography with mass spectrometry; LOQ: limit of quantification.

(a): Additional livestock metabolism studies performed with trifluoromethyl/phenyl ring radiolabel and aniline ring radiolabel are assessed in the framework of the ongoing renewal assessment of the active substance. These studies and their impact on the endpoints on nature of residues in plants will be assessed in the framework of the renewal of the active substance.

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	Bovine	Muscle	–20	127	Days	Flutolanil, M-2, M-4, M-07[(a)]	EFSA (2019b)
	Bovine	Fat	–20	88	Days	Flutolanil[(a)]	EFSA (2019b)
	Bovine	Fat	–20	< 88[(b)]	Days	M-2, M-4, M-07[(a)]	EFSA (2019b)
	Chicken	Liver	–20	122	Days	Flutolanil, M-2, M-4, M-07[(a)]	EFSA (2019b)
	Bovine	Milk	–20	115	Days	Flutolanil, M-2, M-4, M-07[(a)]	EFSA (2019b)
	Chicken	Eggs	–20	125	Days	Flutolanil, M-2, M-4, M-07[(a)]	EFSA (2019b)

(a): Samples were separately fortified with flutolanil or with M-2 or with M-4 or with M-07 to assess the storage stability for each compound independently. However, the method used in the study was a common moiety method which hydrolysed flutolanil and metabolites to 2-trifluoromethylbenzoic acid.
(b): A significant decline was observed for M-2, M-4 and M-07 in fat matrix already at the first time point of 88 days.

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

Calculations performed with Animal model 2017[9] (OECD, 2013).

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		Calculated MRL (mg/kg)
	Mean	Highest	STMR[(a)] (mg/kg)	HR[(b)] (mg/kg)	
Cattle (all) – Closest feeding level (1.6 mg/kg bw; 11.9 N rate)[(c)]					
Muscle	< 0.05	< 0.05	< 0.05	< 0.05	**0.05***
Fat	0.06	0.06	< 0.05	< 0.05	**0.05***
Liver	1.70	2.00	0.13	0.17	**0.2**
Kidney	0.42	0.79	0.03	0.07	**0.07**
Cattle (dairy only) – Closest feeding level (1.6 mg/kg bw; 11.9 N rate)[(c)]					
Milk[(d)]	< 0.05	< 0.05	< 0.05	< 0.05	**0.05***
Sheep (all)[(e)] – Closest feeding level (1.6 mg/kg bw; 10.6 N rate)[(c)]					
Muscle	< 0.05	< 0.05	< 0.05	< 0.05	**0.05***
Fat	0.06	0.06	< 0.05	< 0.05	**0.05***
Liver	1.70	2.00	0.15	0.19	**0.2**
Kidney	0.42	0.79	0.04	0.07	**0.08**
Sheep (ewe only)[(e)] – Closest feeding level (1.6 mg/kg bw; 10.6 N rate)[(c)]					
Milk[(d)]	< 0.05	< 0.05	< 0.05	< 0.05	**0.05***
Swine (all)[(e)] – Closest feeding level (1.6 mg/kg bw; 25.9 N rate)[(c)]					
Muscle	< 0.05	< 0.05	< 0.05	< 0.05	**0.05***
Fat	0.06	0.06	< 0.05	< 0.05	**0.05***
Liver	1.70	2.00	0.06	0.08	**0.08**
Kidney	0.42	0.79	0.05	0.05	**0.05***
Poultry (all) – Closest feeding level (0.039 mg/kg bw; 0.8 N rate)[(c)]					
Muscle	< 0.05	< 0.05	< 0.05	< 0.05	**0.05***
Fat	< 0.05	< 0.05	< 0.05	< 0.05	**0.05***
Liver	< 0.05	< 0.05	< 0.05	< 0.05	**0.05***
Poultry (layer only) – Closest feeding level (0.039 mg/kg bw; 1.1 N rate)[(c)]					
Eggs[(f)]	< 0.05	< 0.05	< 0.05	< 0.05	**0.05***

bw: body weight.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): Median residues recalculated at the 1N rate for the median dietary burden.
(b): Highest residues recalculated at the 1N rate for the maximum dietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): For milk, mean was derived from samplings performed from day 1 to day 28 (daily mean of 3 cows).
(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
(f): For eggs, mean was derived from samplings performed from day 14 to day 28 (at each date, samples of 4 hens among the 20 hens of each dose group were considered).

[9] https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

B.3. Consumer risk assessment

A short-term dietary risk assessment was not required since no ARfD has been considered necessary.

ADI	0.09 mg/kg bw per day (European Commission, 2008)
Highest IEDI, according to EFSA PRIMo	4.3% ADI (NL toddler diet) Contribution of crops assessed: Peanuts: 0.01% of ADI (NL child diet)
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities and animal commodities assessed in the MRL review and its confirmatory data (EFSA, 2013, 2019b). Contribution of Codex MRLs (CXLs) was also considered using the relevant median residue values derived by JMPR (FAO, 2013) and further specific considerations made by EFSA when preparing the EU position for the Codex Committee on Pesticide Residues (CCPR) (EFSA, 2014). The median residues derived according to the residue definition for enforcement was multiplied by the following conversion factors (CF) for risk assessment: 3 for potatoes (EFSA, 2013); 2 (tentative) for peppers (EFSA, 2013); 2 for flowering and head brassica (EFSA, 2014). The contributions of commodities where no GAP or safe Codex MRL (CXL) was reported to EFSA were not included in the calculations. Calculations performed with PRIMo revision 3.1.

ARfD: acute reference dose; ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; JMPR: Joint FAO/WHO Meeting on Pesticide Residues; GAP: good agriculctral practice.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: flutolanil				
401020	Peanuts/groundnuts	0.01*	0.02	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.

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.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Flutolanil

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.09	ARfD (mg/kg bw):	Not necessary
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2008	Year of evaluation:	2008

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
4%	NL toddler	3.86	3%	Milk: Cattle	0.3%	Potatoes	0.3%	Rice		4%
3%	UK infant	2.63	2%	Milk: Cattle	0.3%	Rice	0.2%	Potatoes		3%
2%	FR toddler 2 3 yr	2.09	2%	Milk: Cattle	0.3%	Rice	0.1%	Potatoes		2%
2%	NL child	1.76	1%	Milk: Cattle	0.2%	Potatoes	0.1%	Rice		2%
2%	FR child 3 15 yr	1.74	1%	Milk: Cattle	0.2%	Rice	0.1%	Potatoes		2%
2%	UK toddler	1.66	1%	Milk: Cattle	0.2%	Rice	0.2%	Potatoes		2%
2%	DE child	1.45	1%	Milk: Cattle	0.2%	Potatoes	0.1%	Rice		2%
2%	SE general	1.39	0.7%	Milk: Cattle	0.3%	Potatoes	0.2%	Bovine: Muscle/meat		2%
1%	RO general	1.22	0.6%	Milk: Cattle	0.3%	Potatoes	0.2%	Head cabbages		1%
1%	ES child	1.22	0.7%	Milk: Cattle	0.2%	Rice	0.1%	Potatoes		1%
1%	GEMS/Food G10	1.20	0.5%	Rice	0.3%	Milk: Cattle	0.2%	Potatoes		1%
1%	DK child	1.19	0.7%	Milk: Cattle	0.2%	Potatoes	0.1%	Rice		1%
1%	FR infant	1.10	0.9%	Milk: Cattle	0.1%	Potatoes	0.0%	Rice		1%
1%	GEMS/Food G15	1.01	0.4%	Milk: Cattle	0.2%	Potatoes	0.1%	Rice		1%
1%	GEMS/Food G06	0.98	0.7%	Rice	0.1%	Potatoes	0.1%	Milk: Cattle		1%
1%	GEMS/Food G07	0.96	0.4%	Milk: Cattle	0.3%	Potatoes	0.2%	Rice		1%
1%	GEMS/Food G11	0.96	0.4%	Milk: Cattle	0.3%	Potatoes	0.1%	Rice		1%
1.0%	GEMS/Food G08	0.90	0.3%	Milk: Cattle	0.3%	Potatoes	0.1%	Rice		1.0%
1.0%	DE general	0.86	0.7%	Milk: Cattle	0.1%	Potatoes	0.1%	Swine: Muscle/meat		1.0%
0.9%	DE women 14-50 yr	0.84	0.7%	Milk: Cattle	0.1%	Potatoes	0.0%	Swine: Muscle/meat		0.9%
0.9%	NL general	0.82	0.5%	Milk: Cattle	0.2%	Potatoes	0.1%	Rice		0.9%
0.8%	IE adult	0.69	0.2%	Milk: Cattle	0.2%	Potatoes	0.1%	Rice		0.8%
0.7%	PT general	0.65	0.4%	Potatoes	0.3%	Rice	0.0%	Sweet peppers/bell peppers		0.7%
0.7%	LT adult	0.63	0.2%	Potatoes	0.2%	Milk: Cattle	0.1%	Rice		0.7%
0.6%	ES adult	0.57	0.3%	Milk: Cattle	0.1%	Rice	0.1%	Potatoes		0.6%
0.6%	FI 3 yr	0.54	0.3%	Potatoes	0.2%	Rice	0.0%	Broccoli		0.6%
0.6%	DK adult	0.52	0.3%	Milk: Cattle	0.1%	Potatoes	0.0%	Swine: Muscle/meat		0.6%
0.5%	FR adult	0.49	0.2%	Milk: Cattle	0.1%	Rice	0.1%	Potatoes		0.5%
0.5%	UK adult	0.48	0.2%	Milk: Cattle	0.2%	Rice	0.1%	Potatoes		0.5%
0.5%	UK vegetarian	0.46	0.2%	Milk: Cattle	0.2%	Rice	0.1%	Potatoes		0.5%
0.5%	FI 6 yr	0.43	0.3%	Potatoes	0.2%	Rice	0.0%	Head cabbages		0.5%
0.4%	IE child	0.38	0.2%	Milk: Cattle	0.1%	Rice	0.0%	Potatoes		0.4%
0.3%	PL general	0.27	0.2%	Potatoes	0.0%	Head cabbages	0.0%	Cauliflowers		0.3%
0.2%	FI adult	0.14	0.1%	Potatoes	0.1%	Rice	0.0%	Head cabbages		0.2%
0.2%	IT toddler	0.14	0.1%	Rice	0.1%	Potatoes	0.0%	Cauliflowers		0.2%
0.1%	IT adult	0.13	0.1%	Rice	0.0%	Potatoes	0.0%	Cauliflowers		0.1%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Flutolanil is unlikely to present a public health concern.

Acute risk assessment /children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

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): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:

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
Risk assessment residue definition: Sum of flutolanil and all metabolites containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil				
Potato culls	0.06	$STMR_{Mo}$ × CF (3) (EFSA, 2013)	0.23	HR_{Mo} × CF (3) (EFSA, 2013)
Peanut, meal	**0.26**	**$STMR_{Mo}$ × CF (21.3) × PF (1.2)**[(a)]	**0.26**	**$STMR_{Mo}$ × CF (21.3) × PF (1.2)**[(a)]
Potato, process waste	1.26	$STMR_{Mo}$ (EFSA, 2013) × CF (3) × default PF (20)[(b)]	1.26	$STMR_{Mo}$ (EFSA, 2013) × CF (3) × default PF (20)[(b)]
Potato, dried pulp	2.39	$STMR_{Mo}$ (EFSA, 2013) × CF (3) × default PF (38)[(b)]	2.39	$STMR_{Mo}$ (EFSA, 2013) × CF (3) × default PF (38)[(b)]

STMR: supervised trials median residue; Mo: monitoring; CF: conversion factor; HR: highest residue; PF: processing factor.
(a): Tentative processing factor, see Appendix B.1.2.3.
(b): For potato process waste and potato dried pulp, in the absence of processing factors supported by data, default processing factors of 20 and 38 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

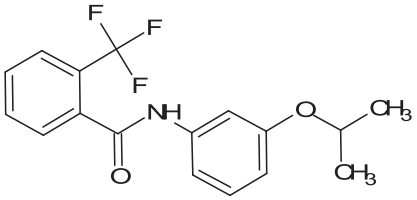
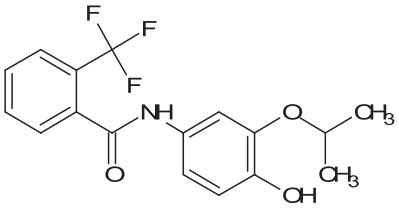
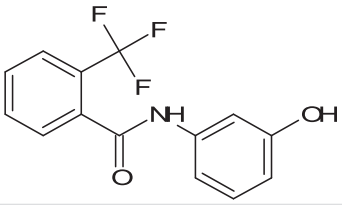
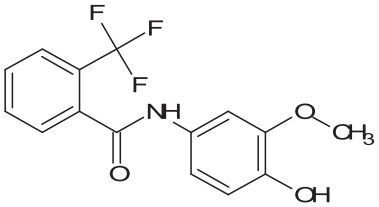
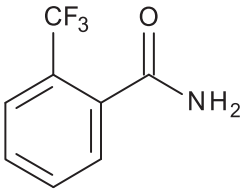
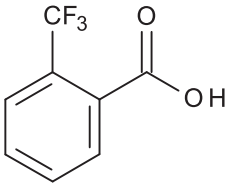
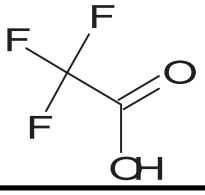
D.2. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment	
			Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of flutolanil, metabolites M-2 and M-4 and their conjugates, expressed as flutolanil				
Potatoes	0.1	EFSA (2013)	0.06	STMR-RAC × CF
Sweet peppers/bell peppers	0.01*	EFSA (2013, 2019b)	0.02	STMR-RAC × CF
Broccoli	0.05	CXL (FAO, 2013)	0.1	STMR-RAC × CF (EFSA, 2014)
Cauliflowers	0.05	CXL (FAO, 2013)	0.1	STMR-RAC × CF (EFSA, 2014)
Other flowering brassica	0.05	CXL (FAO, 2013)	0.1	STMR-RAC × CF (EFSA, 2014)
Brussels sprouts	0.05	CXL (FAO, 2013)	0.1	STMR-RAC × CF (EFSA, 2014)
Head cabbages	0.05	CXL (FAO, 2013)	0.1	STMR-RAC × CF (EFSA, 2014)
Other head brassica	0.05	CXL (FAO, 2013)	0.1	STMR-RAC × CF (EFSA, 2014)
Beans (with pods)	0.01*	EFSA (2019b)	0.03	$STMR_{RA}$-RAC
Globe artichokes	0.01*	EFSA (2019b)	0.03	$STMR_{RA}$-RAC
Peanuts/groundnuts	**0.02**	**MRL proposal**	**0.047**	**$STMR_{RA}$-RAC**
Rice	2	CXL (FAO, 2013)	0.39	STMR-RAC
Risk assessment residue definition: Sum of flutolanil and all metabolites containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil (tentative)				
Swine: Muscle/meat	0.05*	EFSA (2013)	0.05	STMR
Swine: Fat tissue	0.05*	EFSA (2013)	0.05	STMR
Swine: Liver	0.5	CXL (FAO, 2013)	0.147	STMR
Swine: Kidney	0.5	CXL (FAO, 2013)	0.036	STMR
Swine: Edible offals (other than liver and kidney)	0.5	CXL (FAO, 2013)	0.147	STMR
Swine: Other products	0.05*	EFSA (2013)	0.05	STMR

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment	
			Input value (mg/kg)	Comment
Ruminant: Muscle/meat	0.05*	EFSA (2013)	0.05	STMR
Ruminant: Fat tissue	0.05*	EFSA (2013)	0.05	STMR
Ruminant: Liver	0.5	CXL (FAO, 2013)	0.147	STMR
Ruminant: Kidney	0.5	CXL (FAO, 2013)	0.036	STMR
Ruminant: Edible offals (other than liver and kidney)	0.5	CXL (FAO, 2013)	0.147	STMR
Ruminant: Other products	0.05*	EFSA (2013)	0.05	STMR
Equine: Muscle/meat	0.05*	EFSA (2013)	0.05	STMR
Equine: Fat tissue	0.05*	EFSA (2013)	0.05	STMR
Equine: Liver	0.5	CXL (FAO, 2013)	0.147	STMR
Equine: Kidney	0.5	CXL (FAO, 2013)	0.036	STMR
Equine: Edible offals (other than liver and kidney)	0.5	CXL (FAO, 2013)	0.147	STMR
Equine: Other products	0.05*	EFSA (2013)	0.05	STMR
Poultry: Muscle/meat	0.05*	EFSA (2013)	0.05	STMR
Poultry: Fat tissue	0.05*	EFSA (2013)	0.05	STMR
Poultry: Liver	0.05*	EFSA (2013)	0.05	STMR
Other farmed animals: Muscle/meat	0.05*	EFSA (2013)	0.05	STMR
Other farmed animals: Fat tissue	0.05*	EFSA (2013)	0.05	STMR
Other farmed animals: Liver	0.5	CXL (FAO, 2013)	0.147	STMR
Other farmed animals: Kidney	0.5	CXL (FAO, 2013)	0.036	STMR
Other farmed animals: Edible offals (other than liver and kidney)	0.5	CXL (FAO, 2013)	0.147	STMR
Other farmed animals: Other products	0.05*	EFSA (2013)	0.05	STMR
Milk of ruminants	0.05*	EFSA (2013)	0.05	STMR
Bird's Eggs: Chicken	0.05*	EFSA (2013)	0.05	STMR

MRL: maximum residue limit; STMR-RAC: supervised trials median residue in raw agricultural commodity; $STMR_{RA}$: supervised trials median residue in raw agricultural commodity expressed according to the residue definition for risk assessment; CF: conversion factor for enforcement to risk assessment residue definition; CXL: codex maximum residue limit; LOQ: limit of quantification.

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
flutolanil	α,α,α-trifluoro-3′-isopropoxy-o-toluanilide CC(C)Oc1cccc(c1)NC(=O)c1ccccc1C(F)(F)F PTCGDEVVHUXTMP-UHFFFAOYSA-N	
M-2	α,α,α-trifluoro-4′-hydroxy-3′-isopropoxy-*o*-toluanilide CC(C)Oc1cc(ccc1O)NC(=O)c1ccccc1C(F)(F)F MZWZZJVZOQEANE-UHFFFAOYSA-N	
M-4	α,α,α-trifluoro-3′-hydroxy-*o*-toluanilide Oc1cccc(NC(=O)c2ccccc2C(F)(F)F)c1 YUWVGNPIDBYWEW-UHFFFAOYSA-N	
M-07	α,α,α-trifluoro-4′-hydroxy-3′-methoxy-*o*-toluanilide Oc1ccc(cc1OC)NC(=O)c1ccccc1C(F)(F)F ITNBPXXRADXDBD-UHFFFAOYSA-N	
M-101	2-(trifluoromethyl)benzamide FC(F)(F)c1ccccc1C(N)=O QBAYIBZITZBSFO-UHFFFAOYSA-N	
M-102	2-(trifluoromethyl)benzoic acid FC(F)(F)c1ccccc1C(=O)O FBRJYBGLCHWYOE-UHFFFAOYSA-N	
TFA	Trifluoroacetic acid FC(F)(F)C(=O)O DTQVDTLACAAQTR-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 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 July 2018).
(c): ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 7 December 2018).