Setting of import tolerances for flutianil in various crops

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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant OAT Agrio Co. Ltd submitted a request to the competent national authority in Belgium (originally the United Kingdom) to set import tolerances for the active substance flutianil in various crops. The data submitted in support of the request were found to be sufficient to derive MRL proposals for apples, cherries, strawberries, cucumbers and courgettes. For melons, data gaps were identified which precluded the derivation of MRL proposals. Adequate analytical methods for enforcement are available to control the residues of flutianil in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of flutianil according to the reported agricultural practices is unlikely to present a risk to consumer health. It is to be noted that the consumer risk assessment could not be finalised with regard to the potential presence of soil metabolite OC 56635 in rotational crops. The reliable end points appropriate for use in regulatory risk assessment are presented.

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Keywords: flutianil, various crops, pesticide, MRL, consumer risk assessment

Requestor: European Commission
Question number: EFSA-Q-2019-00541
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Declarations of interest: The declarations of interest of all scientific experts active in EFSA’s work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgements: EFSA wishes to thank Stathis Anagnos, Laszlo Bura, Andrea Mioč, Marta Szot, Aikaterini Vlachou for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021. Reasoned Opinion on the setting of import tolerances for flutianil in various crops. EFSA Journal 2021;19(9):6840, 26 pp. https://doi.org/10.2903/j.efsa.2021.6840

ISSN: 1831-4732

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

In accordance with Article 6 of Regulation (EC) No 396/2005, OAT Agrio Co. Ltd submitted an application to the competent national authority in the United Kingdom (evaluating Member State, EMS) to set import tolerances for the active substance flutianil in various crops. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 20 August 2019. The EMS proposed to establish MRLs for apples, cherries (sweet), strawberries, cucumbers and courgettes imported from the United States of America (USA) at the level of 0.15 mg/kg, of 0.40 mg/kg, of 0.30 mg/kg, of 0.03 mg/kg and of 0.03 mg/kg, respectively, by noting that for melons, no MRL proposal could be derived.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification and were requested from the EMS. It is noted that after the withdrawal of the United Kingdom from the Union on 1 February 2020, the application was reallocated to the EMS Belgium. On 20 July 2021, the EMS (Belgium) submitted the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of the EU peer review of the pesticide risk assessment under Regulation (EC) No 1107/2009, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of flutianil following foliar application was investigated in crops belonging to the groups of fruit crops and leafy crops. For the authorised uses under consideration, the metabolic behaviour in primary crops is sufficiently addressed.

Studies investigating the effect of processing on the nature of flutianil (hydrolysis studies) demonstrated that the active substance is stable.

Investigation of residues in rotational crops are in principle not required for imported crops as long as a specific residue definition is not set in the EU to account for soil residue uptake by crops that are grown in a crop rotation. The EU pesticides peer review could not conclude on the residue definition in rotational crops since the confined rotational crop study available at that time was still ongoing. The EU pesticides peer review noted that the potential uptake of residues of the soil and plant metabolite OC 56635 by crops, particularly upon multi-annual applications of parent flutianil, given the very high persistence of this metabolite in soil is not addressed.

In the framework of the present assessment, EFSA requested from the applicant the final study report. Results of the confined rotational crop study confirm that, in rotational crops, the main residue is metabolite OC 56635, resulting from soil uptake. Pending the investigation of the magnitude of metabolite OC 56635 by rotational crops, in particular, following multi-annual application of flutianil, EFSA confirms the proposal of the EU pesticide peer review to tentatively consider metabolite OC 56635 for the risk assessment and, if appropriate, monitoring in rotational crops.

However, since investigation of rotational crop residues is normally not required for import tolerance applications, EFSA recommends that the final conclusion on the residue definition in rotational crops is taken in the framework of the renewal of the approval of the active substance or in the future MRL applications for intended uses of flutianil on crops that can be grown in rotation in EU, should such be submitted before the renewal of the approval process.

Based on the metabolic pattern identified in metabolism studies and hydrolysis studies, the residue definitions for plant products were proposed as flutianil. These residue definitions are applicable to primary crops and processed products.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive MRL proposals for apples, cherries (sweet), strawberries, cucumbers and courgettes. The authorised use in the USA on melons is not adequately supported by residue trials data, and therefore, an MRL proposal cannot be derived.

Specific studies investigating the magnitude of flutianil residues in processed commodities are not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI. Nevertheless, processing factors (PF) for the crops under assessment were derived from processing studies provided and are recommended to be included in Annex VI of Regulation (EC) No 396/2005 as follows:
As apples may be used for feed purposes, a potential carry-over of residues into food of animal origin was assessed. The calculated livestock dietary burden was below the trigger value of 0.1 mg/kg dry matter (DM) for all animal species where apple (wet pomace) forms part of the diet. Therefore, further consideration of the residues in animal commodities is not required.

The toxicological profile of flutianil was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.82 mg/kg bw per day and an acute reference dose (ARfD) of 1.0 mg/kg bw. For metabolite OC 56635, an ADI of 1.38 rounded to 1.4 mg/kg bw per day was derived.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). In the short-term exposure assessment, EFSA focused on the commodities assessed in the present MRL application in accordance with the internationally agreed methodology. The acute exposure calculation did not identify acute consumer intake concerns related to flutianil residues from the authorised uses on apples (0.9% of the ARfD), cherries (0.3% of the ARfD), strawberries (0.3% of the ARfD), cucumber (0.1% of the ARfD) and courgettes (0.09% of the ARfD).

The estimated long-term dietary intake accounted for a maximum of 0.1% of the ADI for DE child, when considering the crops assessed in the present MRL application and grapes as evaluated in the EU pesticides peer review. For the remaining commodities, consumer exposure was not assessed since no uses of flutianil have been authorised since the finalisation of the EU pesticides peer review.

The consumer risk assessment does not consider the contribution of soil metabolite OC 56635 potentially present in rotational crops. Considering that this metabolite is of a lower toxicity than parent compound and taking into account the wide safety margin and the fact that in EU flutianil is only authorised for uses on grapes and ornamentals, it is unlikely that an exceedance of the ADI would occur.

EFSA concluded that the proposed uses of flutianil will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health. It is to be noted that the consumer risk assessment could not be finalised with regard to the potential presence of soil metabolite OC 56635 in rotational crops.

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

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

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0130010 | Apples    | 0.01*                  | 0.15                    | The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.(b) |
| 0140020 | Cherries  | 0.01*                  | 0.40                    | The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.(b) |
| 0152000 | Strawberries | 0.01*               | 0.30                    | The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.(b) |
| 0232010 | Cucumbers | 0.01*                  | 0.03                    | The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.(b) |
| 0232030 | Courgettes | 0.01*                 | 0.03                    | The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.(b) |
| 0233010 | Melons    | 0.01*                  | No MRL proposal         | The submitted data are not sufficient to derive an MRL for the authorised use in the USA. |

MRL: maximum residue level; USA: United States of America; 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): The consumer risk assessment does not consider the potential consumer exposure to the persistent soil metabolite OC 56635, which is the main residue in rotational crops.
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Assessment

The European Food Safety Authority (EFSA) received an application to set import tolerances for flutianil in various crops. The detailed description of flutianil uses authorised in the United States of America (USA) in apples, cherries (sweet), strawberries, cucumbers, courgettes and melons which are the basis for the current MRL application, is reported in Appendix A.

Flutianil is the ISO common name for (Z)-3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene)(x,x,x,4-tetrafluoro-m-tolythio)acetanilide (IUPAC). The chemical structures of the active substance and its main metabolite are reported in Appendix E.

Flutianil was evaluated in the framework of the EU peer review of the pesticide risk assessment under Regulation (EC) No 1107/2009¹ (EU pesticides peer review) with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on grapevines and ornamental crops. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2014). It is to be noted that the EFSA conclusion set a data gap for residues in succeeding crops and following multi-annual application since a confined rotational crop study was ongoing and provided only preliminary results at the time.² In a subsequent EFSA statement which focused on the impact of the harmonised classification on the EFSA peer review conclusion, an ADI for metabolite OC 56635 was derived and a preliminary consumer risk assessment was performed (EFSA, 2018b).³

Flutianil was approved⁴ for the use as fungicide on 14 April 2019. The EU MRLs for flutianil are established in Annex II of Regulation (EC) No 396/2005⁵. MRLs on grapes were derived in the EFSA statement (EFSA, 2018b). The MRLs for table and wine grapes were implemented in EU legislation by Commission Regulation (EU) 2019/1015⁶. There are no other commodities of plant or animal origin for which the existing MRL is set above the limit of quantification (LOQ).

The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is not foreseen because the first establishment of MRLs took place in the framework of the approval of the active substance.

In accordance with Article 6 of Regulation (EC) No 396/2005, OAT Agrio Co. Ltd submitted an application to the competent national authority in the United Kingdom (evaluating Member State, EMS) to set import tolerances for the active substance flutianil in apples, cherries (sweet), strawberries, cucumbers, courgettes and melons. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 20 August 2019. The EMS proposed to establish MRLs for various crops imported from the United States of America (USA) at the level of 0.15 mg/kg for apples, 0.40 mg/kg for cherries (sweet), 0.30 mg/kg for strawberries, 0.03 mg/kg for cucumbers and

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1 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
2 Preliminary data suggest a preferential uptake of significant proportions (88–99% of the TRR) of metabolite OC 56635 from the soil into the crops. Taken all the available information together, OC 56635 was proposed to be tentatively considered for risk assessment and, if appropriate, for monitoring purposes, pending the completion and the assessment of the ongoing confined rotational crop metabolism study (data gap). Even if an assessment of residues in the next growing season is not a usual requirement for perennial crops such as grapevines, a potential for uptake of residues of OC 56635 into the grapes, in particular upon multi-annual applications of flutianil, given the very high persistence of OC 56635 in soil was noted (EFSA, 2014).
3 In this risk assessment, with regard to metabolite OC 56635, the total chronic exposure via food commodities and drinking water was calculated and compared to the ADI of 1.4 mg/kg bw per day for OC 56635. Due to a data gap, residues in succeeding crops could not be considered (mostly relevant to the use in ornamentals), and therefore, the assessment is preliminary. Consumer exposure to OC 56635 is driven by the residue levels predicted for drinking water. Total chronic intakes were preliminary estimated to be < 0.2% ADI for the consumer groups of adults, toddlers and infants. However, as the consumer risk assessment is only preliminary, the groundwater relevance assessment for OC 56635 remains open and not finalised (EFSA, 2018b).
4 Commission Implementing Regulation (EU) 2019/481 of 22 March 2019 approving the active substance flutianil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 C/2019/2141 OJ L 82, 25.3.2019, p. 19–25.
5 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.
6 Commission Regulation (EU) 2019/1015 of 20 June 2019 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 aminopyralid, captan, cyazofamid, flutianil, kresoxim-methyl, lambda-cyhalothrin, mandipropamid, pyraclostrobin, spiromesifen, spirotetramat, tefubenzuron and tetraconazole in or on certain products. OJ L 165/23, 21.6.2019, p. 23–64.

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courgettes (summer squash). The residue definition in place in the USA is flutianil only. The following tolerances are in place in the USA with regards to these crops: for apples 0.15 mg/kg, for cherries (sweet) 0.40 mg/kg, for strawberries 0.50 mg/kg, for cucumbers and courgettes 0.20 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification and were requested from the EMS. It is noted that after the withdrawal of the United Kingdom from the Union on 1 February 2020, the application was reallocated to the EMS Belgium On 20 July 2021, the EMS (Belgium) submitted the requested information in a revised evaluation report (Belgium, 2021), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report as initially submitted by the EMS, United Kingdom, and then updated by Belgium (Belgium, 2021), the draft assessment report (DAR) (United Kingdom, 2013) and its addendum (United Kingdom, 2014) prepared under Regulation (EC) 1107/2009, the Commission review report on flutianil (European Commission, 2019) and the conclusion on the peer review of the pesticide risk assessment of the active substance flutianil (EFSA, 2014).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a-g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, is presented in Appendix B.

The evaluation report submitted by the EMS (Belgium, 2021) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. **Residues in plants**

1.1. **Nature of residues and methods of analysis in plants**

1.1.1. **Nature of residues in primary crops**

The metabolism of flutianil in primary crops belonging to the group of fruit crops (grapes, apples and cucumbers) and leafy crops (lettuces) has been investigated in the framework of the EU pesticides peer review (EFSA, 2014).

In grapes, apples and lettuces, residues largely remained as unchanged flutianil. Metabolite OC 56635 in grape berries and grapevine foliage was below 5% of the total radioactive residue (TRR), in apple fruits below 1% of the TRR and in apple foliage up to 14.7% (0.667 mg eq./kg) at 35 days after the last application (DALA). In cucumber fruits or cucumber foliage, this metabolite was not detected. Overall, the pattern of metabolism was similar across the crops investigated.

For the authorised uses under consideration, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. **Nature of residues in rotational crops**

Studies investigating residues in rotational crops are not normally required in the context of the assessment of import tolerances since cultivation of crops is not carried out in the EU. It is noted that some of the uses under assessment in this application (cucumbers and courgettes) can be grown in rotation.

In the EU pesticides peer review (EFSA, 2014) and in a subsequent EFSA statement, it was concluded that the consumer risk assessment could not be finalised in relation to residues of the highly

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7 Federal Register Volume 84, Issue 245. December 20, 2019. p. 70023–70026. https://www.federalregister.gov/documents/2019/12/20/2019-27361/flutianil-pesticide-tolerances
8 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.
9 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.
persistent soil metabolite OC 56635 in rotational crops (the DT90 of flutianil is 1255.7 days, whereby the DT90 of the metabolite OC 56635 could not be derived since no decline was observed) (EFSA, 2018b).

The preliminary report of a confined rotational crop study was available to the EU pesticides peer review and the available data suggested that, following one application of flutianil at a rate of 224 g a.s./ha on bare soil, at the plant back intervals (PBIs) of 30 and 120 days, the persistent soil and minor plant metabolite OC 56635 is the principle component of the residues in rotational crops, accounting for > 85% of the residue containing the trifluoromethylfluorobenzene moiety. Notably, parent flutianil was not a significant component of the residue in following crops with the label in either of the phenyl rings (EFSA, 2014).

In the framework of the present assessment, EFSA requested from the applicant the final study report of the confined rotational crop study. This study was consequently provided and assessed in the framework of this application (Belgium, 2021).

Results confirm that the major residue in rotational crops is metabolite OC 56635, which accounted for 82% up to 99% of the TRR in the rotational crop matrices investigated. In mature spinach and sorghum grain, the TRR was highest at the PBI of 30 days with up to 0.412 mg eq./kg and 0.059 mg eq./kg, respectively, and decreased at the longer PBIs. For mature radish roots, the highest TRR of up to 0.043 mg eq./kg was reported at a PBI of 365 days. Parent flutianil or other known metabolites were not detected in any significant concentrations apart from immature radish roots where all components were < 0.01 mg eq./kg (Belgium, 2021).

It is therefore concluded that, in rotational crops, the metabolic pathway is characterised by the residue soil uptake and the main residue is metabolite OC 56635, the persistent soil degradation product of flutianil.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of flutianil was investigated in the framework of the EU pesticides peer review (EFSA, 2014). It was concluded that flutianil is hydrolytically stable under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation.

The need to investigate the effects of processing on the nature of main rotational crop metabolite OC 56635 shall be considered once the magnitude of this metabolite in rotational crops is fully addressed and its relevance in the consumer exposure assessed.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of flutianil residues were assessed during the EU pesticides peer review (EFSA, 2014).

The methods are sufficiently validated for residues of flutianil in the crops under consideration. The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg for flutianil in crops belonging to the group of high-water and high-acid content commodities.

1.1.5. Storage stability of residues in plants

The storage stability of flutianil in high-water and high-acid commodities stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2014; United Kingdom, 2014).

Information on the stability of residues in frozen samples of crops classified as matrices with high-water content (apples, cherries, cucumbers, summer squash and melons) and high-acid content (strawberries) crops was submitted with the current application (Belgium, 2021).

It was demonstrated that in crops assessed in the framework of this application, residues were stable for at least 11 months when stored at −20°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in primary crop metabolism studies, the results of hydrolysis studies and the capabilities of analytical enforcement methods, the following residue definitions were proposed by the EU pesticides peer review (EFSA, 2014)

- residue for risk assessment: flutianil (restricted to fruits and leafy crops)
- residue definition for enforcement: flutianil (restricted to fruits and leafy crops)
The proposed residue definitions are applicable also for processed commodities. However, the residue definitions for processed commodities might be subject to change depending on the outcome of further studies on the magnitude of OC 56635 in rotational crops and potential consumer exposure to OC 56635 residues.

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

The submitted confined rotational crop study indicates that metabolite OC 56635 is the principle component of the residues in rotational crops and confirms the preliminary conclusions of the EU pesticide peer review that metabolite OC 56635 might be considered for risk assessment and monitoring in rotational crops. For a final conclusion on the residue definition in rotational crops, the studies investigating the magnitude of metabolite OC 56635 in crops, in particular, after multi-annual applications of flutianil would need to be submitted.

However, since investigation of rotational crop residues is normally not required for import tolerance applications, EFSA recommends that the final conclusion on the residue definition in rotational crops is taken in the framework of the renewal of the approval of the active substance or in the future MRL applications for intended uses of flutianil in EU, should such be submitted before the renewal of the approval process.

For the MRL application under consideration, the current residue definitions for enforcement and risk assessment as parent flutianil are applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials performed on apples, cherries (sweet), strawberries, cucumbers, courgettes and melons. The samples were analysed for flutianil in line with the current residue definition for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Belgium, 2021).

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

Apples

In support of the authorised outdoor Good Agricultural Practice (GAP) on apples in the USA based on foliar spray treatments, the applicant submitted 12 residue trials on apples performed according to the authorised uses. Trials were performed in the USA over the 2006 growing season. Two of the trials were performed as decline studies.

It is concluded that an MRL of 0.15 mg/kg would suffice to support the authorised foliar outdoor use of flutianil on apples.

The tolerance established in the USA for flutianil in apples is 0.15 mg/kg.

Cherries

In support of the authorised outdoor GAP on cherries in the USA based on foliar spray treatments, the applicant submitted 12 residue trials on cherries whereby eight of these trials could be considered as independent. Trials were performed in the USA over the 2007 and 2008 growing season. Two of the trials were performed as decline studies.

Four trials were performed according to the authorised uses (GAPs). For three trials, samples were taken at a preharvest interval (PHI) of 2 days instead of 3 days. One additional trial was also performed at a PHI of 4 days, however, with a fifth application since maturity of cherries was not reached after the fourth application. The EMS provided clarification (Belgium, 2021) and it was demonstrated with decline studies that residues of flutianil are relatively persistent, and therefore, the 1-day deviation for the PHI (at the mature fruit stage) in four of the eight trials can still be considered representative for the GAP. With regard to the fifth application in one trial, the EMS refers to the guidance SANCO 7525/VI/95 rev. 10.3 (European Commission, 2017) where it is outlined that results for residues of relatively persistent substances can be assumed comparable if the number of applications is increased or reduced by no more than 25% i.e. 4 ± 1 application. Considering that the additional (first) application is not expected to have a significant influence on the final residue, particularly in combination with a slightly longer PHI of 4 days, the EMS accepted this trial to support
the GAP. Overall EFSA considered that the residue trials are considered sufficiently representative of the authorised GAP.

It is concluded that an MRL of 0.40 mg/kg would suffice to support the authorised foliar outdoor use of flutianil on cherries.

The tolerance established in the USA for flutianil in cherries is 0.40 mg/kg.

Strawberries

In support of the authorised outdoor GAP on strawberries in the USA based on foliar spray treatments, the applicant submitted eight residue trials on strawberries performed according to the authorised uses. The trials were performed in the USA over the 2006 (seven trials) and 2007 (one trial) growing seasons. One trial was performed as a residue decline study.

It is concluded that a lower MRL of 0.3 mg/kg would be sufficient to support the authorised foliar outdoor use of flutianil on strawberries.

The tolerance established in the USA for flutianil in strawberries (berry, low growing, subgroup 13-07G) is 0.50 mg/kg.

Cucumber and courgettes

In support of the authorised outdoor GAPs on cucumbers and courgettes in the USA based on foliar spray treatments, the applicant submitted six residue trials on cucumbers and six residue trials on courgettes performed according to the authorised uses. The trials were performed in the USA over the 2006 (six trials on cucumbers and five trials on courgettes) and 2007 (one trial on courgette) growing seasons.

It is concluded that an MRL of 0.03 mg/kg would be sufficient to support the authorised foliar outdoor use of flutianil on cucumbers and courgettes. The tolerance established in the USA for flutianil in cucumbers and courgettes (squash/cucumber subgroup 9B) is 0.20 mg/kg.

Melons

In support of the authorised outdoor GAP on melons in the USA based on foliar spray treatments, the applicant submitted seven residue trials on melons performed according to the authorised uses. The trials were performed in the USA over the 2006 and 2007 growing seasons. Two trials were performed as a residue decline study. As melon is a major crop, eight residue trials would be required (European Commission, 2017). One additional trial is missing.

To complement the available residue data set, the applicant submitted additional 15 outdoor trials on melons conducted in southern Europe over the 2008 growing season. The EMS considered it as unclear whether these trials are representative of the agricultural practices and climatic conditions in the USA. Furthermore, the application rate in the trials was higher, above the 25% tolerance (57.1 g a.i./ha up to 66 g a.i./ha in the authorised GAP) and therefore performed to a different GAP for which a significantly higher MRL would be calculated (0.09 mg/kg instead of 0.07 mg/kg). In addition, the trials were carried out with four applications instead of five applications.

It is concluded that European residue trials on melons are not adequate to support the import tolerance, and therefore, an MRL for melons cannot be derived based on only seven residue trials.

The tolerance established in the USA for flutianil in melon (cantaloupe) is 0.07 mg/kg.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of flutianil residues to crops that are grown in a crop rotation has not been assessed in the EU pesticides peer review and a data gap has been set (EFSA, 2014). Rotational crop field studies have also not been submitted in the framework of the present assessment.

The submitted confined rotational crop study gives an indication that OC 56635 residues could theoretically reach significant levels (> 0.01 mg/kg) in rotational crops according to the GAPs considered in the present application. However, to determine realistic amounts of metabolite OC 56635 which may be accumulated into rotational crops via soil uptake, particularly after multi-annual applications of flutianil, rotational crop field studies would need to be submitted.

Since the investigation of the magnitude of residues in rotational crops is not normally required for import tolerance requests, EFSA recommends reconsidering this point in the framework of the peer review for the renewal of approval of the active substance. In case future uses of flutianil are intended on annual primary crops in EU, rotational crop field studies shall be submitted.
1.2.3. Magnitude of residues in processed commodities

A study on the effects of processing on the residue levels was not triggered according to current guidance.

Nonetheless, a processing study in apples is provided (Belgium, 2021). The processing study indicates that residues of flutianil concentrate significantly in wet pomace leading to a median processing factor of 3.3, whereby dilution was observed in apple juice where a median processing factor of 0.11 was derived (Belgium, 2021). The available processing studies are summarised in Appendix B.1.2.3.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation, except for the authorised use on melons (see Appendix B.4). In Section 3, EFSA assessed whether residues on these crops resulting from the uses authorised in the USA are likely to pose a consumer health risk.

2. Residues in livestock

Apples may be used for feed purposes. Hence, it was necessary to perform a dietary burden calculation for livestock to estimate whether the residues in apples from the authorised US use of flutianil would have an impact on the livestock dietary burden.

The input values for the exposure calculations for livestock are presented in Appendix D.1. The results of the dietary burden calculation demonstrated that the exposure of any livestock species did not exceed the trigger values defined in the relevant guidance document (see Section B.2). Therefore, there is no need to consider MRL setting for flutianil in commodities of animal origin.

3. Consumer risk assessment

EFSA performed a dietary risk assessment for residues of flutianil, using revision 3.1 of the EFSA PRIMo (EFSA, 2019). 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 (EFSA, 2018a, 2019).

The toxicological reference values for flutianil used in the risk assessment (i.e. an ADI value of 0.82 mg/kg bw per day and an ARfD value of 1 mg/kg bw) were derived in the framework of the EU pesticides peer review (European Commission, 2019). The toxicity of metabolite OC 56635 was reassessed in the EFSA statement (EFSA, 2018b) and the compound was considered unlikely to be genotoxic based on the data available; an ADI of 1.38 rounded to 1.4 mg/kg bw per day was derived.

The short-term exposure assessment was performed for the commodities assessed in this application. The calculations were based on the highest residue (HR) values derived from supervised field trials. The complete list of input values can be found in Appendix D.2.

In the short-term exposure assessment, EFSA focused on the commodities assessed in the present MRL application in accordance with the internationally agreed methodology. The acute exposure calculation did not identify acute consumer intake concerns related to flutianil residues from the authorised US uses on apples (0.9% of the ARfD), cherries (0.3% of the ARfD), strawberries (0.3% of the ARfD), cucumbers (0.1% of the ARfD) and courgettes (0.09% of the ARfD). The short-term exposure did not exceed the ARfD for any of the crops assessed in this application (see Appendix B.3).

The long-term exposure assessment was performed with the supervised trials median residue (STMR) values derived for the commodities assessed in this application. For grapes, the STMR values derived in the previous EFSA assessment (EFSA, 2014) were considered. For the remaining commodities, consumer exposure was not assessed since no uses of flutianil have been authorised since the finalisation of the EU pesticides peer review.

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

The estimated long-term dietary intake accounted for a maximum of 0.1% of the ADI for DE child diet. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.3. For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

EFSA concluded that the short-term and long-term intake of residues of flutianil resulting in the crops under consideration from the authorised uses are unlikely to present a risk to consumer health.
It shall be noted that the potential consumer exposure to the soil metabolite OC 56635 from the intake of imported crops could not be assessed due to lack of information on the magnitude and uptake of OC 56635 in rotational crops and that therefore the consumer risk assessment is only tentatively finalised.

It is to be noted that during the peer review, a preliminary risk assessment to the soil metabolite OC 56635 was performed, considering residues of metabolite OC 56635 in grapes (primary crop only) and in drinking water (extracted from groundwater) (EFSA, 2014). The chronic intakes were estimated to be largely below the ADI for the consumer groups of adults, toddlers and infants (< 0.2% of the ADI). It was concluded that it is unlikely that an exceedance of the ADI would occur even if residues of metabolite OC 56635 were found in succeeding crops (EFSA, 2018b; European Commission, 2019).

Studies investigating residues in rotational crops are not normally required in the context of the assessment of import tolerances since cultivation of crops is not carried out in the EU However, if in the future, the rotational crop field studies indicate significant levels of metabolite OC 56635 in rotational crops and a specific residue definition is set to account for residue soil uptake, the consumer exposure shall be updated accordingly.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for apples, cherries, strawberries, cucumbers and courgettes however insufficient to derive an MRL proposal for melons.

EFSA concluded that the authorised uses of flutianil on apples, cherries, strawberries, cucumbers and courgettes in the USA will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a risk to consumers’ health. It is to be noted that the consumer risk assessment could not be finalised with regard to the potential presence of soil metabolite OC 56635 in rotational crops.

The MRL recommendations are summarised in Appendix B.4.

References

Belgium, 2021. Evaluation Report Prepared under Article 8 of Regulation (EC) No 396/2005 MRL application on the setting of Import tolerances in Pome Fruits, Cherries, Strawberries, Cucurbits with edible peel and Cucurbits with inedible peel. Originally prepared by the United Kingdom, July 2019, revised by Belgium in July 2020 and July 2021, 100 pp. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance flutianil. EFSA Journal 2014;12(8):3805, 89 pp. https://doi.org/10.2903/j.efsa.2014.3805

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), 2018b. Statement on the impact of the harmonised classification on the conclusion on the peer review of the pesticide risk assessment of the active substance flutianil. EFSA Journal 2018;16(7):5383, 29 pp. https://doi.org/10.2903/j.efsa.2018.5383

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrants JO, Miron I, Pedersen R, Raczky M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019. 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-1605

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

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

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

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

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

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/V/95-rev. 5, 22 July 1997.
European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals.7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

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

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

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

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.

European Commission, 2019. Final Review report for the active substance Flutianil Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 22 February 2019 in view of the approval of Flutianil as active substance, in accordance with Regulation (EC) No 1107/20091 SANTE-2017-11948 Rev 7, 22 February 2019.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.

United Kingdom, 2013. Draft Assessment Report (DAR) on the active substance flutianil prepared by the rapporteur Member State the United Kingdom in the framework of Regulation (EC) No. 1107/2009, June 2013. Available online: www.efsa.europa.eu

United Kingdom, 2014. Final Addendum to the Draft Assessment Report (DAR) on flutianil, compiled by EFSA, July 2014. Available online: www.efsa.europa.eu

Abbreviations

| a.s. | active substance |
| ADI | acceptable daily intake |
| bw | body weight |
| CAS | Chemical Abstract Service |
| CCPR | Codex Committee on Pesticide Residues |
| CF | conversion factor for enforcement to risk assessment residue definition |
| CIRCA | (EU) Communication & Information Resource Centre Administrator |
| CS | capsule suspension |
| DAR | draft assessment report |
| DAT | days after treatment |
| DM | dry matter |
| DT90 | period required for 90% dissipation (define method of estimation) |
| ECD | electron capture detector |
| EDI | estimated daily intake |
| EMS | evaluating Member State |
| eq | residue expressed as a.s. equivalent |
| FID | flame ionisation detector |
| GAP | Good Agricultural Practice |
| GC | gas chromatography |
| GC-ECD | gas chromatography with electron capture detector |
| GC-FID | gas chromatography with flame ionisation detector |
| GC-MS | gas chromatography with mass spectrometry |
| GC-MS/MS | gas chromatography with tandem mass spectrometry |
| GS | growth stage |
| HPLC | high-performance liquid chromatography |
| HPLC-MS | high-performance liquid chromatography with mass spectrometry |
| HPLC-MS/MS | high-performance liquid chromatography with tandem mass spectrometry |
| HR | highest residue |
| IEDI | international estimated daily intake |
| IESTI | international estimated short-term intake |
Setting of import tolerances for flutianil in various crops

ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
MW molecular weight
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PF processing factor
PHI preharvest interval
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SC suspension concentrate
SL soluble concentrate
SP water-soluble powder
STMR supervised trials median residue
TAR total applied radioactivity
TMDI theoretical maximum daily intake
TRR total radioactive residue
UV ultraviolet (detector)
WHO World Health Organization
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F or G or I(a) | Pests or group of pests controlled | Preparation | Type(b) | Conc. a.s. | Method kind | Range of growth stages and season(c) | Number max | Interval between applications (days) min - max | g a.s./hL min - max | Water L/ha min - max | Rate | Unit | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|----------------|-----------------------------------|-------------|---------|-----------|-----------|-------------------------------------|-----------|-----------------------------------------------|-------------------|-----------------|------|-------|-----------|---------|
| Apples                | USA                     | F              | Fungi                             | Foliar treatment – broadcast spraying | See remarks | 50 g/L    | EC        | See remarks                          | 4          | 7                              | 5–24 or 2–5       | 188–935 or 935–1,900 | 45   | g a.s./ha | 14      | Growth stage: maturing fruit, 35 to 14 days preharvest. |
| Cherries (sweet)     | USA                     | F              | Fungi                             | Foliar treatment – broadcast spraying | See remarks | 50 g/L    | EC        | See remarks                          | 4          | 7                              | 5–16 or 1.6–5     | 280–935 or 945–2,800 | 45   | g a.s./ha | 3       | Growth stage: maturing fruit, 31 to 3 days preharvest. |
| Strawberries         | USA                     | F              | Fungi                             | Foliar treatment – broadcast spraying | See remarks | 50 g/L    | EC        | See remarks                          | 5          | 7                              | 2–10              | 460–1,900            | 45   | g a.s./ha | 0       | Growth stage: maturing fruit, 28 to 0 days preharvest. |
| Cucumbers            | USA                     | F              | Fungi                             | Foliar treatment – broadcast spraying | See remarks | 50 g/L    | EC        | See remarks                          | 5          | 7                              | 5–16              | 280–935              | 45   | g a.s./ha | 0       | Growth stage: maturing fruit, 28 to 0 days preharvest. |
| Courgettes           | USA                     | F              | Fungi                             | Foliar treatment – broadcast spraying | See remarks | 50 g/L    | EC        | See remarks                          | 5          | 7                              | 5–16              | 280–935              | 45   | g a.s./ha | 0       | Growth stage: maturing fruit, 28 to 0 days pre-harvest. |
| Melons               | USA                     | F              | Fungi                             | Foliar treatment – broadcast spraying | See remarks | 50 g/L    | EC        | See remarks                          | 5          | 7                              | 5–16              | 280–935              | 45   | g a.s./ha | 0       | Growth stage: maturing fruit, 28 to 0 days preharvest. |

a.s.: active substance; NEU: northern European Union; SEU: southern European Union; MS: Member State; USA: United States of America; EC: emulsifiable 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 (DAT) | Comment/Source |
|----------------------------------|-------------|-------|--------------|----------------|----------------|
| Fruit crops                      | Grapes      | 4 × 40 g a.s./ha | 1, 21, 45 | Foliar application at BBCH 79 and 85; interval of 14 days; radiolabel: 2-methoxyphenyl ring-U-14C-flutianil or trifluoromethylfluorobenzene ring-U-14C-flutianil; sampling grape berries and grapevine foliage (EFSA, 2014; United Kingdom, 2014). |
| Apples                           | 3 × 75 g a.s./ha | 1, 14, 21, 35 | | Foliar application at BBCH 79 and 81; interval of 12 days; radiolabel: 2-methoxyphenyl ring-U-14C-flutianil or trifluoromethylfluorobenzene ring-U-14C-flutianil; sampling of apple fruit and foliage (EFSA, 2014; United Kingdom, 2014). |
| Cucumbers                        | 4 × 60 g a.s./ha | 1, 3, 15 | | Foliar applications close to harvest (last application one day before harvest); interval of 13–14 days; radiolabel: 2-methoxyphenyl ring-U-14C-flutianil or trifluoromethylfluorobenzene ring-U-14C-flutianil; sampling cucumber fruits and foliage (EFSA, 2014; United Kingdom, 2014). |
| Leafy crops                      | Lettuces    | 5 × 45 g a.s./ha | 7 | Foliar applications; interval 7 days; radiolabel: 2-methoxyphenyl ring-U-14C-flutianil or trifluoromethylfluorobenzene ring-U-14C-flutianil; sampling of lettuce wrapper leaves and lettuce head (EFSA, 2014; United Kingdom, 2014). |

| Rotational crops (available studies) | Crop groups | Crop | Application | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|------|-------------|-----------|----------------|
| Studies were not submitted for this application and are not normally required in the framework of an import tolerance application. It is noted that, during the peer review, a data gap was set because of the persistent soil metabolite OC 56635 (EFSA, 2014). Therefore, EFSA requested the final study report of the confined rotational study that was still ongoing at the time of the peer review. The study was provided and assessed in this application however has not been peer reviewed. |
| Root/tuber crops                     | Radishes    | Bare soil, 224 g a.s./ha | 30, 120, 365 | [MeOPh-U-14C]·flutianil and [CF3Ph-U-14C]·flutianil; harvest intervals 61, 70, 150, 166, 507, 515 DAT; Sampling at immature and harvest stages (Belgium, 2021) |
| Leafy crops                         | Spinach     | | | [MeOPh-U-14C]·flutianil and [CF3Ph-U-14C]·flutianil; harvest intervals 41, 60, 146, 174 406, 425 DAT; Sampling at immature and harvest stages (Belgium, 2021) |
| Cereals (small grain)               | Sorghum     | | | [MeOPh-U-14C]·flutianil and [CF3Ph-U-14C]·flutianil; harvest intervals 158, 244, 222, 255, 455, 522 DAT; Sampling at immature and harvest stages (Belgium, 2021) |
| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|-----------------------------------------|------------|--------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)     | Yes        | United Kingdom (2014), EFSA (2014) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes        | United Kingdom (2014), EFSA (2014) |
| Sterilisation (20 min, 120°C, pH 6)     | Yes        | United Kingdom (2014), EFSA (2014) |

Can a general residue definition be proposed for primary crops?

| Condition                              | No | Residue definition is limited to fruit crops and leafy crops, only based on the available metabolism studies. |

Rotational crop and primary crop metabolism similar?

| Condition                              | Inconclusive | The lack of confined rotational crop study considered as a data gap during the peer review (EFSA, 2014). The confined rotational crop study submitted in the framework of the present assessment (Belgium, 2021) indicates that in rotational crops the main residue is soil metabolite OC 56635. The study is not peer reviewed. |

Residue pattern in processed commodities similar to residue pattern in raw commodities?

| Condition                              | Yes | Flutianil is hydrolytically stable under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation. |

Plant residue definition for monitoring (RD-Mo)

| Fruits and leafy crops (only); For primary and processed commodities: tentative for rotational crops, where OC 56635 is the principle component of the residues in rotational crops: Flutianil |

Plant residue definition for risk assessment (RD-RA)

| Fruits and leafy crops (only); For primary and processed commodities: tentative for rotational crops, where OC 56635 is the principle component of the residues in rotational crops: Flutianil |

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

| Matrices with high-water content and high-acid content matrices: GC-ECD, LOQ 0.01 mg/kg (grapes, strawberries, cucumbers and apples); Confirmatory method and ILV available. Matrices with high-water content, high-acid, high-oil and dry content matrices: Multi residue method DFG-S19: GC-MSD, LOQ = 0.01 mg/kg (cucumbers, dry beans, wheat grain, grapes and sunflower seeds) (EFSA, 2014; United Kingdom, 2014) |

DAT: days after treatment; a.s.: active substance; BBCH: growth stages of mono- and dicotyledonous plants; PBI: plant-back interval; LOQ: limit of quantification; GC-ECD: gas chromatography with electron capture detector; ILV: independent laboratory validation; GC-MSD: gas chromatography with mass spectrometry.
### Stability of residues in plants

| Plant products (available studies) | Category            | Commodity  | T (°C) | Stability period Value | Unit | Compounds covered | Comment/Source                                      |
|-----------------------------------|---------------------|------------|--------|------------------------|------|-------------------|-----------------------------------------------------|
|                                   | High-water content  | Apples     | -20    | 12                     | Months | Flutianil       | United Kingdom (2014), EFSA (2014)                  |
|                                   |                     | Apples     | -20    | 528                    | Days  | Flutianil       | Belgium (2021)                                     |
|                                   |                     | Cherries   | -20    | 356                    | Days  | Flutianil       | Belgium (2021)                                     |
|                                   |                     | Cucumbers  | -20    | 455                    | Days  | Flutianil       | Belgium (2021)                                     |
|                                   |                     | Summer squash | -20   | 404                    | Days  | Flutianil       | Belgium (2021)                                     |
|                                   | High-acid content   | Melons     | -20    | 335                    | Days  | Flutianil       | Belgium (2021)                                     |
|                                   |                     | Grapes     | -20    | 12                     | Months | Flutianil       | United Kingdom (2014), EFSA (2014)                  |
|                                   |                     | Strawberries | -20  | 368                    | Days  | Flutianil       | Belgium (2021)                                     |
### B.1.2. Magnitude of residues in plants

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

| Commodity     | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL<sup>(d)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|---------------|-----------------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|-------------------------------------|------------------------|--------------------------|
| Apples        | USA/outdoor                 | < 0.01; 0.025; 0.026; 0.027; 0.030; 0.031; 0.039; 0.043; 0.044; 0.050; 0.052; 0.080 | Residue trials on apple compliant with GAP.                                      | 0.15                                | 0.080                  | 0.035                    |
| Cherries      | USA/outdoor                 | 0.071; 0.081<sup>(d)</sup>; 0.089<sup>(d)</sup><sup>,(c)</sup>; 0.093<sup>(f)</sup>; 0.117; 0.165<sup>(d)</sup><sup>,(h)</sup>; 0.18<sup>(g)</sup><sup>,(h)</sup>; 0.235<sup>(h)</sup> | Residue trials on sweet and sour cherries compliant with GAP. The trials are considered sufficiently representative in support of the GAP. | 0.40                                | 0.235                  | 0.105                    |
| Strawberries  | USA/outdoor                 | 0.025; 0.030; 0.033; 0.048; 0.062; 0.076; 0.098; 0.165             | Residue trials on strawberries compliant with GAP.                               | 0.30                                | 0.165                  | 0.055                    |
| Cucumbers     | USA/outdoor                 | 5 × < 0.01; 0.014                                               | Combined data set of six residue trials on cucumbers and six residue trials on courgette compliant with GAP. | 0.03                                | 0.02                   | 0.01                     |
| Courgette     | USA/outdoor                 | 4 × < 0.01; 0.013; 0.02                                           |                                                                                 |                                     |                        |                          |
| Melons        | USA/outdoor                 | < 0.01; 0.01; 2 × 0.014; 0.016; 0.018; 0.042                     | The number of trials on melons is insufficient to derive an MRL.                  | –                                   | –                      | –                        |

MRL: maximum residue level; USA: United States of America; GAP: Good Agricultural Practice.

- <sup>(a)</sup> 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.
- <sup>(b)</sup> Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
- <sup>(c)</sup> Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
- <sup>(d)</sup> Trial with a PHI of 2 days (deviation of 1 day from the PHI in the authorised GAP).
- <sup>(e)</sup> Trial performed with 5 instead of 4 applications and a PHI of 4 days.
- <sup>(f)</sup> Trial performed with 5 instead of 4 applications and a PHI of 4 days.
- <sup>(g)</sup> Residue value represents mean of two duplicate trials (four residue values).
- <sup>(h)</sup> Residue trial performed on ‘sour’ cherries.
B.1.2.2. Residues in rotational crops

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

| Inconclusive | A confined rotational crop study provided in this assessment indicates significant residues of the persistent soil metabolite OC 56635 in mature radish roots (up to 0.025 mg/kg), spinach (up to 0.23 mg/kg) and sorghum grain (up to 0.034 mg/kg) (Belgium (2021)).

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

| Inconclusive | Studies no available and not required for the present import tolerance assessment.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | CF_P (b) | Comment/Source |
|---------------------|---------------------------|------------------------|----------|---------------|
|                     |                           | Individual values      | Median PF|               |
| Apples, juice       | 3                         | 0.09; 0.11; 0.16       | 0.11     | 1 Belgium (2021) |
| Apples, wet pomace  | 3                         | 3.2; 3.3; 14.3         | 3.3      | 1 Belgium (2021) |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Dietary burden calculation according to OECD, 2013.

| Relevant groups        | Dietary burden expressed in | Most critical diet (a) | Most critical commodity (b) | Trigger exceeded (Yes/No) | Previous assessment (EFSA, 2014) |
|------------------------|-----------------------------|------------------------|-----------------------------|---------------------------|----------------------------------|
|                        | mg/kg bw per day            | mg/kg DM               |                             |                           |                                  |
|                        | Median | Maximum | Median | Maximum | mg/kg DM | mg/kg DM |
| Cattle (all diets)     | 0.001  | 0.001   | 0.06   | 0.06    | Beef cattle | Apple Wet pomace | No | n.a. |
| Cattle (dairy only)    | 0.001  | 0.001   | 0.03   | 0.03    | Dairy cattle | Apple Wet pomace | No | n.a. |
| Sheep (all diets)      | 0.001  | 0.001   | 0.03   | 0.03    | Lamb | Apple Wet pomace | No | n.a. |
| Sheep (ewe only)       | 0.001  | 0.001   | 0.03   | 0.03    | Ram/ewe | Apple Wet pomace | No | n.a. |
| Swine (all diets)      | –      | –       | –      | –       | –   | –   | No | n.a. |
| Poultry (all diets)    | –      | –       | –      | –       | –   | –   | No | n.a. |
| Poultry (layer only)   | –      | –       | –      | –       | –   | –   | No | n.a. |
| Fish                   | Not investigated.           | –                     | –      | –       | –   | –   | n.a. |
(a): When several diets are relevant (e.g. cattle, sheep and poultry ‘all diets’), the most critical diet is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

### B.3. Consumer risk assessment

| ARFD | 1.0 mg/kg bw (European Commission, 2019) |
|------|----------------------------------------|
| Highest IESTI, according to EFSA PRIMO | Apples: 0.9% of ARFD  
Cherries: 0.3% of ARFD  
Strawberries: 0.3% of ARFD  
Cucumbers: 0.1% of ARFD  
Courgettes: 0.09% of ARFD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities including apples, cherries, strawberries, cucumbers and courgettes. Calculations performed with PRIMO revision 3.1. |

| ADI | 0.82 mg/kg bw per day (European Commission, 2019) |
|-----|----------------------------------------|
| Highest IEDI, according to EFSA PRIMO | 0.1% of ADI (DE, child)  
Contribution of crops assessed:  
Apples: 0.05% of ADI (DE, child)  
For other commodities under assessment (cherries, strawberries, cucumbers and courgettes) the individual exposure is below 0.05% of the ADI |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities under consideration.  
For table and wine grapes the STMR values as derived in the previous EFSA assessments (EFSA, 2014) were considered.  
For the remaining commodities consumer exposure was not assessed since no uses of flutianil have been authorised since the finalisation of the EU pesticides peer review. Calculations performed with PRIMO revision 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; STMR: supervised trials median residue.

### B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0130010 | Apples    | 0.01*                  | 0.15                    | The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.^(b) |
| 0140020 | Cherries (sweet) | 0.01* | 0.40 | The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.^(b) |
| 0152000 | Strawberries | 0.01* | 0.30 | The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.^(b) |

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; STMR: supervised trials median residue.
| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|------------|-------------------------|------------------------|-----------------------|
| 0232010           | Cucumbers  | 0.01*                   | 0.03                   | The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.<sup>(b)</sup> |
| 0232030           | Courgettes | 0.01*                   | 0.03                   | The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.<sup>(b)</sup> |
| 0233010           | Melons     | 0.01*                   | No MRL proposal        | The submitted data are not sufficient to derive an MRL for the authorised use in the USA. |

MRL: maximum residue level; USA: United States of America; 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): The consumer risk assessment does not consider the persistent soil metabolite OC 56635.
### Setting of import tolerances for flutianil in various crops

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

#### Flutianil

| Toxicological tolerance value | LOQs (mg/kg) range from: | 
|-------------------------------|---------------------------|
| Setting of import tolerances  | 0.05 to:                  |

**Input values**

- **Flutianil**
  - LOQs (mg/kg): 0.01

**Supplementary results – Toxicological reference values**

- **Chronic risk assessment**
  - **ADI (mg/kg bw per day):** 1
  - **ARfD (mg/kg bw):** Details – acute risk

**Comments:**

- **Source of ADI:** EC 2019
- **Source of ARfD:** EC 2019
- **Year of evaluation:** EFSA PRIMo revision 3.1; 2021/01/06

#### Refined calculation results

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

- **No of diets exceeding the ADI:** ---

| Commodity/group of commodities | Exposure resulting from | Highest contributor to | 2nd contributor to | 3rd contributor to | (in % of ADI) | (in % of ADI) | (in % of ADI) |
|-------------------------------|-------------------------|------------------------|---------------------|---------------------|--------------|--------------|--------------|
| Apples                        |                         |                        |                     |                     |              |              |              |
| Cherries (sweet)              |                         |                        |                     |                     |              |              |              |
| Cucumbers                     |                         |                        |                     |                     |              |              |              |
| Table grapes                  |                         |                        |                     |                     |              |              |              |
| Wine grapes                   |                         |                        |                     |                     |              |              |              |
| Strawberries                  |                         |                        |                     |                     |              |              |              |
| Apples<br> NL toddler         |                         |                        |                     |                     |              |              |              |
| Apples<br> DE child           |                         |                        |                     |                     |              |              |              |
| Apples<br> NL child           |                         |                        |                     |                     |              |              |              |
| Apples<br> DE women 14-50 yr  |                         |                        |                     |                     |              |              |              |
| Apples<br> FI 3 yr            |                         |                        |                     |                     |              |              |              |
| Apples<br> ES child           |                         |                        |                     |                     |              |              |              |
| Apples<br> ES adult           |                         |                        |                     |                     |              |              |              |
| Apples<br> IE child           |                         |                        |                     |                     |              |              |              |
| Apples<br> FI 6 yr            |                         |                        |                     |                     |              |              |              |
| Apples<br> IT toddler         |                         |                        |                     |                     |              |              |              |
| Apples<br> IT adult           |                         |                        |                     |                     |              |              |              |
| Apples<br> DK child           |                         |                        |                     |                     |              |              |              |
| Apples<br> DK adult           |                         |                        |                     |                     |              |              |              |
| Apples<br> RO general         |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G06      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G07      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G08      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G09      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G10      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G11      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G12      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G13      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G14      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G15      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G16      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G17      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G18      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G19      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G20      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G21      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G22      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G23      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G24      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G25      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G26      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G27      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G28      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G29      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G30      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G31      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G32      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G33      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G34      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G35      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G36      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G37      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G38      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G39      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G40      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G41      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G42      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G43      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G44      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G45      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G46      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G47      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G48      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G49      |                         |                        |                     |                     |              |              |              |
| Apples<br> GEMS/Food G50      |                         |                        |                     |                     |              |              |              |

**Conclusion:**

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

**DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
### Unprocessed Commodities

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

### Results for children

| Highest % of ARfD/ADI | Commodities     | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|----------------|-------------------|---------------------|
| 0.9%                  | Apples         | 0.01/0.08         | 8.6                 |
| 0.7%                  | Table grapes   | 0.15/0.1          | 7.4                 |
| 0.3%                  | Cherries (sweet) | 0.01/0.24     | 2.9                 |
| 0.2%                  | Strawberries   | 0.01/0.17         | 2.7                 |
| 0.2%                  | Melons         | 0.01/0.01         | 1.5                 |
| 0.1%                  | Cucumbers      | 0.01/0.02         | 1.3                 |
| 0.09%                 | Wine grapes    | 0.15/0.1          | 0.94                |
| 0.09%                 | Courgettes     | 0.01/0.02         | 0.83                |

### Results for adults

| Highest % of ARfD/ADI | Commodities     | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|----------------|-------------------|---------------------|
| 0.3%                  | Apples/juice   | 0.01/0.04         | 1.9                 |
| 0.1%                  | Wine grapes/juice | 0.15/0.02    | 0.79                |
| 0.1%                  | Courgettes/boiled | 0.01/0.02    | 0.71                |

### Results for processed commodities

| Highest % of ARfD/ADI | Processed commodities | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-----------------------|-------------------|---------------------|
| 0.2%                  | Apples/juice         | 0.01/0.04         | 1.9                 |
| 0.1%                  | Wine grapes/juice    | 0.15/0.02         | 0.79                |
| 0.09%                 | Wine grapes/juice    | 0.15/0.1          | 0.94                |

Conclusion:

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

For processed commodities, no exceedance of the ARfD/ADI was identified.

### Details - acute risk assessment/children

Setting of import tolerances for flutianil in various crops

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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                |
| Apple pomace       | 0.116                 | STMR × PF\(^{(a)}\)   |

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

(a): For apple pomace a median processing factor of 3.3 (see Section B.1.2.3) was applied as derived from the submitted processing studies.

D.2. Consumer risk assessment

| Commodity          | Existing/Proposed MRL (mg/kg) | Source          | Chronic risk assessment | Acute risk assessment |
|--------------------|-------------------------------|-----------------|-------------------------|-----------------------|
|                    |                               |                 | Input value (mg/kg)     | Comment               |
| Apples             | 0.15                          | MRL proposal    | 0.035                   | STMR-RAC              |
| Cherries (sweet)   | 0.40                          | MRL proposal    | 0.105                   | STMR-RAC              |
| Strawberries       | 0.30                          | MRL proposal    | 0.055                   | STMR-RAC              |
| Cucumbers          | 0.03                          | MRL proposal    | 0.01                    | STMR-RAC              |
| Courgettes         | 0.03                          | MRL proposal    | 0.01                    | STMR-RAC              |
| Melons             | 0.01                          | Existing MRL    | –                       |                       |
| Table grapes       | 0.15                          | EFSA (2014)     | 0.018                   | STMR-RAC              |
| Wine grapes        | 0.15                          | EFSA (2014)     | 0.018                   | STMR-RAC              |

MRL: maximum residue level; STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity.
## Appendix E – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChiKey\(^{(a)}\) | Structural formula\(^{(b)}\) |
|-------------------|---------------------------------------------|-----------------------------|
| Flutianil         | \(\{(\alpha, \alpha, \alpha, 4\text{-t}	ext{trafluoro-2-methyl)	ext{thiophenyl\text{-}	ext{1,3-thiazolidin-2-ylidene}}}\text{[\text{acetonitrile}}\) | ![Structural formula](image) |
| OC 56635          | 2-fluoro-5-(trifluoromethyl)benzene-1-sulfonic acid | ![Structural formula](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).