Evaluation of confirmatory data following the Article 12 MRL review and setting of an import tolerance for flutriafol in cucurbits (inedible peel)

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

Abstract

The applicant Cheminova A/S submitted a request to the competent national authority in the United Kingdom to evaluate the confirmatory data for the active substance flutriafol that were identified in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005. The applicant provided residue trials on rice representative for an adjusted Good Agricultural Practice (GAP), metabolism studies in goats and storage stability data in tissues of animal origin addressing the data gaps identified in the MRL review. For the nature of residues in processed commodities, relevant to confirm the MRLs on pome fruits and wine grapes, the applicant referred to the information provided in a previous MRL application and already assessed by EFSA. The data gaps on the authorised uses on beetroots, melons and watermelons assessed in the MRL review were not addressed. At the same time, the applicant submitted a request to the United Kingdom to modify the existing maximum residue level (MRL) for flutriafol in cucurbits with inedible peel according to Article 6 of Regulation (EC) No 396/2005. The data submitted were found to be sufficient to derive an MRL proposal for these crops. EFSA concluded that the proposed use of flutriafol on the crops under assessment will not result in a consumer exposure exceeding the toxicological reference values for flutriafol and therefore is unlikely to pose a risk to consumers’ health. Regarding the triazole derivative metabolites (TDMs), the conclusions reached in a previously issued assessment for another triazole fungicide are still valid. An update of the indicative consumer risk assessment for each individual metabolite is not necessary since the residues expected in the concerned commodities are covered.

© 2020 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: flutriafol, triazole derivative metabolites, confirmatory data, cucurbits and rice, pesticide, MRL review, risk assessment

Requestor: European Commission
Question numbers: EFSA-Q-2019-00797; EFSA-Q-2019-00798
Correspondence: pesticides.mrl@efsa.europa.eu
Acknowledgements: EFSA wishes to thank: Stathis Anagnos, Laszlo Bura, Viktoria Krivova, Silvia Ruocco and Viktor Toth for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2020. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review and setting of an import tolerance for flutriafol in cucurbits (inedible peel). EFSA Journal 2020;18(12):6315, 40 pp. https://doi.org/10.2903/j.efsa.2020.6315

ISSN: 1831-4732

© 2020 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

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

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

In 2014, when the European Food Safety Authority (EFSA) reviewed the existing Maximum Residue Levels (MRLs) for the active substance flutriafol according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses (Good Agricultural Practice (GAP)) which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) an independent laboratory validation (ILV) and a confirmatory method for the enforcement of flutriafol residues in fat;
2) eight and four residue trials supporting, respectively, the northern and southern outdoor GAPs on beetroots;
3) eight residue trials supporting the indoor GAP and eight residue trials supporting the southern outdoor GAP on tomatoes;
4) eight residue trials on melons supporting the indoor GAP on melons and watermelons, and eight residue trials on melons supporting the southern outdoor GAP on melons and watermelons;
5) four residue trials supporting the northern outdoor GAP on sweet corn;
6) four residue trials supporting the northern outdoor GAP on beet leaves (chard) and four residue trials supporting the southern outdoor GAP on beet leaves (chard);
7) five and seven additional residue trials supporting, respectively, the northern and southern outdoor GAPs on fresh peas (without pods);
8) four residue trials supporting the southern outdoor GAP on lentils (fresh); clarifications on the southern outdoor GAP (number of applications, PHI, application rate in g a.s./ha) on asparagus and four residue trials supporting that GAP;
9) eight residue trials on dry beans or dry peas supporting the northern outdoor GAP on dry pulses;
10) eight residue trials on barley supporting the southern outdoor GAP on barley and oats (relevant to support the MRL in oats because the MRL for barley is derived from the northern GAP and fully supported by data);
11) eight residue trials supporting the northern outdoor GAP on maize and eight residue trials supporting the southern outdoor GAP on maize;
12) eight residue trials supporting the southern outdoor GAP on rice grain;
13) data investigating the effect of processing on the nature of flutriafol residues in plant commodities (relevant to support the MRLs in pome fruits, wine grapes, strawberries, tomatoes);
14) an appropriate ruminant metabolism study with radiolabelling of both the carbinol and triazolyl moieties of flutriafol;
15) storage conditions of the samples from the feeding studies.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2016/71, including footnotes related to data gaps number 2, 3, 4, 12, 13, 14, 15 reported in the list above, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 27 January 2018. Data gaps number 1, 5, 6, 7, 8, 9, 10, 11, of the above list were not translated into footnotes and implemented in the MRL regulation. Risk managers set MRLs at the specific limit of quantification (LOQ) without requesting confirmatory data. The footnote related to data gaps number 3 and 13 becomes obsolete for tomatoes and was deleted from the MRL legislation when the Codex MRL (CXL) was implemented in the EU MRL regulation. Although the general data gap on the nature of residues in processed products was addressed in a previous MRL application, the footnote related to data gap number 13 was deleted for strawberries only and is still in place for pome fruits and wine grapes.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, Cheminova A/S submitted an application to the competent national authority in the United Kingdom (rapporteur Member State, RMS) to evaluate the confirmatory data gaps number 2, 4, 12, 14 and 15 identified during the MRL review. For the data gap number 13, the applicant referred to the information provided and assessed in a previous EFSA opinion.

Together with the confirmatory data, Cheminova A/S submitted in accordance with Article 6 of Regulation (EC) No 396/2005, an application to set an import tolerance for flutriafol in cucurbits with inedible peel. The EMS produced a single evaluation report, which was submitted to the European
Commission and forwarded to the European Food Safety Authority (EFSA) on 11 December 2019. The EMS proposed to establish MRLs for cucurbits with inedible peel imported from the US at the level of 0.3 mg/kg. After the withdrawal of the United Kingdom from the Union on 1 February 2020, the application was reallocated to the EMS Slovakia. When assessing the evaluation report, EFSA identified data gaps and points requiring clarification, which were requested from the EMS. On 1 June 2020, the EMS Slovakia submitted a revised version of the 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 in the framework of the present applications, the following conclusions are derived.

Studies investigating the metabolism of flutriafol in primary and rotational crops showed that the major component of residues was composed of parent flutriafol and the triazole derivative metabolites (TDMs). TDMs are common plant and soil metabolites for a number of active substances belonging to the class of triazole fungicides. Information regarding the effect of processing on the nature (hydrolysis studies) of flutriafol residues was addressed in a previous EFSA opinion. Flutriafol and the TDMs are stable under standard hydrolysis conditions representative for food processing.

Based on the metabolic pattern identified in metabolism studies, the hydrolysis studies, and the toxicological significance of metabolites, the residue definition for enforcement in plant products was set as flutriafol. For risk assessment, separate residue definitions were set for flutriafol, triazole alanine (TA), triazole lactic acid (TLA), triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-T). These residue definitions are applicable to primary crops, rotational crops and processed products. EFSA concluded that for the crops assessed in the MRL review confirmatory data and the MRL application, the metabolism of flutriafol in primary and in rotational 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 are available to quantify residues in the crops assessed according to the enforcement residue definition flutriafol. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive MRL proposal of 0.3 mg/kg for cucurbits with inedible peel imported from the United States. The MRL level corresponds to the tolerance established in the country of origin for the residue as flutriafol. Regarding the MRL review confirmatory data, the data gaps are considered addressed for an adjusted GAP on rice leading to a lower MRL proposal of 1 mg/kg and for pome fruits and wine grapes, whereas the data gaps on the authorised uses on beetroots, melons and watermelons assessed in the MRL review were not addressed.

Processing studies with rice were submitted. EFSA recommends including the processing factors of 0.46 for husked rice and 0.36 for polished rice established for flutriafol in Annex VI of Regulation (EC) No 396/2005.

Considering that flutriafol and TDMs are persistent in soil, accumulation may occur after repeated/multiannual applications. Based on the available information, the possible transfer of flutriafol and TDM residues in significant levels (> 0.01 mg/kg) to rice grown on the same field following consecutive annual applications of flutriafol according to the proposed GAP cannot be excluded. Therefore, Member States are recommended to consider the need for specific risk mitigation measures to avoid the presence of significant residues (< 0.01 mg/kg) in rotational crops.

Since the rice by-product bran and straw can be fed to livestock, the potential carry-over into food of animal origin was assessed. EFSA calculated the livestock dietary burdens for flutriafol using the updated OECD Table of Feedstuffs which have now been agreed upon at EU level. The expected residues derived from the intended use on rice and from the authorised EU uses on feed crops were used as input values. The calculated livestock dietary burdens exceeded the trigger value 0.1 mg/kg dry matter (DM) for all relevant animal species. The contribution of flutriafol residues in the concerned products to the total livestock exposure was insignificant. Compared to dietary intake calculations performed in the MRL review, the new calculation methodology lowered the dietary burden in ruminants and swine and triggered the value of 0.1 mg/kg dry matter for the investigations on potential carry over of residues in food of poultry origin. It is noted that the information available on the authorised crops is not sufficient to perform a livestock dietary burden for each individual TDM.

In the framework of the review of the existing MRLs, EFSA provisionally proposed the residue definition for enforcement and risk assessment for ruminants as parent flutriafol pending the submission of an appropriate ruminant metabolism study. Metabolism studies in goats were submitted as confirmatory data. Flutriafol showed to be extensively metabolised to several hydroxylated and
glucuronide metabolites and to 1,2,4-T, which need further consideration for possible inclusion in the final animal residue definitions. EFSA proposed to defer the review of these studies and the final decision on the residue definitions for products of animal origin to the EU pesticides peer review for the renewal of the approval of the active substance.

Information on the storage conditions of the samples from the feeding studies and new data on storage stability have been provided to support the ruminant feeding study assessed during the MRL review and to address the confirmatory data gap. Considering the results of the available feeding studies in ruminant and poultry, a change of the existing MRLs is not necessary.

Toxicological reference values (acute reference dose (ARfD) and acceptable daily intake (ADI)) were set for flutriafol in the framework of the EU pesticide peer review of the active substance. Toxicological reference values have been established also for each TDM.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). For flutriafol, the chronic consumer risk assessment performed in the framework of the MRL review was revised to include median residue levels (STMRs) assessed in EFSA reasoned opinions issued after the MRL review and safe Codex MRLs implemented in the EU legislation. The calculation was revised further with the STMRs derived for the crops under consideration. The acute exposure assessment was performed only with regard to the commodities under consideration. A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be 33% of the ADI (NL toddler). The contribution of residues to the total consumer exposure accounted for a maximum of 5.7% of the ADI for rice and for 1.0% of the ADI or less for each of the cucurbit commodities with inedible peel. An acute consumer risk was not identified in relation to the MRL proposals for the crops under consideration.

Regarding the TDMs, EFSA concluded that the indicative consumer risk assessments conducted for each individual metabolite with EFSA Primo 3.1 in a previously issued EFSA opinion are still valid as covering the residues expected in the crops under consideration. Overall, the short-term and long-term estimated exposure for TDMs is not expected to exceed the toxicological reference values set for the individual compounds.

EFSA concluded that the proposed uses of flutriafol on the crops under assessment will not result in a consumer exposure exceeding the toxicological reference values of flutriafol and therefore is unlikely to pose a risk to consumers’ health.

The renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing, and therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the renewal.

The summary table below provides an overview of the assessment of confirmatory data and import tolerance request with the recommended MRL modifications to Regulation (EU) No 396/2005.

| Code(a) | Commodity                  | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                 |
|---------|----------------------------|-----------------|--------------|----------------------------------------------------------------------------------------|
| 0130010 | Apples                     | 4 (ft 1)        | 4            | The data gap identified in the MRL review for information on the nature of residues in processed commodities (hydrolysis study) has been addressed in a previous EFSA opinion. The MRL is confirmed. Risk for consumer unlikely |
| 0130020 | Pears                      | 4 (ft 1)        | 4            |                                                                                        |
| 0130030 | Quinces                    | 4 (ft 1)        | 4            |                                                                                        |
| 0130040 | Medlars                    | 4 (ft 1)        | 4            |                                                                                        |
| 0130050 | Loquats/Japanese medlars    | 4 (ft 1)        | 4            |                                                                                        |
| 0130990 | Other pome fruits          | 4 (ft 1)        | 4            |                                                                                        |

www.efsa.europa.eu/efsajournal 5 EFSA Journal 2020;18(12):6315
| Code<sup>(a)</sup> | Commodity                                      | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation                                                                                                                                 |
|------------------|------------------------------------------------|---------------------------|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0151020          | Wine grapes                                    | 1.5 (ft 1)                | 1.5          | The data gap identified in the MRL review for information on the nature of residues in processed commodities (hydrolysis study) has been addressed in a previous EFSA opinion. The MRL is confirmed. Risk for consumer unlikely |
| 0213010          | Beetroots                                      | 0.06 (ft 2)               | Further risk management consideration required | The data gap identified in the MRL review for information on residue trials has not been addressed. The lowering of the MRL to the LOQ of 0.01 mg/kg should be considered. Risk for consumer unlikely |
| 0233010          | Melons                                         | 2 (ft 2)                  | 0.3          | The import tolerance (US) request has been supported by extrapolation from residue trials on melons. MRL proposal corresponds to the value set in the country of origin. Risk for consumers unlikely |
| 0233020          | Pumpkins                                       | 0.01* (ft 2)              | 0.3          | The import tolerance (US) request has been supported by extrapolation from residue trials on melons. MRL proposal corresponds to the value set in the country of origin. Risk for consumers unlikely |
| 0233030          | Watermelons                                    | 2 (ft 2)                  | 0.3          | The data gap identified in the MRL review for information on residue trials has not been addressed with residue trials representative for an adjusted, less critical GAP. The submitted data support a lower MRL proposal. Risk for consumer unlikely |
| 0233990          | Other cucurbits with inedible peel             | 0.01* (ft 2)              | 0.3          | The data gap identified in the MRL review for information on residue trials has not been addressed with residue trials representative for an adjusted, less critical GAP. The submitted data support a lower MRL proposal. Risk for consumer unlikely |
| 0500060          | Rice                                           | 1.5 (ft 2)                | 1            | The data gap identified in the MRL review for information on residue trials has been addressed with residue trials representative for an adjusted, less critical GAP. The submitted data support a lower MRL proposal. Risk for consumer unlikely |
| 1011030          | Swine, Liver                                   | 0.1 (ft 3)                | 0.1          | The data gap identified in the MRL review has been addressed. Information on the storage conditions of the samples from the feeding studies and new data on storage stability confirm the validity of the results of the feeding study in ruminants (extrapolated to pigs) assessed in the MRL review. Risk for consumers unlikely |
| 1012030          | Bovine, Liver                                  | 0.3 (ft 4)                | 0.3          | The data gap identified in the MRL review for an appropriate metabolism study in ruminants has been addressed. EFSA proposed to defer the review of this and the metabolism studies previously assessed and the final decision on the residue definitions for products of animal origin to the EU pesticides peer review for the renewal of the approval of flutriafol. Information on the storage conditions of the samples from the feeding studies and new data on storage stability confirm the validity of the results of the feeding study in ruminants assessed in the MRL review. Risk for consumers unlikely |
| 1013030          | Sheep, Liver                                   | 0.3 (ft 4)                | 0.3          | The data gap identified in the MRL review for an appropriate metabolism study in ruminants has been addressed. EFSA proposed to defer the review of this and the metabolism studies previously assessed and the final decision on the residue definitions for products of animal origin to the EU pesticides peer review for the renewal of the approval of flutriafol. Information on the storage conditions of the samples from the feeding studies and new data on storage stability confirm the validity of the results of the feeding study in ruminants assessed in the MRL review. Risk for consumers unlikely |
| 1014030          | Goat, Liver                                    | 0.3 (ft 4)                | 0.3          | The data gap identified in the MRL review for an appropriate metabolism study in ruminants has been addressed. EFSA proposed to defer the review of this and the metabolism studies previously assessed and the final decision on the residue definitions for products of animal origin to the EU pesticides peer review for the renewal of the approval of flutriafol. Information on the storage conditions of the samples from the feeding studies and new data on storage stability confirm the validity of the results of the feeding study in ruminants assessed in the MRL review. Risk for consumers unlikely |
| 1015030          | Equine, Liver                                  | 0.3 (ft 3)                | 0.3          | See 1011030 Swine, Liver                                                                                                                                 |
| 1017030          | Other farmed terrestrial animals, Liver        | 0.3 (ft 4)                | 0.3          | See 1012030 Bovine, Liver                                                                                                                                 |

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

* Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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

(b): Existing EU MRL and corresponding footnote on confirmatory data.

ft 1: The European Food Safety Authority identified some information on the nature of residues in processed commodities as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 13).

ft 2: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 2, 4, 12).

ft 3: The European Food Safety Authority identified some information on the storage conditions of the samples from the feeding studies as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 13).
first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 15).

ft 4: The European Food Safety Authority identified some information on ruminant metabolism and storage conditions of the samples from the feeding studies as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 14 and 15).
### Table of contents

| Section                                      | Page |
|----------------------------------------------|------|
| Abstract                                     | 1    |
| Summary                                      | 3    |
| Assessment                                   | 9    |
| 1. Residues in plants                        | 10   |
| 1.1. Nature of residues and methods of analysis in plants | 10   |
| 1.1.1. Nature of residues in primary crops   | 10   |
| 1.1.2. Nature of residues in rotational crops| 11   |
| 1.1.3. Nature of residues in processed commodities | 11   |
| 1.1.4. Methods of analysis in plants         | 11   |
| 1.1.5. Stability of residues in plants       | 11   |
| 1.1.6. Proposed residue definitions          | 11   |
| 1.2. Magnitude of residues in plants         | 12   |
| 1.2.1. Magnitude of residues in primary crops| 12   |
| 1.2.2. Magnitude of residues in rotational crops | 13   |
| 1.2.3. Magnitude of residues in processed commodities | 13   |
| 1.2.4. Proposed MRLs                         | 14   |
| 2. Residues in livestock                     | 14   |
| 2.1. Nature of residues                      | 14   |
| 2.2. Methods of analysis in livestock        | 15   |
| 2.3. Magnitude of residues in livestock      | 15   |
| 3. Consumer risk assessment                  | 16   |
| 4. Conclusion and Recommendations            | 17   |
| References                                   | 17   |
| Abbreviations                                | 19   |
| Appendix A – Summary of GAPs assessed        | 21   |
| Appendix B – List of end points              | 23   |
| Appendix C – Pesticide Residue Intake Model (PRIMo) | 34   |
| Appendix D – Input values for the exposure calculations | 36   |
| Appendix E – Used compound codes             | 39   |
Assessment

Flutriafol is the ISO common name for (RS)-2,4′-difluoro-α-(1H-1,2,4-triazol-1-ylmethyl)benzhydryl alcohol (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Flutriafol was first evaluated in the framework of Directive 91/414/EEC1 with the United Kingdom designated as rapporteur Member State (RMS) for the representative use as foliar applications on wheat. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2010). Flutriafol was approved2 for the use as fungicide on 1 June 2011. The process of renewal of the first approval has been initiated.

The EU MRLs for flutriafol are established in Annexes II of Regulation (EC) No 396/20053. The review of existing MRLs for the active substance flutriafol according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed in 2014 (EFSA, 2014). During the MRL review, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified.

A detailed description of the good agricultural practices (GAPs) for the uses of flutriafol based on which tentative MRLs were derived in the framework of the MRL review and the proposed adjusted GAP on rice (Appendix A.1) as well as the new intended GAPs (Appendix A.2), which are relevant for the current MRL applications, are listed in Appendix A.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2016/714, including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 27 January 2018.

After completion of the MRL review, EFSA has issued a number of reasoned opinions on the modification of MRLs for flutriafol (EFSA, 2016a,b, 2017). The proposals from these reasoned opinions have been considered in recent MRL regulations.5 Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.6,7,8

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016) the applicant, Cheminova A/S submitted an application to the competent national authority in the United Kingdom (designated rapporteur Member State, RMS) to evaluate the confirmatory data for the active substance flutriafol identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided residue trials on rice representative for an adjusted Good Agricultural Practice (GAP), new metabolism studies in goats and storage stability data in products of animal origin. For the nature of residues in

1 Commission 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 Directive 2011/42/EU of 11 April 2011 amending Council Directive 91/414/EEC to include flutriafol as active substance and amending Commission Decision 2008/934/EC. OJ L 97, 12.4.2011, p. 42–45.
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 Commission Regulation (EU) 2016/71 of 26 January 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1-methylcyclopropene, flonicamid, flutriafol, indolylacetic acid, indolylbutyric acid, pethoxamid, pirimicarb, prothioconazole and tefubenzuron in or on certain products. OJ L 20, 27.1.2016 p. 1–47.
5 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
6 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
7 Commission Regulation (EU) No 293/2013 of 20 March 2013 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 emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, phosmet, pyraclostrobin, spinosad and spirotetramat in or on certain products. OJ L 96, 5.4.2013, p. 1–30.
8 Commission Regulation (EU) No 491/2014 of 5 May 2014 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 acetamiprid, azoxystrobin, cyfluthrin, cyfluthrin, dinotefuran, fenbuconazole, fencarafuran, fenchlorothrin, fluoxuron, flupyradifurone, flutriafol, flusilazole, flusilazole, fluopicolide, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products OJ L 146, 16.5.2014, p. 1–91.
9 Commission Regulation (EU) 2017/626 of 31 March 2017 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 acetamiprid, cyrantraniliprole, cypermethrin, cyproconazole, difenoconazole, ethephon, flutriafol, flupyradifurone, imazapic, imazapyr, lambda-cyhalothrin, mefenacet, profenofos, propiconazole, pyrimethanil, spinetoram, trifloxystrobin in or on certain products C/2017/2035 OJ L 96, 7.4.2017, p. 1–43.
processed commodities, the applicant referred to the information provided in a previous MRL application (EFSA, 2016a).

Together with the confirmatory data, Cheminova A/S submitted in accordance with Article 6 of Regulation (EC) No 396/2005, an application to set an import tolerance for flutriafol in cucurbits with inedible peel. The EMS produced a single evaluation report, which was submitted to the European Commission and forwarded to EFSA on 11 December 2019. The EMS proposed to establish MRLs for cucurbits (inedible peel) imported from the US at the level of 0.3 mg/kg. The detailed description of the notified use of flutriafol which is the basis for the MRL application is reported in Appendix A.

After the withdrawal of the United Kingdom from the Union on 1 February 2020, the application was reallocated to the EMS, Slovakia. When assessing the evaluation report, EFSA identified data gaps and points requiring clarification, which were requested from the EMS. On 1 June 2020, the EMS, Slovakia, submitted a revised version of the evaluation report, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the RMS, United Kingdom, and updated by Slovakia (United Kingdom, 2019), the draft assessment report (DAR), the additional report to the draft assessment report and its addenda (United Kingdom, 2006, 2010a,b) prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance flutriafol (EFSA, 2010), the Commission review report on flutriafol (European Commission, 2011), the Joint Meeting on Pesticide Residues (JMPR) evaluation report (FAO, 2015) as well as the conclusions from previous EFSA opinions on flutriafol (EFSA, 2016a,b, 2017) including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014).

For this application, the data requirements established in Regulation (EU) No 544/20119 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013, 2016). 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 546/201110.

An updated list of end points, including the end points of relevant studies assessed previously and in the framework of the current assessment of confirmatory data and the MRL application, is presented in Appendix B. The evaluation report submitted by the RMS, United Kingdom, and updated by Slovakia (United Kingdom, 2019) is considered a supporting document to this reasoned opinion and, thus, is made publicly available.

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 flutriafol in primary crops belonging to the groups of root crops, cereals/grass and pulses/oilseeds has been investigated in the framework of EU pesticides peer review (EFSA, 2010). An additional metabolism study on the fruit group (apple) was assessed in the MRL review (EFSA, 2014). After foliar applications, parent flutriafol was the predominant residue in tested crops (50–71% total radioactive residues (TRR)) and in cereal straw (38–63% TRR), except in cereal grains. In cereal grains, triazole alanine (TA) (up to 58% TRR) and triazole acetic acid (TAA) (up to 28% TRR) were the predominant compounds of the total radioactive residues. In apple fruits, triazole alanine (TA) and triazole acetic acid (TAA) were detected at trace level (< 0.001 mg eq/kg) and 1,2,4-triazole (1,2,4-T) was not detected. No information was reported about the presence of triazole lactic acid (TLA), which was not analysed in the residue trials submitted on cucurbits with inedible peel. Nevertheless, the information available suggests limited cleavage of the parent molecule in the fruit crop group, to which cucurbits belong.

A possible preferential metabolism or uptake of one of the two flutriafol enantiomers in plants was not assessed. EFSA recommends reconsidering the need for specific investigations when the EFSA guidance on the consideration of isomer ratios in the consumer risk assessment is implemented (EFSA, 2019b).

---

9 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.
10 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.
For the notified use on cucurbits with inedible peel (MRL application), the metabolic behaviour in primary crops is sufficiently addressed.

### 1.1.2. Nature of residues in rotational crops

Accumulation of flutriafol in soil is expected (DT$_{90}$ 1,051–13,583 days). The metabolism of flutriafol in rotational crops was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2010, 2014). The metabolism of flutriafol in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).

### 1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of flutriafol residues was investigated in a previous EFSA opinion and it was concluded that flutriafol is hydrolytically stable under standard hydrolysis conditions (EFSA, 2016a). Triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) remain stable under the standard processing conditions (EFSA, 2018b). EFSA concluded that the data gap number 13$^{\text{11}}$ identified in the framework of the MRL review was addressed.

### 1.1.4. Methods of analysis in plants

Analytical methods for the determination of flutriafol residues were assessed during the EU pesticides peer review and the MRL review (EFSA, 2010, 2014). The methods, which are based on high-performance liquid chromatography tandem mass spectrometry (HPLC-MS/MS), are sufficiently validated for residues of flutriafol in plants. They allow quantification of flutriafol at or above the limit of quantification (LOQ) of 0.01 mg/kg in the crops under assessment.

For the notified use on cucurbits with inedible peel (high-water content matrices), the proposed MRL can be enforced and further data are not required.

### 1.1.5. Stability of residues in plants

The stability of flutriafol in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2010, 2014). The available data on the storage stability for the TDMs were overall assessed in the framework of the EU peer review of confirmatory data for TDMs (EFSA, 2018b).

In high-water content commodities and in dry matrices, relevant for the current assessment, residues of flutriafol were shown to be stable for at least 12 months. The stability of TDMs ranged from 6 to 53 months (stability in wheat forage was demonstrated 4 months for 1,2,4-T).

### 1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, and the toxicological significance of the relevant metabolites, the following residue definitions were proposed for plants:

#### Residue definition for enforcement:

- Flutriafol

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

#### Residue definition for risk assessment:

- Flutriafol
- Triazole alanine (TA)
- Triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-T)

For processed commodities and rotational crops, the same residue definitions were proposed.

---

$^{11}$ Data gap number 13: data investigating the effect of processing on the nature of flutriafol residues in plant commodities.
Taking into account the notified use assessed in the MRL application, EFSA concluded that these residue definitions are appropriate.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

The applicant proposed an adjusted GAP for rice and no further data was submitted to address the data gaps identified by EFSA in the framework of the MRL review. Residue trials on melons were submitted to support, by extrapolation, the import tolerance request on cucurbits with inedible peel.

The samples from the trials on rice were analysed for the parent compound, TA, TLA, TAA and 1,2,4-T. The samples from residue trials on melons were analysed for the same compounds except for TLA. Most control samples contained background levels of TDMs, which were occasionally at concentrations higher than those in treated samples. Those higher residue values were selected for the consumer risk assessment. According to the EMS, the methods used to analyse the samples were sufficiently validated and were proven to be fit for purpose (United Kingdom, 2019). The residue data are valid regarding storage stability for both flutriafol and TDMs since the samples from the trials were stored prior to analysis for no more than 3 months.

The residues levels in the supervised residue trials submitted for flutriafol and TDMs are reported in Appendix B.1.2.1.

Beetroots

NEU/SEU uses (MRL review confirmatory data). The applicant did not provide new residue data to address the data gap number 2.13

Cucurbits with inedible peel

SEU/Indoor use (MRL review confirmatory data). The applicant did not provide new residue trials to address the data gap number 4.14

Import tolerance (MRL application). The applicant submitted the results of eight residue trials conducted on melons according to the US GAP. An adjuvant (non-ionic surfactant) was used. In four trials, samples of the whole fruit were separated between peel and pulp.

Although it was reported that triazole fungicides were not used in the previous season, TA was quantified in four untreated control samples but at concentrations lower than the residues measured in the corresponding treated samples. Flutriafol, TAA and 1,2,4-T were not quantified (< LOQ) in all untreated control samples.

The number of trials available is sufficient to derive an MRL proposal for melons and, by extrapolation, to the whole group of cucurbits with inedible peel (European Commission, 2017).

Rice

SEU use (MRL review confirmatory data). The applicant proposed to address the data gap number 1215 identified during the MRL review with an adjusted, less critical GAP (one application at 0.125 kg/ha instead of two applications at 0.188 kg/ha, same PHI of 28 days).

The results of eight residue trials conducted on paddy fields in the SEU and compliant with the adjusted GAP were provided. The grain was processed to brown (husked) rice (the part of the product to which the EU MRL applies) to derive an MRL proposal. Residues of flutriafol and TDMs were also determined in rice straw, which is used as feed item.

Flutriafol and 1,2,4-T were not quantified (< LOQ) in any of the untreated control samples, whereas the other TDMs were observed in several untreated control samples. Residues measured in control samples were higher than the residues levels measured in the corresponding treated sample in one brown rice sample for TA and for TAA, in one straw sample for TA, in four straw samples for TAA and in two straw samples for TLA.

---

12 EFSA will systematically request missing data on TDMs for applications submitted after 1 September 2019 (Summary Reports. Meetings held on 13–14 June 2019: Phytopharmaceuticals - Pesticide Residue, available online).
13 Data gap number 2: 8 and 4 residue trials supporting, respectively, the northern and southern outdoor GAPs on beetroots.
14 Data gap number 4: 8 residue trials on melons supporting the indoor GAP on melons and watermelons and 8 residue trials on melons supporting the southern outdoor GAP on melons and watermelons.
15 Data gap number 12: 8 residue trials supporting the southern outdoor GAP on rice grain.
EFSA concluded that the data gap number 12 identified during the MRL review was addressed with residue trials representative for an adjusted GAP.

1.2.2. Magnitude of residues in rotational crops

Flutriafol exhibited very high persistence in soil (DT₉₀ range between 1,050 and 13,583 days) and accumulation following subsequent years of treatment is expected (EFSA, 2010). Beside the active substance, possible uptake of the relevant soil metabolites of flutriafol and other triazole fungicides, the TDMs, cannot be excluded (EFSA, 2018b).

Investigations of residues in rotational crops are not required for the notified uses of flutriafol on cucurbits with inedible peel, because the request is on imported commodities. However, the possibility that flutriafol and TDMs be present in treated crops due to the uptake from the soil cannot be excluded also in crops which are cultivated outside Europe. Regarding rice, possible uptake of residues can occur from the paddy soil in succeeding rice planted for consecutive years on the same paddy field.

Residues of flutriafol in rotational crops of potential significance were identified in the limited field rotational crop studies assessed in the framework of the EU pesticides peer review and the MRL review (EFSA, 2010, 2014). Sugar beet, fodder beet, potatoes, carrots and spring barley were grown/planted in sites where wheat was previously treated for five consecutive years at 188/225 g/ha per year and a total application rate of 1.19 kg/ha (see Appendix B.1.2.2). Specifically, for rice, the applicant submitted the results of a field rotational crop study conducted in the US (United Kingdom, 2019). Rice was planted 1 month after bare soil treatment at 547 g flutriafol/ha. At harvest, maximum flutriafol residues were 0.38 mg/kg in grain and 1.04 mg/kg in straw.

The EMS verified whether these studies (and consequently the MRL derived under Section 1.2) cover the plateau concentration expected in paddy soil after multiannual applications according to the use under assessment. Considering the dissipation of flutriafol in soil (DT₉₀ soil 1,500 days; EFSA, 2010) and the application rate on rice (125 g/ha, BBCH 40–69, PHI 28 days), the EMS calculated a plateau concentration in soil following long-term use of flutriafol at the rate of 68 g/ha (assuming soil depth: 20 cm, soil density 1.5 g/cm³, 90% interception). Even though that immediate replanting of rice in a flooded paddy field during the same season is unlikely, the maximum seasonal application rate was added to the plateau background to address potential crop failure, leading to a total predicted level of 80.5 g/ha (PEC soil total).

Assuming a linear relationship between concentrations, results from these studies were used to calculate maximum residues of flutriafol of 0.06 mg/kg in rice grain and of 0.15 mg/kg in rice straw as PEC soil total. Since the expected additional contribution of flutriafol residues derived from soil uptake is well below the 25% of the residues arising after primary treatment, it is not necessary to consider these residues in the MRL setting, the consumer risk assessment and the dietary burden calculations (OECD, 2016).

Regarding TDMs, which are common metabolites to the triazole fungicides, due to the lack of a comprehensive overview of residues in all authorised uses of flutriafol and of the various triazole active substances, a reliable estimation of residues expected in rotational crops grown in soil containing residues of TDMs at the soil plateau concentration cannot be performed. Therefore, as a general recommendation, Member States should consider setting specific risk mitigation measures to limit the uptake of flutriafol and the TDMs in rotational crops.

1.2.3. Magnitude of residues in processed commodities

The results of the distribution of residues in the peel and the pulp from four residue trials on melons and in milled rice were provided (United Kingdom, 2019). Samples were analysed for parent flutriafol and the TDMs (except for TLA in melons). For flutriafol, a peeling factor of 0.15 was derived for melons and the processing factors (PF) of 0.46 for husked (brown) rice and 0.36 for polished (white) rice obtained from paddy rice, the PF of 0.05 for polished rice obtained from husked rice and the PF of 0.62 for bran (relevant for the livestock dietary burden calculations). For TDMs, processing factors were derived when data allowed it (i.e. residues above the LOQ in both raw agricultural commodity (RAC) and processed product).

EFSA recommends including the mean processing factors established for flutriafol for husked and polished rice in Annex VI of Regulation (EC) No 396/2005.

16 The proportionality principle is not applicable as the study rate (6.8N the predicted PEC soil total) was not in the acceptable range of 0.3 X to 4X (EFSA, 2018c).
1.2.4. Proposed MRLs

In support of the import tolerance for cucurbits with inedible peel from US, an MRL of 0.3 mg/kg is proposed, which corresponds to the tolerance established in the country of origin for the residue as flutriafol.

Regarding the assessment of confirmatory data identified in the MRL review, the data gaps are considered addressed for an adjusted GAP on rice leading to a lower MRL proposal of 1 mg/kg and for pome fruits and wine grapes, whereas the data gaps on the authorised uses on beetroots, melons and watermelons assessed in the MRL review were not addressed.

In Section 3, EFSA assessed whether residues on these crops resulting from the US use in cucurbits with inedible peel and the SEU use on rice are likely to pose a consumer health risk.

2. Residues in livestock

Rice grain in the form of bran/pollard and rice straw may be used for feed purposes. The most recent dietary burden calculations for flutriafol in livestock were performed in the framework of the MRL review using the feed consumption data reported in the European guidance document on livestock feeding studies (European Commission, 1996). EFSA has updated those calculations using the OECD Table of Feedstuffs reported in the guidance document on residues in livestock – Series on Pesticides No 73 (OECD, 2013) now agreed upon at EU level. The animal dietary burden Model calculator developed by EFSA was used to perform the calculations. The expected residues derived from the intended use on rice and from the authorised EU uses on feed items were used as input values. The processing factor of 0.62 was used to calculate residues in rice bran.

The updated calculations confirmed that the livestock dietary burdens for flutriafol exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant species. The input values for the exposure calculations for livestock are presented in Appendix D.1 and the results of the dietary burden calculation are presented in Appendix B.2.

The new calculation methodology led to lower intake estimations compared to the estimations calculated during the MRL review and triggered the need to assess the transfer of residues in poultry. In order to assess whether the intended use on rice has a significant contribution to the livestock exposure to flutriafol residues and whether the existing MRLs for flutriafol in products of animal origin need to be amended, EFSA performed two separate calculations: one with and one without residues as derived from the submitted trials on rice. The inclusion of rice did not have an impact on the median and maximum livestock burden calculations, which are driven by the exposure from the existing uses on barley straw and sugar beet tops.

It is noted that the information available on the authorised crops is not sufficient to perform a livestock dietary burden for each individual TDM.

2.1. Nature of residues

The applicant provided the results of metabolism studies in goats conducted with flutriafol radiolabelled in the triazole and carbinol ring structures at dose rates covering the maximum dietary burdens estimated in the MRL review confirmatory data application (see Appendix B.2.1).

The lactating goats were administered orally for five consecutive days with daily doses of 12 mg/kg DM (low dose) or 30 mg/kg DM (high dose) of flutriafol radiolabelled either in the triazole (TZ) or the carbinol (CA) moiety. Samples of kidney, liver, fat, muscle, bile, blood, gastrointestinal tract were collected approximately 20–22 h after the last administration. Milk and excreta were collected during and at the end of the in-life phase of the study. All samples were analysed within 6 months and are therefore valid as per storage stability.

Flutriafol was almost completely eliminated into the excreta with only a 0.33–0.40% (low dose) and 0.28–0.29% (high dose) of the administered dose recovered in edible tissues and organs. The TRR were low. In the low-dose group, TRR were equal or less than 0.01 mg eq/kg (LOQ), except in liver (0.26–0.31 mg eq/kg) and kidney (0.04–0.06 mg eq/kg). In the high-dose group, TRR were equal or less than 0.02 mg eq/kg, except in liver (0.68–0.70 mg eq/kg) and kidney (0.11–0.31 mg eq/kg). A maximum of 0.06% (low dose) and 0.10% (high dose) of the administered dose was excreted in milk.

Good extractability was achieved for the tissue, organ and milk samples tested, with greater than 80% TRR recovered in the solvent extract and after subsequent enzymatic treatment in liver (except for the liver sample from the high-dose group with CA label = 53%). The identification rates ranged from 14% to 78%.
In the low-dose group, identification of extracted radioactivity was limited in tissues because of the low amounts. In organs, the only metabolites identified at or above 10% TRR were 1,2,4-T in kidney (10% TRR); hydroxy flutriafol glucuronide (M3) in kidney (31% TRR) and hydroxymethyl flutriafol (M5) in liver (11% TRR).

In the high-dose group, unchanged parent compound was not present in muscle and represented only 2.5%, 0.7% and 4.3% of the TRR in liver, kidney and milk, respectively; in fat, flutriafol represented up to 99% TRR (CA label). The metabolites identified at or above the 10% TRR were 1,2,4-T in muscle (42% TRR), fat (27% TRR) and milk (15% TRR); hydroxy flutriafol glucuronide (M3) in kidney (13% TRR), muscle (10% TRR) and milk (44% TRR); flutriafol glucuronide (M4) in kidney (25% TRR) and muscle (17% TRR); methoxy flutriafol glucuronide (M7) in kidney (11% TRR) and dihydroxy flutriafol (M3e) in milk (35% TRR). All the other identified metabolites were individually present at level below 10% TRR.

Results from the studies in goats are consistent with the results observed in the metabolism study in cow assessed in the framework of the EU pesticide peer review and the MRL review (EFSA, 2010, 2014). Since the potential for a preferential metabolism or uptake of one of the two flutriafol enantiomers was not addressed, EFSA recommends reconsidering the need for specific investigations when the EFSA guidance on the consideration of isomer ratios in the consumer risk assessment is implemented (EFSA, 2019b).

In summary, flutriafol was rapidly excreted through urine and faeces and extensively metabolised in tissues, organs and milk to several hydroxylated and glucuronide forms and to 1,2,4-T. These compounds may be considered for inclusion in the residue definition for products of animal origin, which was provisionally proposed as flutriafol parent compound for both enforcement and risk assessment (EFSA, 2014). The residue definition for enforcement set in Regulation (EC) No 396/2005 is flutriafol. In livestock, the residue definition for risk assessment should include, separately, the triazole derivative metabolites (TA, TLA, TAA, 1,2,4-T) as agreed during the EU peer review of confirmatory data for TDMs (EFSA, 2018b).

EFSA proposed to defer the review of these studies and the final decision on the residue definitions for products of animal origin to the EU pesticides peer review (renewal process for the active substance), as suggested in the Commission Working Document SANTE/10235/2016.

Meanwhile, EFSA concluded that the data gap number 1417 identified in the framework of the MRL review was formally addressed.

2.2. Methods of analysis in livestock

The lack of data for a confirmatory method and ILV for the enforcement of flutriafol residues in fat, identified by EFSA during the MRL review (data gap number 1), has not been implemented as a confirmatory data requirement in the EU MRL legislation. Nevertheless, the applicant proposed a method for the determination of residues of flutriafol in fat tissue. Analysis of residues is performed by the multiresidue DFG S19 method, using module E6 for extraction and high-performance liquid chromatography with mass spectrometric detection (HPLC-MS/MS) for the determination. Two ion transitions (for quantification and for confirmation) are tested. The validated LOQ level is at or above 0.01 mg/kg. Since the method is highly specific, a confirmatory method is not necessary.

Regarding the need for an independent laboratory validation (ILV), considering that there is not a confirmatory data request, EFSA agrees with the RMS to reconsider the requirement in the framework of either the renewal of the approval for the active substance or the potential future setting of MRLs in fat tissues.

2.3. Magnitude of residues in livestock

The RMS reported that the samples from the cow feeding study assessed in the framework of the MRL review were stored prior to analysis for a period of 2 months for milk, 4 months for muscle, fat and kidney and up to 4.4 months (131 days) for liver (United Kingdom, 2019).

Additional freezer storage stability data on flutriafol in animal tissues were submitted in the MRL review confirmatory data. Samples of bovine tissues were spiked with the test item at 0.1 mg/kg (10× the LOQ) and stored frozen (−10 to −25°C) for 12 months. The studies demonstrated that flutriafol is stable in all tested animal matrices for the whole investigated period. In milk, residues of flutriafol

\^1 Data gap number 14: An appropriate ruminant metabolism study with radiolabelling of both the carbinol and triazolyl moieties of flutriafol.
were shown to be stable for 4 months (EFSA, 2014). Thus, the results of the feeding study in ruminants are valid for flutriafol residues.

The submitted storage stability study addressed also the stability of TA, TAA and 1,2,4-T. Storage stability of TA and TAA was demonstrated for 12 months in all matrices tested; 1,2,4-T was shown to be stable for 12 months in muscle and liver, 6 months in kidney; in fat, a firm conclusion cannot be drawn because a degradation of more than 30% was observed at 6 and 12 months but not at 9 months storage intervals.

EFSA concluded that the data gap number 15\textsuperscript{18} identified in the framework of the MRL review was addressed.

Since the intended use on rice as a feed item does not contribute significantly to the ruminant dietary burden (see Appendix B.2) and considering that the residue definition is provisional, there is no need to modify the existing EU MRLs in products of ruminants. For poultry, the existing EU MRLs reflect the Codex MRLs (CXLs), which were derived based on a significantly higher livestock dietary burden (FAO, 2015) and their modification is also not necessary at present.

3. **Consumer risk assessment**

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

The toxicological reference values for flutriafol used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2011). Toxicological reference values have been established for each triazole derivative metabolites during the EU peer review of confirmatory data for TDMs (EFSA, 2018b). The reference values for TDMs have been formally taken note by the European Commission.

- **Consumer risk assessment for flutriafol**
  
  a) **Short-term (acute) dietary risk assessment**
  
  The short-term exposure assessment was performed for the commodities assessed in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the HR for cucurbits and the STMR for rice derived from the data submitted. The input values used in the exposure calculations are summarised in Appendix D.2.
  
  The short-term exposure did not exceed the ARfD for any crops assessed (see Appendix B.3).

  b) **Long-term (chronic) dietary risk assessment**
  
  In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2014). EFSA updated the calculation with the relevant STMR values derived from the residue trials on melons and rice submitted in support of the present MRL application; in addition, the STMRs derived in EFSA opinions issued after the MRL review (EFSA, 2016a,b, 2017) and the STMRs derived for the CXLs implemented in the EU MRL regulation (FAO, 2015). The peeling factor was applied to bananas (EFSA, 2014). For cucurbits with inedible peel, the effect of peeling was not considered. Those food commodities, for which no uses of flutriafol were reported in the framework of the MRL review and in the subsequent reasoned opinions or for which no safe CXLs were identified, were excluded from the exposure calculation, assuming that there are no uses on these crops. The input values used in the exposure calculations are summarised in Appendix D.2.
  
  The estimated long-term dietary intake was up to 33% of the ADI (NL toddler). The contribution of residues expected in the commodities assessed to the overall long-term exposure is presented in more detail in Appendix B.3.

  c) **Overall conclusion for flutriafol**
  
  EFSA concluded that the uses of flutriafol on the crops under assessment will not result in a consumer exposure exceeding the toxicological reference values for flutriafol and therefore are unlikely to pose a risk to consumers’ health.

\textsuperscript{18} Data gap number 15: Storage conditions of the samples from the feeding studies.
It is noted that the risk assessment for flutriafol does not consider the possible impact of plant and animal metabolism on the isomer ratio of the active substance and the impact on the dietary exposure of the metabolites observed in the submitted metabolisms studies in goats (see Section 2.1).

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

- **Indicative consumer risk assessment for TDMs**

TDMs may be generated by several pesticides belonging to the class of triazole fungicides. Under the assumption that different triazole pesticides can be used simultaneously on a crop, comprehensive ‘worst-case’ consumer intake assessments were conducted for TA, TAA, TLA and 1,2,4-T in the framework of the confirmatory data for various triazole pesticides using the information available (EFSA, 2018b). EFSA recently updated those calculations using the revised version of the EFSA PRIMo model 3.1 and concluded that the short-term and long-term estimated exposure for TDMs did not exceed the toxicological reference values set for the individual compounds (EFSA, 2020).

Comparing the input values (HR/STMR) derived under the current assessment with the input values used in the previous assessment, it became evident that following the use of flutriafol less critical residues of TA, TAA and TLA are expected. For 1,2,4-T, a comparison was not deemed necessary because residues above LOQ were not measured in the concerned commodities.

EFSA concluded that the acute and chronic consumer risk assessments previously conducted for TDMs are still valid as covering the notified use of flutriafol on cucurbits with inedible peel and the intended use on rice under assessment. It is noted that the consumer risk assessment for the TDMs is indicative, since a comprehensive database for all authorised EU uses and import tolerances on triazole fungicides is not yet available. The calculations are also affected by additional non-standard uncertainties related to the data gaps identified in the EU peer review of confirmatory data for TDMs (EFSA, 2018b).

4. **Conclusion and Recommendations**

To address data gaps identified in the framework of the MRL review, the applicant provided residue trials on rice representative of an adjusted GAP, metabolism studies in goats and storage stability data in tissues of animal origin. For the nature of residues in processed commodities, relevant to confirm the MRLs on pome fruits and wine grapes, the applicant referred to the information provided in a previous MRL application and already assessed by EFSA. The data gaps on the authorised uses on beetroots, melons and watermelons assessed in the MRL review were not addressed.

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for the import tolerance request for cucurbits with inedible peel from US.

EFSA concluded that the proposed use of flutriafol on the crops under assessment will not result in a consumer exposure exceeding the toxicological reference values for flutriafol and therefore is unlikely to pose a risk to consumers’ health. Regarding the TDMs, the conclusion reached in a previous assessment for another triazole fungicide is still valid. An update of the indicative consumer risk assessment for each individual metabolite is not necessary since the expected residues in the commodities under consideration are covered by previous assessment.

The renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing, and therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the renewal.

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix B.4.

**References**

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance flutriafol. EFSA Journal 2010;8(10):1868, 50 pp. [https://doi.org/10.2903/j.efsa.2010.1868](https://doi.org/10.2903/j.efsa.2010.1868)

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for flutriafol according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(5):3687, 64 pp. [https://doi.org/10.2903/j.efsa.2014.3687](https://doi.org/10.2903/j.efsa.2014.3687)

EFSA (European Food Safety Authority), 2016a. Reasoned opinion on the setting of import tolerance for flutriafol in strawberries. EFSA Journal 2016;14(3):4427, 20 pp. [https://doi.org/10.2903/j.efsa.2016.4427](https://doi.org/10.2903/j.efsa.2016.4427)
EFSA (European Food Safety Authority), 2016b. Reasoned opinion on the setting of import tolerance for flutriafol in cucurbits with edible peel. EFSA Journal 2016;14(9):4577, 16 pp. https://doi.org/10.2903/j.efsa.2016.4577

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017. Reasoned opinion on the setting of import tolerance for flutriafol in hops. EFSA Journal 2017;15(6):4875, 23 pp. https://doi.org/10.2903/j.efsa.2017.4875

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018a. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, Chiusolo A, Civitella C, Court Marques D, Crivellente F, De Lentdecker C, Erdos Z, Ferreira L, Goumenou M, Greco L, Istance F, Jarrah S, Kardassi D, Leuschner R, Medina P, Mineo D, Miron I, Molnar T, Nave S, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Terron A, Theobald A, Vagenende B and Villamar-Bouza L, 2018b. Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, 20 pp. https://doi.org/10.2903/j.efsa.2018.5376

EFSA (European Food Safety Authority), 2018c. Recommendations on the use of the proportionality approach in the framework of risk assessment for pesticide residues. EFSA supporting publication 2017;EN-1503, 18 pp. https://doi.org/10.2903/sp.efsa.2017.en-1503

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Racyzk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019a. Pesticide Residue Intake Model - EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA supporting publication 2019;EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.en

EFSA (European Food Safety Authority), Bura L, Friel A, Magrans JO, Parra Morte JM and Szentes C, 2019b. Guidance of EFSA on risk assessments for active substances of plant protection products that have stereoisomers as components or impurities and for transformation products of active substances that may have stereoisomers. EFSA Journal 2019;17(8):5804, 33 pp. https://doi.org/10.2903/j.efsa.2019.5804

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2020. Reasoned Opinion on the modification and setting of maximum residue levels for mefentriquinazalone in various crops. EFSA Journal 2020;18(7):6193, 60 pp. https://doi.org/10.2903/j.efsa.2020.6193

European Commission, 1996. Appendix G. Livestock feeding studies. 7031/V1/95-rev.4.

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

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/V1/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/V1/95-rev. 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/V1/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/V1/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/V1/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/V1/95-rev. 5, 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414). SANCO/3029/99-rev. 4.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2011. Review report for the active substance flutriafol. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 11 March 2011 in view of the inclusion of flutriafol in Annex I of Council Directive 91/414/EEC. SANCO/10096/2011 final, 11 March 2011, 7 pp.

European Commission, 2016. Commission working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 17 June 2016. SANTE/E4/VW 10235/2016 - Rev. 2, 3 pp., Brussels, 17 June 2016.

www.efsa.europa.eu/efsajournal
European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.
FAO (Food and Agriculture Organization of the United Nations), 2015. Flutriafol. In: Pesticide residues in food – 2015. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 223.
FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org
OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.
OECD (Organisation for Economic Co-operation and Development), 2016. Guidance Document on Crop Field Trials. In: Series on Pesticides No 66/Series on Testing and Assessment No 164. 2nd Edition. ENV/JM/MONO (2011)50/REV1, ENV/JM/MONO(2011)50/REV1/ANN, 7 September 2016.
United Kingdom, 2006. Draft assessment report on the active substance flutriafol prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, May 2006.
United Kingdom, 2010a. Additional report to the draft assessment report on the active substance flutriafol prepared by the rapporteur Member State United Kingdom in the framework of Council Regulation (EC) No 33/2008, January 2010.
United Kingdom, 2010b. Final Addendum to Draft Assessment Report and Additional Report on flutriafol, compiled by EFSA, September 2010. Available online: www.efsa.europa.eu
United Kingdom, 2019. Confirmatory Data on the setting of flutriafol MRLs in various matrices following Article 12 Review. October 2019, revised by Slovakia in May 2020, 213 pp.

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
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
DP dustable powder
DS powder for dry seed treatment
DT₉₀ period required for 90% dissipation (define method of estimation)
EC emulsifiable concentrate
EDI estimated daily intake
EMS evaluating Member State
Eq residue expressed as a.s. equivalent
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
### Appendix A – Summary of GAPs assessed

#### A.1. Summary of GAPs assessed in the evaluation of confirmatory data and the proposed adjusted GAPs

| Crop and/or situation | NEU, SEU, MS or country | F, G or I(a) | Pest(s) or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-------------|-------------------------------------|-------------|----------------|-------------------------------|--------------|---------|
| **Type(b)** | **Conc. a.s.** | **Method kind** | **Range of growth stages & season(e)** | **Number min-max** | **Interval between application (min)** | **g a.s./hL min-max** | **Water L/ha min-max** | **Rate** | **Unit** | **Remarks** |
| Beet roots | NEU | F | | Foliar treatment – spraying | BBCH 39-49 | 2 | 20 | 0.125 | kg a.i./ha | 28 |
| Beet roots | SEU | F | | Foliar treatment – spraying | BBCH 39-49 | 2 | 20 | 0.125 | kg a.i./ha | 28 |
| Melons | SEU | F | Powdery mildew | SC 125.0 g/L | Foliar treatment – spraying | BBCH 13–89 | 1–3 | 10 | 0.31 | kg a.i./ha | 10 |
| Watermelons | SEU | F | Powdery mildew | SC 125.0 g/L | Foliar treatment – spraying | BBCH 13–89 | 1–3 | 10 | 0.31 | kg a.i./ha | 10 |
| Melons | EU | I | Powdery mildew | SC 125.0 g/L | Foliar treatment – spraying | BBCH 13-89 | 1-3 | 10 | 0.31 | kg a.i./ha | 10 |
| Watermelons | EU | I | Powdery mildew | SC 125.0 g/L | Foliar treatment – spraying | BBCH 13-89 | 1-3 | 10 | 0.31 | kg a.i./ha | 10 |
| Rice | SEU | F | Pyricularia oryzae Drechslera oryzae | SC 250.0 g/L | Foliar treatment – spraying | 2 | | | 0.188 | kg a.i./ha | 28 | Original GAP for which data gap was identified in MRL review (EFSA, 2014) |
### A.2. Summary of intended new GAP triggering the amendment of existing MRLs

| Crop and/or situation | NEU, SEU, MS or country | F, G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|------------------------|-------------|-----------------------------------|-------------|----------------|--------------------------------|--------------|---------|
| Rice                  | SEU                    | F           | Pyricularia oryzae, Drechslera oryzae | SC          | Foliar treatment – broadcast spraying | 250.0 g/L From BBCH 40 1 | 20.8–31.3 400–600 0.125 kg a.i./ha 28 | Proposed less critical GAP Application on paddy fields/flooded sites |
| Cucurbits – inedible peel | US                    | F           | Powdery Mildew P. macularis, S. macularis | SC          | Foliar treatment – broadcast spraying | 250.0 g/L 1–4 7 | 27.4–272 47–467 0.128 kg a.i./ha 0 Mixed with non-ionic surfactant |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; a.i.: active ingredient; 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 | Crops | Applications | Sampling (DALA) | Comment/Source |
|-----------------------------------|-------------|-------|--------------|-----------------|----------------|
| Fruit crops                       | Apple       | Foliar | $1 \times 0.118$ kg/ha | 64 | Radiolabelled active substance: $[^14C]$-carbinol and $[^14C]$-triazole radiolabel flutriafol (EFSA, 2014) |
| Root crops                        | Sugar beets | Foliar | $1 \times 0.125$ kg/ha | 0, 16, 21 | Radiolabelled active substance: $[^14C]$-carbinol and $[^14C]$-triazole flutriafol (EFSA, 2010) |
| Cereals/grass                     | Barley, Wheat | Foliar | $1 \times 0.081-0.105$ kg/ha | 44 to 94 |  |
| Pulses/oilseeds                   | Oilseed rape | Foliar | $1 \times 0.125$ kg/ha | 0, 14, 42 |  |

| Rotational crops (available studies) | Crop groups | Crops | Application | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|-------|-------------|-----------|----------------|
| Root/tuber crops                     | Sugar beet | Bare soil | $1 \times 0.25$ kg/ha | 30, 120, 365 | Radiolabelled active substance: $[^14C]$-carbinol and $[^14C]$-triazole flutriafol (EFSA, 2010) |
| Radish                              | Bare soil, $1 \times 0.26$ kg/ha | 30, 120, 365 |  |
| Leafy crops                         | Lettuce     | Bare soil | $1 \times 0.26$ kg/ha | 30, 120, 365 |  |
| Cereal (small grain)                | Wheat       | Bare soil | $1 \times 0.25$ kg/ha or $0.26$ kg/ha | 30, 120, 365 |  |

| Processed commodities (hydrolysis study) | Conditions | Compound | Stable? | Comment/Source |
|-----------------------------------------|------------|----------|---------|----------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4) | F, 1,2,4-T, TA, TAA, TLA | Yes | Radiolabelled active substance: $[^14C]$ triazole flutriafol (EFSA, 2016a) |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5) | F, 1,2,4-T, TA, TAA, TLA | Yes | TDMs (EFSA, 2018b) |
|                                        | Sterilisation (20 min, 120°C, pH 6) | F, 1,2,4-T, TA, TAA, TLA | Yes |  |

$F$, flutriafol; 1,2,4-T, 1,2,4-triazole; TA, triazole alanine; TAA, triazole acetic acid; TLA, triazole lactic acid.
Can a general residue definition be proposed for primary crops?  
Yes EFSA (2010)

Rotational crop and primary crop metabolism similar?  
Yes EFSA (2010)

Residue pattern in processed commodities similar to residue pattern in raw commodities?  
Yes EFSA (2016a)

Plant residue definition for monitoring (RD-Mo)  
Flutriafol

Plant residue definition for risk assessment (RD-RA)  
a) Flutriafol  
b) TDMs, with a separate assessment of:  
   TA and TLA  
   TAA  
   1,2,4-Triazole

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:  
HPLC–MS/MS, LOQ of 0.01 mg/kg (EFSA, 2010, 2014)  
Wheat straw: HPLC–MS/MS, LOQ of 0.05 mg/kg (EFSA, 2014)

DAT: days after treatment; PBI: plant-back interval; DALA: days after last application; LOQ: limit of quantification; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry.

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

| Plant products (available studies) | Category | Commodity          | T (°C) | Stability (months) | Comment/Source<sup>(a)</sup> |
|-----------------------------------|----------|--------------------|--------|-------------------|-------------------------------|
|                                   |          |                    |        | F 1,2,4-T TA TAA TLA |                               |
| High water content                | Tomato   | ≤ –18°C            | –      | 6 53 53 –          | EFSA (2018b)                  |
|                                   | Apple    | ≤ –18°C            | 12     | 6 12 12 –          | EFSA (2014, 2018b)            |
|                                   | Lettuce  | ≤ –18°C            | –      | – – 48 –           | EFSA (2018b)                  |
|                                   | Mustard greens | ≤ –18°C            | –      | 6 53 53 –          | EFSA (2018b)                  |
|                                   | Radish tops | ≤ –18°C            | –      | 12 26 12 –         | EFSA (2018b)                  |
|                                   | Wheat forage | ≤ –18°C          | 12     | 4 53 53 –          | EFSA (2010, 2018b)            |
| High oil content                  | Soybean  | ≤ –18°C            | –      | 12 26 26 48        | EFSA (2018b)                  |
|                                   | Rape seed | ≤ –18°C          | 12     | Not stable Not stable 53 48 | EFSA (2014, 2018b) |
| Dry/High protein content          | Dried pea, Dried bean | ≤ –18°C           | –      | 15 25 48           | EFSA (2018b)                  |
| Dry/High starch content           | Barley, Wheat | ≤ –18°C          | –      | 12 26 26 48        | EFSA (2018b)                  |
|                                   | Wheat    | ≤ –23°C            | 12     | – – – –            | EFSA (2014)                   |
| High acid content                 | Grape    | ≤ –18°C            | 23     | – – – –            | EFSA (2014)                   |
|                                   | Lemon, Orange | ≤ –18°C       | –      | – – 48 –           | EFSA (2018b)                  |
| Other                             | Wheat straw | ≤ –18°C        | 12     | 12 53 40 –         | EFSA (2010, 2018b)            |

F, flutriafol; 1,2,4-T, 1,2,4-triazole; TA, triazole alanine; TAA, triazole acetic acid; TLA, triazole lactic acid.

<sup>(a)</sup>: Storage stability of flutriafol (F) assessed in EFSA (2010, 2014); storage stability of TDMs assessed in EFSA (2018b).
B.1.2. Magnitude of residues in plants

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

- **Flutriafol**

| 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) |
|--------------------------------------------------------------------------|------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Melons, pumpkins, watermelons, other cucurbits with inedible peel       | US               | 0.02; 0.05; 0.07; 0.08; 0.10; 0.11; 0.12; 0.13                  | Residue trials on melons compliant with the US GAP: Higher value measured at a longer PHI of 14 days (underlined) Extrapolation to the group of cucurbits with inedible peel possible | 0.3                    | 0.13         | 0.09           | n/a   |
| Rice grain                                                               | SEU              | 0.13; 0.14; 0.29; 0.34; 0.39; 0.44; 0.49; 0.54                  | Residue trials on rice compliant with the intended GAP. Residues refer to (husked) brown rice | 1                      | 0.54         | 0.37           | n/a   |
| Rice straw                                                               | SEU              | 0.45; 0.76; 0.92; 1.10; 1.10; 1.30; 1.40; 1.90; 2.10; 2.40; 4.00 | Residue trials on rice compliant with the intended GAP                          | n/a                    | 4.00         | 1.35           | n/a   |

MRL: maximum residue level; GAP: Good Agricultural Practice; n/a: not applicable.
(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. n/a, not applicable.

- **Triazole derivative metabolites (TDMs)**

| 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) |
|--------------------------------------------------------------------------|------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Melons, pumpkins, watermelons, other cucurbits with inedible peel       | US               | < 0.01; 0.01; 0.02; 0.02; 0.02; 0.03; 0.05; 0.07                | See comments reported for flutriafol                                            | n/a                    | 0.07         | 0.02           | n/a   |
| Rice grain                                                               | SEU              | 0.03; 0.03; 0.04; 0.05; 0.08; 0.18; 0.19; 0.25(b)              | See comments reported for flutriafol                                            | n/a                    | 0.25         | 0.07           | n/a   |

MRL: maximum residue level; GAP: Good Agricultural Practice; n/a: not applicable.
(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. n/a, not applicable.
| Commodity          | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-------------------|-----------------------------|---------------------------------------------------------------|----------------|------------------------|--------------------------|---------------------------|----------------|
| Rice straw        | SEU                         | 9 × < 0.01; 0.01; 0.02; 0.08<sup>(e)</sup>                   | See comments reported for flutriafol | n/a        | 0.08                     | 0.01                        | n/a        |
|                   |                              | **Residue definition for risk assessment: 1,2,4-T (1,2,4 Triazole)** |
| Melons, pumpkins, | US                          | 8 × < 0.01                                                  | See comments reported for flutriafol | n/a        | 0.01                     | 0.01                        | n/a        |
| watermelons, other cucurbits with inedible peel |        |                                                              |                              |            |                          |                            |            |
| Rice gain         | SEU                         | 8 × < 0.01                                                  | See comments reported for flutriafol | n/a        | 0.01                     | 0.01                        | n/a        |
| Rice straw        | SEU                         | 12 × < 0.01                                                | See comments reported for flutriafol | n/a        | 0.01                     | 0.01                        | n/a        |
|                   |                              | **Residue definition for risk assessment: Triazole acetic acid (TAA)** |
| Melons, pumpkins, | US                          | 8 × < 0.01                                                  | See comments reported for flutriafol | n/a        | 0.01                     | 0.01                        | n/a        |
| watermelons, other cucurbits with inedible peel |        |                                                              |                              |            |                          |                            |            |
| Rice gain         | SEU                         | < 0.01; 0.03; 0.04; 0.07; 0.09; 0.10; 0.19; 0.25<sup>(e)</sup> | See comments reported for flutriafol | n/a        | 0.25                     | 0.08                        | n/a        |
| Rice straw        | SEU                         | < 0.01; 0.01; 0.03; 0.04<sup>(e)</sup>; 0.06; 2 × 0.06<sup>(e)</sup>; 0.08; 0.09<sup>(e)</sup>; 0.20; 0.26; 0.32 | See comments reported for flutriafol | n/a        | 0.32                     | 0.06                        | n/a        |
|                   |                              | **Residue definition for risk assessment: Triazole lactic acid (TLA)** |
| Melons, pumpkins, | US                          | Not analysed                                                | See comments reported for flutriafol | –          | –                        | –                          | –          |
| watermelons, other cucurbits with inedible peel |        |                                                              |                              |            |                          |                            |            |
| Rice gain         | SEU                         | 8 × < 0.01                                                  | See comments reported for flutriafol | n/a        | 0.01                     | 0.01                        | n/a        |
| Rice straw        | SEU                         | 2 × < 0.01; 2 × 0.01; 2 × 0.03<sup>(e)</sup>; 2 × 0.04; 0.10; 0.11; 0.17; 0.18 | See comments reported for flutriafol | n/a        | 0.18                     | 0.04                        | n/a        |

MRL: maximum residue level; n/a: not applicable.

(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): EFSA selected the value measured in untreated control sample instead of the corresponding value in the treated sample because higher.
B.1.2.2. Residues in rotational crops

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

Yes

Parent flutriafol, triazole alanine (TA) and triazole acetic acid (TAA) were the major components of residues in rotational crops (EFSA, 2010)

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

Yes

Clear evidence that flutriafol residues above 0.01 mg/kg could be present in crops sown/planted in rotation with wheat previously treated for five consecutive years (188/225 g/ha per year; total rate 1.19kg/ha). Flutriafol residues were detected in sugar beet and fodder beet roots, potatoes and carrots at levels up to 0.02 mg/kg, in sugar beet and fodder beet tops at levels up to 0.08 mg/kg and in barley grain and straw at levels of 0.05 mg/kg and 0.38 mg/kg, respectively (EFSA, 2010, 2014). Maximum flutriafol residues in rice planted 1 month after bare soil application at 547 g/ha were 0.38 mg/kg in grain and 1.04 mg/kg in straw (United Kingdom, 2019)

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies (a) | Processing Factor (PF) | Median PF | Comment/Source |
|---------------------|-----------------------------|------------------------|-----------|----------------|
|                     |                             | Individual values      |           |                |
| Residence definition for enforcement and risk assessment: Flutriafol |
| Melons, peeled       | 4                           | 0.09; 0.14; 0.15; 0.37 | 0.15      | n/a United Kingdom (2019) |
| Rice, husked from paddy rice | 4                        | 0.35; 0.40; 0.51; 0.60 | 0.46      | n/a United Kingdom (2019) |
| Rice, polished from paddy rice | 4                     | 0.16; 0.34; 0.38; 0.44 | 0.36      | n/a United Kingdom (2019) |
| Rice, polished from husked rice | 4                 | 0.04; 0.05; 0.05; 0.05 | 0.05      | n/a United Kingdom (2019) |
| Rice, bran           | 4                           | 0.44; 0.57; 0.67; 3.73 | 0.62      | n/a United Kingdom (2019) |

| Residence definition for risk assessment: Triazole alanine (TA) |
| Melons, peeled       | 3                           | 0.73; 0.85; 1.20 | 0.85      | n/a United Kingdom (2019) |
| Rice, husked from paddy rice | 4                       | 0.71; 1.00; 1.20; 1.33 | 1.10      | n/a United Kingdom (2019) |
| Rice, polished from paddy rice | 4                     | 0.71; 0.75; 1.00; 1.00; | 0.88      | n/a United Kingdom (2019) |
| Rice, bran           | 4                           | 0.14; 2.56; 3.00; 4.50 | 2.78      | n/a United Kingdom (2019) |

| Residence definition for risk assessment: Triazole acetic acid (TAA) |
| Rice, husked from paddy rice | 4                           | 1.00; 1.11; 1.29; 1.40 | 1.20      | n/a United Kingdom (2019) |
| Rice, polished from paddy rice | 3                        | 0.75;0.86; 1.00; | 0.86      | n/a United Kingdom (2019) |
| Rice, bran           | 3                           | 0.25; 2.00; 5.00 | 2.00      | n/a United Kingdom (2019) |

PF: processing factor; n/a: not applicable.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (i.e. peeling factors for T and TAA in melons and processing factors for T and TLA in rice).
(b): Conversion factor for risk assessment in the processed commodity; not applicable.
### B.2. Residues in livestock

Calculation performed according to OECD, 2013

| Relevant groups (subgroups) | Dietary burden (including rice) expressed in mg/kg bw per day Median | Maximum | mg/kg DM Median | Maximum | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | DB w/out rice mg/kg DM Maximum | Previous assessment Max burden mg/kg DM |
|-----------------------------|---------------------------------------------------------------|----------|-----------------|---------|---------------------------|--------------------------|----------------------|-------------------------------|----------------------------------|
| Cattle (all)                | 0.024                                                         | 0.059    | 0.62            | 1.52    | Dairy cattle               | Barley                   | Straw                | 1.52                          | 3.98 EFSA (2014)                  |
| Cattle (dairy only)         | 0.024                                                         | 0.059    | 0.62            | 1.52    | Dairy cattle               | Barley                   | Straw                | 1.52                          | 2.63 EFSA (2014)                  |
| Sheep (all)                 | 0.038                                                         | 0.124    | 0.89            | 2.91    | Lamb                       | Barley                   | Straw                | 2.91                          | –                                 |
| Sheep (ewe only)            | 0.030                                                         | 0.097    | 0.89            | 2.91    | Ram/Ewe                    | Barley                   | Straw                | 2.91                          | –                                 |
| Swine (all)                 | 0.007                                                         | 0.012    | 0.29            | 0.50    | Swine (breeding)           | Beet, sugar              | Tops                 | 0.50                          | 1.46 EFSA (2014)                  |
| Poultry (all)               | 0.017                                                         | 0.038    | 0.26            | 0.55    | Poultry layer              | Wheat                    | Straw                | 0.55                          | 7.90 FAO (2015)                   |
| Poultry (layer only)        | 0.017                                                         | 0.038    | 0.26            | 0.55    | Poultry layer              | Wheat                    | Straw                | 0.55                          | 7.90 FAO (2015)                   |

bw: body weight; DM: dry matter; DB: dietary burden.

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

(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                   | 12 mg/kg feed/day | 14 mg/kg feed/d   | 7              | Label position: [^{14}C-triazole]-flutriafol and [^{14}C-carbinol]-flutriafol (EFSA, 2010) |
| Lactating cow                | 2 mg/kg feed/d   |                   | 7              | Label position: [^{14}C-triazole] flutriafol (EFSA, 2010)                     |
| Lactating goat               | 12 mg/kg feed/day| 30 mg/kg feed/d   | 5              | Label position: [^{14}C-triazole]-flutriafol and [^{14}C-carbinol]-flutriafol Not peer reviewed (United Kingdom, 2019) |
| Pig                          | –               | –                 | –              | Open                                                                            |
| Fish                         | –               | –                 | –              | n/a                                                                             |

bw: body weight; n/a: not applicable.

Time needed to reach a plateau concentration in milk and eggs (days)

- Milk: Inconclusive
- Eggs: 7 days (EFSA, 2010)

Metabolism in rat and ruminant similar
- Yes

Can a general residue definition be proposed for animals?
- Open

Animal residue definition for monitoring (RD-Mo)
- Flutriafol (Reg. (EU) No 396/2005)
- Ruminant products: Flutriafol (provisional) (EFSA, 2014)

Animal residue definition for risk assessment (RD-RA)
- Flutriafol (provisional) (EFSA, 2014).

B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (months) | Source(a) |
|-------------------------------------|--------|-----------|--------|--------------------|-----------|
|                                     |        |           |        | F 1,2,4-T TA TAA TLA |           |
| Bovine                              | Muscle | ≤ –25     | 12     | 12 12 12 12         | United Kingdom (2019), EFSA (2018b) |
| Bovine                              | Liver  | ≤ –25     | 12     | 12 12 12 12         | No data  |
| Bovine                              | Kidney | ≤ –25     | 12     | 12 12 12 12         | No data  |
| Bovine                              | Milk   | ≤ –18     | 4      | 18 No data No data  | EFSA (2014, 2018b) |
| Poultry                             | Eggs   | ≤ –18     | No data| 12 No data No data  | EFSA (2018b) |

(a): Storage stability of flutriafol (F) assessed in United Kingdom, 2019 (tissues) and EFSA, 2014 (milk); storage stability of TDMs assessed in EFSA (2018b) (1,2,4-T) and in United Kingdom, 2019 (TA, TAA).

B.2.2. Magnitude of residues in livestock

Not relevant.
### B.3. Consumer risk assessment

| ARfD | Flutriafol: 0.05 mg/kg bw (European Commission, 2011) |
|------|--------------------------------------------------|
|      | **Triazole derivative metabolites** (TDMs): |
|      | Triazole alanine: 0.3 mg/kg bw (EFSA, 2018b) |
|      | Triazole lactic acid: 0.3 mg/kg bw (EFSA, 2018b) |
|      | Triazole acetic acid: 1 mg/kg bw (EFSA, 2018b) |
|      | 1,2,4-Triazole: 0.1 mg/kg bw (EFSA, 2018b) |

| Highest IESTI, according to EFSA PRIMO | Flutriafol: |
|-----------------------------------------|-------------|
| Melons: 39.4% of ARfD                   |             |
| Pumpkins: 7% of ARfD                    |             |
| Watermelons: 32% of ARfD                |             |
| Rice: 9% of ARfD                        |             |

| TDMs: |
|-------|
| Triazole alanine, triazole lactic acid, triazole acetic acid: crops assessed are covered by previous risk assessment (EFSA, 2020) |
| 1,2,4-triazole: not necessary |

| Assumptions made for the calculations | Flutriafol: |
|--------------------------------------|-------------|
| The calculation is based on the highest residue level for cucurbits with inedible peel and the median residue level for rice (husked) grain expected in raw agricultural commodities. |

| TDMs: |
|-------|
| The highest/median residues of TA, TAA and TLA derived from the uses of flutriafol on cucurbits with inedible peels and rice are covered in the assessment of the EU pesticides peer review confirmatory data for TDMs as revised by using the actual PRIMO 3.1 model in the reasoned opinion on the modification and setting of MRLs for mefentrifluconazole in various crops (EFSA, 2020). |
| Calculations for 1,2,4-T not necessary (no residues expected in the commodities under concern) |

Calculations were performed with PRIMO 3.1
### ADI

**Flutriafol:**
0.01 mg/kg bw per day (European Commission, 2011)

### TDMs:
- Triazole alanine: 0.3 mg/kg bw per day (EFSA, 2018b)
- Triazole lactic acid: 0.3 mg/kg bw per day (EFSA, 2018b)
- Triazole acetic acid: 1 mg/kg bw per day (EFSA, 2018b)
- 1,2,4-Triazole: 0.023 mg/kg bw per day (EFSA, 2018b)

### Highest IEDI, according to EFSA PRIMo

**Flutriafol:**
33% of ADI (NL toddler)

**Contribution of crops assessed:**
- Melons: 0.73% of ADI
- Pumpkins: 0.22% of ADI
- Watermelons: 1.00% of ADI
- Rice: 5.74% of ADI

**TDMs:**
- Triazole alanine: 6% ADI (NL toddler)
- Triazole acetic acid: 1% ADI (NL toddler)
- Triazole lactic acid: 1% ADI (NL toddler)

**Contribution of crops assessed:**
Covered by previous risk assessment (EFSA, 2020).

**1,2,4 Triazole:**
Not necessary

### Assumptions made for the calculations

**Flutriafol**
The calculation is based on the median residue levels derived for the raw agricultural commodities as estimated in cucurbits with edible peel and (husked) rice and in previous EFSA assessments (EFSA, 2014, 2016a,b, 2017) plus the STMRs derived for the CXLs (FAO, 2015) implemented in the EU regulation. Peeling factor for banana was applied.

The contributions of commodities where no GAP or no safe CXLs was reported in the framework of the MRL review and in the EFSA assessments following the MRL review were not included in the calculation.

**TDMs:**
The calculations for TA, TAA and TLA are based on the median residue levels expected in raw agricultural commodities for a number of triazole fungicides, the highest level selected, derived in the framework of the EU pesticides peer review of confirmatory data for TDMs as revised in the previously issued reasoned opinion on mfenflurconazole (EFSA, 2020).

Median residues of TDMs derived from the uses under assessment are covered by the previous assessment.

Calculations for 1,2,4-T not necessary (no residues expected in the commodities under concern).

Calculations were performed with PRIMo 3.1

---

**ARfD:** acute reference dose; **bw:** body weight; **IESTI:** international estimated short-term intake; **PRIMo:** (EFSA) Pesticide Residues Intake Model; **ADI:** acceptable daily intake; **IEDI:** international estimated daily intake; **MRL:** maximum residue level; **STMR:** supervised trials median residue; **CXL:** codex maximum residue limit.
### B.4. Recommended MRLs

| Code(a) | Commodity                          | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                 |
|---------|------------------------------------|-----------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0130010 | Apples                             | 4 (ft 1)        | 4            | The data gap identified in the MRL review for information on the nature of residues in processed commodities (hydrolysis study) has been addressed in a previous EFSA opinion. The MRL is confirmed. Risk for consumer unlikely |
| 0130020 | Pears                              | 4 (ft 1)        | 4            | The data gap identified in the MRL review for information on the nature of residues in processed commodities (hydrolysis study) has been addressed in a previous EFSA opinion. The MRL is confirmed. Risk for consumer unlikely |
| 0130030 | Quinces                            | 4 (ft 1)        | 4            | The data gap identified in the MRL review for information on the nature of residues in processed commodities (hydrolysis study) has been addressed in a previous EFSA opinion. The MRL is confirmed. Risk for consumer unlikely |
| 0130040 | Medlars                            | 4 (ft 1)        | 4            | The data gap identified in the MRL review for information on the nature of residues in processed commodities (hydrolysis study) has been addressed in a previous EFSA opinion. The MRL is confirmed. Risk for consumer unlikely |
| 0130050 | Loquats/Japanese medlars            | 4 (ft 1)        | 4            | The data gap identified in the MRL review for information on the nature of residues in processed commodities (hydrolysis study) has been addressed in a previous EFSA opinion. The MRL is confirmed. Risk for consumer unlikely |
| 0130990 | Other pome fruits                  | 4 (ft 1)        | 4            | The data gap identified in the MRL review for information on the nature of residues in processed commodities (hydrolysis study) has been addressed in a previous EFSA opinion. The MRL is confirmed. Risk for consumer unlikely |
| 0151020 | Wine grapes                         | 1.5 (ft 1)      | 1.5          | The import tolerance (US) request has been supported by extrapolation from residue trials on melons. MRL proposal corresponds to the value set in the country of origin. Risk for consumers unlikely |
| 0213010 | Beetroots                           | 0.06 (ft 2)     | Further risk management consideration required | The data gap identified in the MRL review for information on residue trials has not been addressed. The lowering of the MRL to the LOQ of 0.01 mg/kg should be considered. Risk for consumer unlikely |
| 0233010 | Melons                              | 2 (ft 2)        | 0.3          | The data gap identified in the MRL review for information on residue trials has not been addressed. The lowering of the MRL to the LOQ of 0.01 mg/kg should be considered. Risk for consumer unlikely |
| 0233020 | Pumpkins                            | 0.01*           | 0.3          | The data gap identified in the MRL review for information on residue trials has not been addressed. The lowering of the MRL to the LOQ of 0.01 mg/kg should be considered. Risk for consumer unlikely |
| 0233030 | Watermelons                         | 2 (ft 2)        | 0.3          | The data gap identified in the MRL review for information on residue trials has not been addressed. The lowering of the MRL to the LOQ of 0.01 mg/kg should be considered. Risk for consumer unlikely |
| 0233990 | Other cucurbits with inedible peel  | 0.01*           | 0.3          | The data gap identified in the MRL review for information on residue trials has not been addressed. The lowering of the MRL to the LOQ of 0.01 mg/kg should be considered. Risk for consumer unlikely |
| 0500060 | Rice                                | 1.5 (ft 2)      | 1            | The data gap identified in the MRL review for information on residue trials has not been addressed. The submitted data support a lower MRL proposal. Risk for consumer unlikely |
| 1011030 | Swine, Liver                        | 0.1 (ft 3)      | 0.1          | The data gap identified in the MRL review for information on residue trials has not been addressed. The submitted data support a lower MRL proposal. Risk for consumer unlikely |
| 1012030 | Bovine, Liver                       | 0.3 (ft 4)      | 0.3          | The data gap identified in the MRL review for an appropriate metabolism study in ruminants has been addressed. EFSA proposed to defer the review of this and the metabolism studies previously assessed and the final decision on the residue definitions for products of animal origin to the EU pesticides peer review for the renewal of the approval of flutriafol. Information on the storage conditions of the samples from the feeding studies and new data on storage stability confirm the validity of the results of the feeding study in ruminants (extrapolated to pigs) assessed in the MRL review. Risk for consumers unlikely |
| 1013030 | Sheep, Liver                        | 0.3 (ft 4)      | 0.3          | The data gap identified in the MRL review for an appropriate metabolism study in ruminants has been addressed. EFSA proposed to defer the review of this and the metabolism studies previously assessed and the final decision on the residue definitions for products of animal origin to the EU pesticides peer review for the renewal of the approval of flutriafol. Information on the storage conditions of the samples from the feeding studies and new data on storage stability confirm the validity of the results of the feeding study in ruminants assessed in the MRL review. Risk for consumers unlikely |
| 1014030 | Goat, Liver                         | 0.3 (ft 4)      | 0.3          | The data gap identified in the MRL review for an appropriate metabolism study in ruminants has been addressed. EFSA proposed to defer the review of this and the metabolism studies previously assessed and the final decision on the residue definitions for products of animal origin to the EU pesticides peer review for the renewal of the approval of flutriafol. Information on the storage conditions of the samples from the feeding studies and new data on storage stability confirm the validity of the results of the feeding study in ruminants assessed in the MRL review. Risk for consumers unlikely |
| Code<sup>(a)</sup> | Commodity | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation |
|------------------|-----------|--------------------------|--------------|---------------------------|
| 1015030          | Equine, Liver | 0.3 (ft 3)              | 0.3          | See 1011030 Swine, Liver   |
| 1017030          | Other farmed terrestrial animals, Liver | 0.3 (ft 4)            | 0.3          | See 1012030 Bovine, Liver  |

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

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.

<sup>(b)</sup>: Existing EU MRL and corresponding footnote on confirmatory data.

*Footnote related to data gap No 13.*

*Footnote related to data gap No 2, 4, 12.*

*Footnote related to data gap No 15.*

*Footnote related to data gap No 14 and 15.*
Appendix C – Pesticide Residue Intake Model (PRIMo)

Flutriafol

| Commodity/group of commodities | Calculated exposure (% of ADI) | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity/group of commodities | Contribution to ADI (in % of ADI) | Commodity/group of commodities | Contribution to ADI (in % of ADI) | Commodity/group of commodities | Contribution to ADI (in % of ADI) | Commodity/group of commodities | Contribution to ADI (in % of ADI) | Commodity/group of commodities | Contribution to ADI (in % of ADI) |
|--------------------------------|-------------------------------|-----------------------------|-----------------------------------------------|--------------------------------|-------------------------------|--------------------------------|-------------------------------|--------------------------------|-------------------------------|--------------------------------|-------------------------------|--------------------------------|-------------------------------|
| Bananas                        | 33%                           | 3.28                        | 8%                                            | Apples                        | 33%                           | Table grapes                   | 2%                            | Table grapes                   | 2%                            | Table grapes                   | 2%                            | Table grapes                   | 2%                            | Table grapes                   |
| Strawberries                   | 24%                           | 2.42                        | 9%                                            | Rice                          | 24%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Table grapes                   | 21%                           | 1.92                        | 9%                                            | Rice                          | 21%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Table grapes                   | 18%                           | 1.55                        | 4%                                            | Rice                          | 18%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Tomatoes                       | 17%                           | 1.69                        | 5%                                            | Rice                          | 17%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Tomatoes                       | 16%                           | 1.54                        | 6%                                            | Rice                          | 16%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Sweet peppers/bell peppers    | 15%                           | 1.37                        | 7%                                            | Rice                          | 15%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Soyabean                      | 14%                           | 1.22                        | 6%                                            | Rice                          | 14%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Soyabean                      | 13%                           | 1.08                        | 7%                                            | Rice                          | 13%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Tomatoes                       | 12%                           | 1.00                        | 6%                                            | Rice                          | 12%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Tomatoes                       | 11%                           | 0.91                        | 6%                                            | Rice                          | 11%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Tomatoes                       | 10%                           | 0.82                        | 6%                                            | Rice                          | 10%                           | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Bananas                        | 9%                            | 0.73                        | 6%                                            | Rice                          | 9%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Bananas                        | 8%                            | 0.64                        | 6%                                            | Rice                          | 8%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Bananas                        | 7%                            | 0.56                        | 6%                                            | Rice                          | 7%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Bananas                        | 6%                            | 0.48                        | 6%                                            | Rice                          | 6%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Bananas                        | 5%                            | 0.40                        | 6%                                            | Rice                          | 5%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |
| Bananas                        | 4%                            | 0.32                        | 6%                                            | Rice                          | 4%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     | 2%                            | Tannatines                     |

Flutriafol (C16H17O2N3Cl) was used as a surrogate. The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Flutriafol is unlikely to present a public health concern.

Comments:

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

Evaluation of confirmatory data and setting of an import tolerance for flutriafol
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Acute risk assessment/children

| Commodity | MRL/Input (mg/kg) | Exposure (µg/kg bw) |
|-----------|-------------------|---------------------|
| Table grapes | 0.8/0.61 | 44 |
| Peaches | 0.6/0.41 | 39 |
| Pears | 0.4/0.24 | 33 |
| Apples | 0.4/0.24 | 26 |
| Lettuces | 1.5/0.67 | 24 |
| Sweet peppers/bell peppers | 1/0.41 | 20 |
| Melons | 0.3/0.13 | 16 |
| Watermelons | 0.3/0.13 | 13 |
| Bananas | 0.3/0.13 | 12 |
| Strawberries | 1.5/0.73 | 11 |
| Plums | 0.4/0.23 | 9.7 |
| Wine grapes | 1.5/0.89 | 8.3 |
| Cherries (sweet) | 1/0.59 | 7.2 |
| Quinces | 0.4/0.24 | 5.9 |
| Rice | 1/0.37 | 4.7 |
| Cucumbers | 0.15/0.07 | 4.6 |
| Pumpkins | 0.3/0.13 | 3.5 |

### Acute risk assessment/adults/general population

| Commodity | MRL/Input (mg/kg) | Exposure (µg/kg bw) |
|-----------|-------------------|---------------------|
| Wine grapes | 1.5/0.89 | 21 |
| Table grapes | 0.8/0.61 | 21 |
| Lettuces | 1.5/0.67 | 8.1 |
| Peaches | 0.6/0.41 | 7.7 |
| Pears | 0.4/0.24 | 7.3 |
| Strawberries | 1.5/0.73 | 6.8 |
| Apples | 0.4/0.24 | 6.7 |
| Sweet peppers/bell peppers | 1/0.41 | 6.7 |
| Melons | 0.3/0.13 | 5.9 |
| Watermelons | 0.3/0.13 | 5.3 |
| Plums | 0.3/0.13 | 5.1 |
| Rice | 1/0.37 | 3.2 |
| Cucumbers | 0.15/0.07 | 1.9 |
| Pumpkins | 0.3/0.13 | 1.9 |

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of Flutriafol is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.
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                |
| Barley straw                    | 1.00                  | STMR (EFSA, 2014)      | 4.00                  | HR (EFSA, 2014)        |
| Beet, sugar tops                | 0.34                  | STMR (EFSA, 2014)      | 0.84                  | HR (EFSA, 2014)        |
| Oat straw                       | 1.00                  | STMR (EFSA, 2014)      | 4.00                  | HR (EFSA, 2014)        |
| Rice straw                      | 1.35                  | STMR                   | 4.00                  | HR                     |
| Rye straw                       | 1.46                  | STMR (EFSA, 2014)      | 4.08                  | HR (EFSA, 2014)        |
| Wheat straw                     | 1.46                  | STMR (EFSA, 2014)      | 4.08                  | HR (EFSA, 2014)        |
| Barley grain                    | 0.04                  | STMR (EFSA, 2014)      | 0.04                  | STMR (EFSA, 2014)      |
| Oat grain                       | 0.04                  | STMR (EFSA, 2014)      | 0.04                  | STMR (EFSA, 2014)      |
| Rye grain                       | 0.02                  | STMR (EFSA, 2014)      | 0.02                  | STMR (EFSA, 2014)      |
| Soybean seed                    | 0.07                  | STMR (EFSA, 2014)      | 0.07                  | STMR (EFSA, 2014)      |
| Wheat grain                     | 0.02                  | STMR (EFSA, 2014)      | 0.02                  | STMR (EFSA, 2014)      |
| Apple pomace, wet               | 0.13                  | STMR × PF (1.88) (EFSA, 2014) | 0.13 | STMR × PF (1.88) (EFSA, 2014) |
| Beet, sugar dried pulp          | 0.36                  | STMR (EFSA, 2014) × default PF (18)(a) | 0.36 | STMR (EFSA, 2014) × default PF (18)(a) |
| Beet, sugar ensiled pulp        | 0.06                  | STMR (EFSA, 2014) × default PF (3)(a) | 0.06 | STMR (EFSA, 2014) × default PF (3)(a) |
| Beet, sugar molasses            | 0.56                  | STMR (EFSA, 2014) × default PF (28)(a) | 0.56 | STMR (EFSA, 2014) × default PF (28)(a) |
| Brewer's grain dried            | 0.13                  | STMR (EFSA, 2014) × default PF (3.3)(a) | 0.13 | STMR (EFSA, 2014) × default PF (3.3)(a) |
| Canola (Rape seed) meal         | 0.18                  | STMR (EFSA, 2014) × default PF (2)(a) | 0.18 | STMR (EFSA, 2014) × default PF (2)(a) |
| Distiller's grain dried         | 0.07                  | STMR (EFSA, 2014) × default PF (3.3)(a) | 0.07 | STMR (EFSA, 2014) × default PF (3.3)(a) |
| Rape meal                       | 0.18                  | STMR (EFSA, 2014) × default PF (2)(a) | 0.18 | STMR (EFSA, 2014) × default PF (2)(a) |
| Rice bran/pollard               | 0.23                  | STMR × PF (0.62)       | 0.23                  | STMR × PF (0.62)       |
| Soybean meal                    | 0.09                  | STMR × PF (1.3) (EFSA, 2014) | 0.09 | STMR × PF (1.3) (EFSA, 2014) |
| Soybean hulls                   | 0.91                  | STMR (EFSA, 2014) × default PF (13)(a) | 0.91 | STMR (EFSA, 2014) × default PF (13)(a) |
| Wheat gluten meal               | 0.04                  | STMR (EFSA, 2014) × default PF (1.8)(a) | 0.04 | STMR (EFSA, 2014) × default PF (1.8)(a) |
| Wheat milled by-products        | 0.04                  | STMR × PF (2.1) (EFSA, 2014) | 0.04 | STMR × PF (2.1) (EFSA, 2014) |
| Wheat gluten meal               | 0.63                  | STMR (EFSA, 2014) × default PF (1.8)(a) | 0.63 | STMR (EFSA, 2014) × default PF (1.8)(a) |
| Wheat milled by-products        | 2.45                  | STMR (EFSA, 2014) × default PF (7)(a) | 2.45 | STMR (EFSA, 2014) × default PF (7)(a) |

**Risk assessment residue definition:**
- triazole alanine (TA)
- triazole lactic acid (TLA)
- triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-T)

Insufficient data available

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): In the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities.
### D.2. Consumer risk assessment

| Commodity               | Chronic risk assessment | Acute risk assessment |
|-------------------------|-------------------------|-----------------------|
|                         | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| **Residue definition**: | Flutriafol (provisional for products of animal origin) |                        |                       |
| Apples                  | 0.07 STMR-RAC           | EFSA (2014)           | 0.24 HR-RAC         | EFSA (2014) |
| Pears                   | 0.07 STMR-RAC           | EFSA (2014)           | 0.24 HR-RAC         | EFSA (2014) |
| Quinces                 | 0.07 STMR-RAC           | EFSA (2014)           | 0.24 HR-RAC         | EFSA (2014) |
| Medlar                  | 0.07 STMR-RAC           | EFSA (2014)           | 0.24 HR-RAC         | EFSA (2014) |
| Loquats/J. medlars      | 0.07 STMR-RAC           | EFSA (2014)           | 0.24 HR-RAC         | EFSA (2014) |
| Other pome fruit        | 0.07 STMR-RAC           | EFSA (2014)           | 0.24 HR-RAC         | EFSA (2014) |
| Cherries (sweet)        | 0.34 STMR-RAC           | EFSA (2014)           | 0.59 HR-RAC         | EFSA (2014) |
| Peaches                 | 0.18 STMR-RAC           | EFSA (2014)           | 0.41 HR-RAC         | EFSA (2014) |
| Plums                   | 0.08 STMR-RAC           | EFSA (2014)           | 0.23 HR-RAC         | EFSA (2014) |
| Table grapes            | 0.21 STMR-RAC           | EFSA (2014)           | 0.61 HR-RAC         | EFSA (2014) |
| Wine grapes             | 0.34 STMR-RAC           | EFSA (2014)           | 0.89 HR-RAC         | EFSA (2014) |
| Strawberries            | 0.42 STMR-RAC           | EFSA (2014)           | 0.73 HR-RAC         | EFSA (2016a) |
| Bananas                 | 0.07 STMR-RAC × PeF (0.76) | EFSA (2014)         | 0.13 HR-RAC × PeF (0.76) | EFSA (2014) |
| Tomatoes                | 0.11 STMR-RAC           | FAO (2015)            | 0.63 HR-RAC         | FAO (2015)  |
| Sweet peppers/bell peppers | 0.28 STMR-RAC            | EFSA (2014)           | 0.41 HR-RAC         | EFSA (2014) |
| Cucumbers               | 0.05 STMR-RAC           | EFSA (2014)           | 0.07 HR-RAC         | EFSA (2016b) |
| Gherkins                | 0.05 STMR-RAC           | EFSA (2014)           | 0.07 HR-RAC         | EFSA (2016b) |
| Courgettes              | 0.05 STMR-RAC           | EFSA (2014)           | 0.07 HR-RAC         | EFSA (2016b) |
| Other cucurbits – edible peel | 0.05 STMR-RAC            | EFSA (2014)           | 0.07 HR-RAC         | EFSA (2016b) |
| Melons                  | 0.09 STMR-RAC           | EFSA (2014)           | 0.13 HR-RAC         |                       |
| Pumpkins                | 0.09 STMR-RAC           | EFSA (2014)           | 0.13 HR-RAC         |                       |
| Watermelons             | 0.09 STMR-RAC           | EFSA (2014)           | 0.13 HR-RAC         |                       |
| Other cucurbits – inedible peel | 0.09 STMR-RAC            | EFSA (2014)           | 0.13 HR-RAC         |                       |
| Lettuces                | 0.22 STMR-RAC           | FAO (2015)            | 0.67 HR-RAC         | FAO (2015)  |
| Rapeseeds               | 0.08 STMR-RAC           | EFSA (2015)           | 0.08 STMR-RAC       | EFSA (2014) |
| Soyabeans               | 0.07 STMR-RAC           | EFSA (2014)           | 0.07 STMR-RAC       | EFSA (2014) |
| Mustard seeds           | 0.08 STMR-RAC           | EFSA (2014)           | 0.08 STMR-RAC       | EFSA (2014) |
| Cotton seeds            | 0.08 STMR-RAC           | FAO (2015)            | 0.08 STMR-RAC       | FAO (2015)  |
| Gold of pleasure seeds  | 0.08 STMR-RAC           | EFSA (2014)           | 0.08 STMR-RAC       | EFSA (2014) |
| Barley                  | 0.04 STMR-RAC           | EFSA (2014)           | 0.04 STMR-RAC       | EFSA (2014) |
| Rice                    | 0.37 STMR-RAC           | EFSA (2014)           | 0.37 STMR-RAC       |                       |
| Rye                     | 0.02 STMR-RAC           | EFSA (2014)           | 0.02 STMR-RAC       | EFSA (2014) |
| Sorghum                 | 0.27 STMR-RAC           | FAO (2015)            | 0.27 STMR-RAC       | FAO (2015)  |
| Wheat                   | 0.02 STMR-RAC           | EFSA (2014)           | 0.02 STMR-RAC       | EFSA (2014) |
| Coffee beans            | 0.05 STMR-RAC           | EFSA (2014)           | 0.05 STMR-RAC       | EFSA (2014) |
| Hops (dried)            | 5.99 STMR-RAC           | EFSA (2017)           | 7.96 HR-RAC         | EFSA (2017) |
| Sugar beet roots        | 0.02 STMR-RAC           | EFSA (2014)           | 0.04 HR-RAC         | EFSA (2014) |
| Swine: Muscle/meat      | 0.01 STMR-RAC           | EFSA (2014)           | 0.01 HR-RAC         | EFSA (2014) |
| Swine: Fat tissue       | 0.01 STMR-RAC           | EFSA (2014)           | 0.01 HR-RAC         | EFSA (2014) |
| Swine: Liver            | 0.04 STMR-RAC           | EFSA (2014)           | 0.1 HR-RAC          | EFSA (2014) |
| Swine: Kidney           | 0.01 STMR-RAC           | EFSA (2014)           | 0.01 HR-RAC         | EFSA (2014) |
| Commodity                  | Chronic risk assessment | Acute risk assessment |
|---------------------------|-------------------------|-----------------------|
|                           | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment^a |
| Swine: Edible offal       | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Bovine: Meat              | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Bovine: Fat tissue        | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Bovine: Liver             | 0.11 STMR-RAC          | EFSA (2014)           | 0.27 HR-RAC        | EFSA (2014) |
| Bovine: Kidney            | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Bovine: Edible offal      | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Sheep: Meat               | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Sheep: Edible offal       | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Goat: Meat                | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Goat: Fat tissue          | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Goat: Liver               | 0.11 STMR-RAC          | EFSA (2014)           | 0.27 HR-RAC        | EFSA (2014) |
| Goat: Kidney              | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Goat: Edible offal        | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Equine: Meat              | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Equine: Fat tissue        | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Equine: Liver             | 0.11 STMR-RAC          | EFSA (2014)           | 0.27 HR-RAC        | EFSA (2014) |
| Equine: Kidney            | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Equine: Edible offal      | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Poultry: Meat             | 0.01 STMR-RAC          | FAO (2015)            | 0.01 HR-RAC        | FAO (2015)  |
| Poultry: Liver            | 0.0105 STMR-RAC        | FAO (2015)            | 0.027 HR-RAC       | FAO (2015)  |
| Poultry: Kidney           | 0.0105 STMR-RAC        | FAO (2015)            | 0.027 HR-RAC       | FAO (2015)  |
| Poultry: Edible offal     | 0.0105 STMR-RAC        | FAO (2015)            | 0.027 HR-RAC       | FAO (2015)  |
| Other farmed animals:     | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Meat                      |                        |                       |                     |             |
| Other farmed animals:     | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Fat tissue                | 0.01 STMR-RAC          | EFSA (2014)           | 0.27 HR-RAC        | EFSA (2014) |
| Other farmed animals:     | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Liver                     | 0.11 STMR-RAC          | EFSA (2014)           |                     |             |
| Other farmed animals:     | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Kidney                    | 0.01 STMR-RAC          | EFSA (2014)           |                     |             |
| Other farmed animals:     | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 HR-RAC        | EFSA (2014) |
| Edible offal              | 0.01 STMR-RAC          | EFSA (2014)           |                     |             |
| Milks                      | 0.01 STMR-RAC          | EFSA (2014)           | 0.01 STMR-RAC      | EFSA (2014) |
| Birds’ Eggs               | 0.01 STMR-RAC          | FAO (2015)            | 0.01 HR-RAC        | FAO (2015)  |

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.

^a: Input values for the commodities which are not under consideration are reported in grey.
### Appendix E – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChIKey(a) | Structural formula(b) |
|------------------|----------------------------------------|-----------------------|
| **Flutriafol**   | (RS)-2,4′-difluoro-2-[(1H-1,2,4-triazol-1-ylmethyl)benzhydryl alcohol OC(Cn1cnc1)(c1cccc1F)c1ccc(F)cc1 JWUCHKB5LVQCO-UHFFFAOYSA-N | ![Structural formula](image) |
| **Hydroxy flutriafol glucuronide (M3)** | One example of several possible forms of Hydroxy flutriafol glucuronide: 3-fluoro-4-[1-(4-fluorophenyl)-1-hydroxy-2-(1H-1,2,4-triazol-1-yl)ethyl]-2-hydroxyphenyl [β-D-glucopyranosiduronic acid Fc1ccc(cc1)C(O)(Cn1cnc1)c1cc(cc1F)O[C@H]10[C@H][C@H](O)[C@H][O][C@H][C@H]10(C(=O)O)c(O)c1F YITGHPMPMULZ-NIJDYXHPSA-N | ![Structural formula](image) |
| **Dihydroxy flutriafol (M3e)** | One example of several possible forms of Dihydroxy Flutriafol: 3-fluoro-4-[1-(4-fluorophenyl)-1-hydroxy-2-(1H-1,2,4-triazol-1-yl)ethyl]benzene-1,2-diol OC(Cn1cnc1)(c1cccc1F)c1ccc(F)cc1 BTYMAQUQVYIJEX-UHFFFAOYSA-N | ![Structural formula](image) |
| **Flutriafol glucuronide (M4)** | One example of several possible forms of a Flutriafol glucuronide: 3-fluoro-4-[1-(4-fluorophenyl)-1-hydroxy-2-(1H-1,2,4-triazol-1-yl)ethyl]phenyl [β-D-glucopyranosiduronic acid Fc1ccc(cc1)C(O)(Cn1cnc1)c1cc(cc1F)O[C@H][C@H][C@H][C@H](O)[C@H][C@H]10(C(=O)O) NMWCAMVKMRHSRK-NIJDYXHPSA-N | ![Structural formula](image) |
| **Hydroxymethoxy flutriafol (M5)** | One example of several possible forms of Hydroxymethoxy Flutriafol: 3-fluoro-4-[1-(4-fluorophenyl)-1-hydroxy-2-(1H-1,2,4-triazol-1-yl)ethyl]-2-methoxyphenol OC(Cn1cnc1)(c1cccc1F)c1cc(F)cc1 QIXNZIIRMMEGHJ-UHFFFAOYSA-N | ![Structural formula](image) |
| Code/trivial name | IUPAC name/SMILES notation/InChiKey | Structural formula |
|------------------|------------------------------------|--------------------|
| Methoxy flutriafol glucuronide (M7) | One example of several possible forms of Methoxy flutriafol glucuronide: 3-fluoro-4-[1-(4-fluorophenyl)-1-hydroxy-2-(1H-1,2,4-triazol-1-yl)ethyl]-2-methoxyphenyl ß-D-glucopyranosiduronic acid Fc1ccc(cc1)C(O)(Cn1cncn1)c1cc(O[C@@H](2O[C@@H]((C@@H)[(C@@H][O][C@@H][O][C@@H]2O)(-O)O)c(OC)c1F BO8NNFHTDCLWAX-WGMBEJHESA-N | |
| Methoxy flutriafol glucuronide (M7) | | [Image] |

**Triazole derivative metabolites**

| Code/trivial name | IUPAC name/SMILES notation/InChiKey | Structural formula |
|------------------|------------------------------------|--------------------|
| 1,2,4-triazole 1,2,4-T | 1H-1,2,4-triazole c1cncn1 NSPMIYGTKQPBQR-UHFFFAOYSA-N | [Image] |
| Triazole alanine TA | 3-(1H-1,2,4-triazol-1-yl)-D,L-alanine NC(Cn1cncn1)C(-O)O XVWFTOJHOHJIMQ-UHFFFAOYSA-N | [Image] |
| Triazole acetic acid TAA | 1H-1,2,4-triazol-1-ylacetic acid O=C(O)Cn1cncn1 RXDBSQXFIIWBJSR-UHFFFAOYSA-N | [Image] |
| Triazole lactic acid or Triazole hydroxy propionic acid TLA | (2RS)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl) propanoic acid OC(Cn1cncn1)C(-O)O KJRGHGWTVMENC-UHFFFAOYSA-N | [Image] |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(b): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).