Modification of the existing maximum residue level for fluazifop-P in tomato

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Crop Protection AG submitted a request to the competent national authority in Portugal to modify the existing maximum residue level (MRL) for the active substance fluazifop-P in tomato. The data submitted in support of the request were found to be sufficient to derive MRL proposal for tomato. An adequate analytical method for enforcement is available to control the residues of fluazifop-P in tomato 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 fluazifop-P according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Keywords: fluazifop-P, tomato, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Portugal (evaluating Member State (EMS)) to modify the existing maximum residue level (MRL) for the active substance fluazifop-P in tomato. Portugal 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 31 October 2017. To accommodate for the intended use of fluazifop-P, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.06 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessment and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

Based on the metabolic pattern identified in metabolism studies, hydrolysis data and the toxicological significance of metabolites, the residue definitions for plant products were proposed for fluazifop-P as the sum of all constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop for enforcement and risk assessment. This residue definition is applicable to primary crops, rotational crops and processed products. EFSA concluded that for the crops assessed in this application, metabolism of fluazifop-P 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.

A sufficiently validated analytical method is available to quantify residues in dry, acidic, high water content and high oil content commodities according to the enforcement residue definition. The method allows quantification of residues at or above 0.01 mg/kg in the crop assessed (LOQ).

Although the residue trials submitted in support of the MRL application were not exactly reflecting the intended Good Agricultural Practice (GAP), EFSA is of the opinion that the data are sufficient to derive a MRL proposal of 0.06 mg/kg for tomato. Due to these deficiencies of the residue trials, the MRL proposal is affected by a higher level of uncertainty than usual resulting from the fact that the residue trials were not exactly reflecting the most critical application conditions.

No processing studies were evaluated in this application. However, robust processing factors for juice, paste, purée and canned tomatoes were evaluated in a previous reasoned opinion and are available.

The occurrence of fluazifop-P residues in rotational crops was investigated in the framework of the European Union (EU) pesticides peer review and by EFSA in the MRL review. Based on this available information on the nature and magnitude of residues, it is concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed GAP.

Residues of fluazifop-P in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock in the EU.

The toxicological profile of fluazifop-P was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.017 mg/kg bw, both values expressed as racemic fluazifop in accordance with the residue definition for dietary risk assessment.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure assessment performed for tomato did not exceed the ARfD when using the highest residue (HR). The estimated long-term dietary intake ranged from 1% to 41% of the ADI. The contribution of residues expected in tomato assessed in this application to the overall long-term exposure is of 0.3% of the ADI.

EFSA concluded that the proposed use of fluazifop-P on tomato will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

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

| Code\(^{(a)}\) | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|------------|-------------------------|------------------------|-----------------------|
| 231010         | Tomatoes   | 0.01*                   | 0.06                   | The submitted data are considered sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely. The MRL proposal is affected by non-standard uncertainties, resulting from the fact that the residue trials were not exactly reflecting the most critical application conditions. |

**Enforcement residue definition:** sum of all constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop.

MRL: maximum residue level; SEU: southern Europe.

*: 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.
Assessment

The detailed description of the intended use of fluazifop-P in tomato, which is the basis for the current MRL application, is reported in Appendix A.

Fluazifop-P is the ISO common name for (R)-2-\{(4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy)propionic acid (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Fluazifop-P was evaluated in the framework of Directive 91/414/EEC\(^1\) with France designated as rapporteur Member State (RMS) for the representative uses as a single foliar application on pome fruits, peas, beans, pulses, potatoes and rapeseeds. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2010, 2012). Following the first peer review, which was carried out by EFSA, a decision on non-inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Decision 2008/934/EC\(^2\). A resubmission application was subsequently made in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No 33/2008\(^3\). Following this second peer review, which was carried out by EFSA, fluazifop-P was approved under Regulation (EU) No 1107/2009\(^4\) in accordance with Regulation (EU) No 540/2011\(^5\). This decision was published by means of Commission Implementing Regulation (EU) No 788/2011\(^6\), which entered into force on 1 January 2012. It was a specific provision of the approval that only use as an herbicide for orchards (basal application) with one application may be authorised. After amendment to the conditions of approval of the active substance, the restriction was lifted and other uses as an herbicide were authorised under Commission Implementing Regulation (EU) No 201/2013\(^7\).

The process of renewal of the first approval has not yet been initiated. The review of existing maximum residue levels (MRLs) according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2015b) and the proposed modifications have been implemented in the MRL legislation (Annexes II of Regulation (EC) No 396/2005\(^8\)). After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for fluazifop-P. The proposals from these reasoned opinions have been considered in recent regulations\(^9\) for the European Union (EU) MRL legislation. It is noted that in 2017 EFSA assessed a MRL request for fluazifop-P in tomatoes for a different Good Agricultural Practice (GAP); in its assessment EFSA did not recommend the raising of the existing MRL since the residue trials were found insufficient to support the intended GAP (EFSA, 2017).

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Portugal (evaluating Member State (EMS)) to modify the existing MRL for the active substance fluazifop-P in tomato. Portugal drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to

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1. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2. Commission decision of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances. OJ L 333, 11.12.2008, p. 11–14.
3. Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.
4. 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.
5. Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
6. Commission Implementing Regulation (EU) No 788/2011 of 5 August 2011 approving the active substance fluazifop-P, in accordance with Regulation (EC) No 1107/2009 for 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 and Commission Decision 2008/934/EC. OJ L 203, 6.8.2011, p. 21–25.
7. Commission Implementing Regulation (EU) No 201/2013 of 8 March 2013 amending Implementing Regulations (EU) No 788/2011 and (EU) No 540/2011 as regards an extension of the uses for which the active substance fluazifop-P is approved. OJ L 67, 9.3.2019, p. 6-9.
8. 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.
9. 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
the European Commission and forwarded to the EFSA on 31 October 2017. To accommodate for the intended uses of fluazifop-P, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.06 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

EFSA based its assessment on the evaluation report submitted by the EMS (Portugal, 2017), the DAR (France, 2007), prepared under Council Directive 91/414/EEC, the final addendum and its additional report to the DAR (France, 2010), the final addendum to the additional report (France, 2012), the revised European Commission review report on fluazifop-P (European Commission, 2015), the conclusion on the peer review of the pesticide risk assessment of the active substance fluazifop-P (EFSA, 2010, 2012), as well as the conclusions from previous EFSA opinions on fluazifop-P including the review of existing MRLs according to Article 12 (EFSA, 2015a,b, 2016, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011\textsuperscript{10} 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). 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\textsuperscript{11}.

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

The evaluation report submitted by the EMS (Portugal, 2017) 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 fluazifop-P-butyl in primary crops belonging to the group of fruit crops (tomatoes), root crops, leafy crops and pulses/oilseeds was investigated in the framework of EU pesticides peer review and the MRL review (EFSA, 2012, 2015b). The predominant compound of the total residues was fluazifop, free and conjugated (20-70% of total radioactive residue (TRR) in all the different crops tested). Overall, a similar metabolic pattern was observed in all crops investigated. In tests using the single enantiomers and racemic fluazifop-butyl, a significant change in the ratio of the R and S enantiomers of the residues was not observed (EFSA, 2012).

1.1.2. Nature of residues in rotational crops

Tomatoes can be grown in crop rotation. Fluazifop-P has a DT\textsubscript{90} of over 100 days being therefore considered a persistent substance (EFSA, 2012).

Metabolism was investigated in three different crop groups (root crops, leafy crops and cereals) by means of a confined rotational crop metabolism study (EFSA, 2012). Only compound X, either free or hexose conjugated, was recovered at relevant levels in harvested wheat (forage, straw, grain) (30-70% TRR), lettuce (64% TRR) and carrot (foliage) (44-60% TRR) sown 60 days after a bare soil treatment with fluazifop-P-butyl. Compound X is the predominant metabolite in soil and it is assumed that its presence in the edible parts of the rotated crops is due to its uptake from the soil (EFSA, 2012). The MRL review concluded that considering the occurrence of compound X at insignificant levels in rotational crop trials (see also Section 1.2.2), the residue definition for the rotational crops can be set as the same as for the primary crops (EFSA, 2015b).

\textsuperscript{10} 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.

\textsuperscript{11} 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.
1.1.3. Nature of residues in processed commodities

The nature of residues in processed commodities was not investigated under standardised hydrolytic conditions for fluazifop-P-butyl. However, analytical methods reported for enforcement of residues include severe hydrolytic conditions. Under these conditions, conjugates and esters of fluazifop did not hydrolyse beyond the stable fluazifop moiety itself. It was therefore concluded that the metabolic pattern in processed commodities will not differ significantly from the metabolic pattern observed in raw commodities (EFSA, 2015b).

1.1.4. Methods of analysis in plants

An analytical method for the determination of fluazifop residues (including all fluazifop isomers, its esters and its conjugates) was assessed during the EU pesticides peer review (EFSA, 2012).

The method was validated for dry, acidic, high water content and high oil content commodities. It is based on the Quick, Easy, Cheap, Effective, Rugged, and Safe (QuECHERS) method involving an additional hydrolysis step under acidic conditions (using acetonitrile/concentrated hydrochloric acid solution (98:2 v/v)); the determination is performed using triple quadrupole high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS).

The method is applicable for tomatoes to quantify residues at or above the LOQ of 0.01 mg/kg (total residues of fluazifop-P determined as fluazifop, its esters and its conjugates).

1.1.5. Stability of residues in plants

The stability of fluazifop-P-butyl was investigated in the framework of the peer review in high water content, high oil content and dry commodities stored under frozen conditions. The findings for fluazifop-P-butyl were considered sufficient to demonstrate storage stability for all constituent isomers of fluazifop, its esters and its conjugates (EFSA, 2012). It is sufficiently demonstrated that residues of fluazifop (including all constituent isomers, its esters and conjugates) in tomatoes are stable for at least 18 months when stored at −18°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the toxicological significance of metabolites and degradation products and the capabilities of enforcement analytical methods, the following residue definitions were proposed under the MRL review (EFSA, 2015b):

- residue definition for risk assessment: sum of all constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop.
- residue definition for enforcement: sum of all constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop.

The same residue definitions are applicable to rotational crops and processed products. The residue definition set in Regulation (EC) No 396/2005 for enforcement is equivalent to the enforcement residue definition mentioned above (i.e. fluazifop-P (sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop)).

Taking into account the proposed use assessed in this application, EFSA concludes that these residue definitions are appropriate and no modification is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted eight residue trials performed on tomato. The samples were analysed for all constituents of the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose and the sample integrity demonstrated for the storage stability of these residue trials (Portugal, 2017).

The residue trials were conducted in the south of France, Greece, Italy and Spain in the years 1999, 2001 and 2002 were provided.

The intended GAP for tomato is described as a single application at 312.5 g/ha at the growth stages before BBCH 61 (before first flower opens) and a preharvest interval (PHI) of 70 days.
Two of the eight trials match the application rate, whereas in the remaining six trials the application rate was below the intended GAP but within the acceptable deviation of 25%. In all residue trials, the samples were taken at a slightly longer or shorter PHIs (65–87 days) than the one described in the GAP of 70 days. Despite the general principle that trials may not deviate more than on one parameter (European Commission, 2017), the deviations on the PHI are not expected to have a significant impact on the final residue level as the intended interval between the last application and the harvest is long. The timing of the application did not fully match with the growth stage defined in the GAP (BBCH 51 instead of close to BBCH 61). Considering that the time between BBCH 51 and BBCH 61 is relatively short compared to the PHI and since fluazifop-P is a systemic herbicide where the early timing of application should not impact greatly on the residues, the residue trials were considered acceptable to support the intended SEU outdoor use and to derive a MRL proposal for tomato. However, the MRL proposal is affected by a higher level of uncertainty compared to other cases where the residue trials would reflect the intended GAP exactly in terms of application rate, BBCH and PHI.

1.2.2. Magnitude of residues in rotational crops

Tomatoes can be grown in a crop rotation. The possible transfer of residues to crops that are grown in a crop rotation has been assessed in the framework of the EU pesticides review and the MRL review with fluazifop-P-butyl (EFSA, 2012, 2015b). The available studies demonstrated that significant residues are not expected in succeeding crops planted in soil treated once at a dose rate 375–475 g a.s./ha. Since the maximum annual application rate for the crops under consideration is lower (312 g/ha; 0.8N) than the lowest application rate tested in the rotational crop field trials, it is concluded that no residues are expected in rotational crops, provided that the active substance is applied according to the proposed GAP.

1.2.3. Magnitude of residues in processed commodities

No new processing studies were submitted in the framework of this application but robust processing factors for juice, paste, purée and canned tomatoes were derived in a previous reasoned opinion and recommended for inclusion in Annex VI of Regulation (EC) No 396/2005 (EFSA, 2017).

1.2.4. Proposed MRLs

Although the residue trials submitted in support of the MRL application were not exactly reflecting the intended GAP, EFSA is of the opinion that the data are sufficient to derive a MRL proposal of 0.06 mg/kg for tomato. Due to these deficiencies of the residue trials, the MRL proposal is affected by a higher level of uncertainty than usually resulting from the fact that the residue trials were not exactly reflecting the most critical application conditions.

In Section 3, EFSA assessed whether residues on tomato resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as tomato is not used for feed purposes in Europe.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (EFSA, 2007).

The toxicological reference values used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review on fluazifop-P (EFSA, 2012) and were expressed as racemic fluazifop in accordance with the residue definition for dietary risk assessment.

The short-term exposure assessment performed for tomato did not exceed the ARfD when using the highest residue (HR).

The long-term exposure assessment was performed using the supervised trials median residue (STMR) values of the previous reasoned opinion (EFSA, 2017), including the STMR values for certain Codex MRLs (FAO, 2016) that were taken over in the EU legislation recently, as well as the STMR value
derived for tomato under this application. The estimated long-term dietary intake ranged from 1% to 41% of the ADI. The contribution of residues expected in tomato assessed in this application to the overall long-term exposure is of 0.3% of the ADI.

Therefore, EFSA concludes that neither the short- nor the long-term intake of residues resulting from the existing uses of fluazifop-P and the new use in tomato is unlikely to present a risk to consumer health.

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive a MRL proposal for tomato, noting that the derived MRL may not cover the most critical application conditions (treatment at BBCH between 51 and 61).

EFSA concluded that the proposed use of fluazifop-P on tomato will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendations are summarised in Appendix B.4.

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**Abbreviations**

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfd acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
DAR draft assessment report
DAT days after treatment
DM dry matter
DT$_{90}$ period required for 90% dissipation (define method of estimation)
EC emulsifiable concentrate
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GS growth stage
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
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LOQ limit of quantification
MRL maximum residue level
MS mass spectrometry detector
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers

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| Abbreviation | Definition |
|--------------|------------|
| SEU          | southern Europe |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TRR          | total radioactive residue |
| WHO          | World Health Organization |
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|----------------------|-------------------------|-------------|-----------------------------------|-------------|-----------------|-------------------------------|---------------|--------|
| Tomato               | SEU                     | F           | Annual and perennial grasses      | EC 125 g/L  | Foliar spray   | Before any flowers open (< BBCH 61) | 1             | 78.125–312.5 | Application rate expressed as fluazifop-P-butyl |

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; MRL: maximum residue level; a.s.: active substance; EC: emulsifiable concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
## Appendix B – List of end points

### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/source |
|-----------------------------------|-------------|---------|----------------|----------------|---------------|
| Fruit crops                       | Grapes      | Soil, 670 + 160 g a.s./ha | 14, 30 | Study carried out with fluazifop-P-butyl, labelled both on the phenyl and pyridyl moieties/EFSA (2012) |
| Root crops                        | Carrot      | Foliar, 1 × 250 g a.s./ha | 45 | Study includes a comparative assessment of fluazifop-P-butyl labelled on the phenyl moiety (low application rate) and fluazifop-butyl labelled on both moieties (high application rate)/EFSA (2012) |
|                                  | Sugar beet  | Foliar, 1 × 250 g a.s./ha | 45 | Study includes a comparative assessment of fluazifop-P-butyl labelled on the phenyl moiety (low application rate) and fluazifop-butyl labelled on both moieties (high application rate)/EFSA (2012) |
|                                  |             | Foliar, 1 × 500 g a.s./ha | 90 | |
| Leafy crops                       | Celery      | Foliar, 1 × 250 g a.s./ha | 30 | Study carried out with fluazifop-P-butyl, labelled both on the phenyl and pyridyl moieties/EFSA (2012) |
|                                  | Lettuce     | Foliar, 1 × 250 g a.s./ha | 27 | Study carried out with fluazifop-butyl (R and S enantiomers separately), labelled on the phenyl moiety/EFSA (2012) |
| Pulses/oilseeds                   | Soya bean   | Foliar, 1 × 560 g a.s./ha | BBCH 61 and Maturity | Study carried out with fluazifop-P-butyl, labelled both on the phenyl and pyridyl moieties/EFSA (2012) |
|                                  |             | Foliar, 560 + 211 g a.s./ha | Maturity | |
| Cotton                            | Foliar, 1 × 450 g a.s./ha | 27 | Study carried out with fluazifop-butyl (R and S enantiomers separately), labelled on the phenyl moiety/EFSA (2012) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|-------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                    | Carrot      | Soil, 1 × 470 g a.s./ha | 30 | 14C-phenyl and 14C-pyridinyl fluazifop-P EFSA (2012) |
|                                    |             | Soil, 1 × 970 g a.s./ha | 90, 270 | 14C-phenyl and 14C-pyridinyl fluazifop-P EFSA (2012) |
| Leafy crops                        | Lettuce     | Soil, 1 × 470 g a.s./ha | 30 | 14C-phenyl and 14C-pyridinyl fluazifop-P EFSA (2012) |
|                                    |             | Soil, 1 × 970 g a.s./ha | 90, 270 | 14C-phenyl and 14C-pyridinyl fluazifop-P EFSA (2012) |
| Cereal (small grain)               | Wheat       | Soil, 1 × 470 g a.s./ha | 30 | 14C-phenyl and 14C-pyridinyl fluazifop-P EFSA (2012) |
|                                    |             | Soil, 1 × 970 g a.s./ha | 90, 270 | 14C-phenyl and 14C-pyridinyl fluazifop-P EFSA (2012) |
| Processed commodities (hydrolysis study) | Conditions                                           | Stable?   | Comment/source                                                                 |
|-----------------------------------------|-----------------------------------------------------|-----------|-------------------------------------------------------------------------------|
|                                         | Pasteurisation (20 min, 90 °C, pH 4)                | Inconclusive | Study not available                                                            |
|                                         | Baking, brewing and boiling (60 min, 100 °C, pH 5) | Inconclusive | Study not available                                                            |
|                                         | Sterilisation (20 min, 120 °C, pH 6)                | Inconclusive | Study not available                                                            |
|                                         | Other processing conditions                         | Yes       | Severe hydrolytic conditions were evaluated under the analytical enforcement method demonstrating stability to hydrolysis conditions |

Can a general residue definition be proposed for primary crops? Yes

Rotational crop and primary crop metabolism similar? Yes

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

Plant residue definition for monitoring (RD-Mo) Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop

Plant residue definition for risk assessment (RD-RA) Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop

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: acidified modification of QuECHERS method and determination using triple quad HPLC–MS/MS, with LOQ 0.01 mg/kg (EFSA, 2012). ILV available. Analytical method is not available for hops, herbal infusions and spices (EFSA, 2015b)
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category       | Commodity       | Commodity T (°C) | Stability period | Value | Unit | Compounds covered | Comment/source                                                                 |
|-----------------------------------|----------------|-----------------|------------------|------------------|-------|------|------------------|--------------------------------------------------------------------------------|
|                                   | High water content | Sugar beet     | 18               | 12               | Months | Fluazifop-butyl | Additional studies lasting 9 and 4 months are also available for cauliflower and tomatoes, respectively/EFSA (2015b) |
|                                   | High water content | Fresh beans    | 18               | 12               | Months | Fluazifop-butyl | EFSA (2015b)                                                             |
|                                   | High oil content   | Oilseed rape   | 18               | 9                | Months | Fluazifop-butyl | EFSA (2015b)                                                             |
|                                   | High acid content  | Strawberries   | 18               | 9                | Months | Fluazifop-butyl | EFSA (2015b)                                                             |
|                                   | High water content | Onions         | 18               | 28               | Months | Fluazifop-P-butyl | Additional study lasting 18 months is also available for potatoes, lettuce, cabbage and tomatoes/EFSA (2015b) |
|                                   | High oil content   | Soya bean      | 18               | 18               | Months | Fluazifop-P-butyl | EFSA (2015b)                                                             |
|                                   | Dry/high protein   | Dry beans      | 18               | 18               | Months | Fluazifop-P-butyl | EFSA (2015b)                                                             |

### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/indoor (a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR (b) (mg/kg) | STMR (c) (mg/kg) |
|-----------|-------------------|----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------|-----------------|
| Tomato    | SEU               | Trials performed at 1 × 313 g a.s./ha; PHI: 67 days 0.015 (d)            | Sufficient number of trials to derive a MRL. The MRL proposal is affected by non-standard uncertainties, resulting from the fact that the residue trials were not exactly reflecting the most critical application conditions                                                                 | 0.06                  | 0.03           | 0.01            |

MRL: maximum residue level; a.s.: active substance; PHI: preharvest interval.

(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): Mean of a replicate trial.

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B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No |
|----------------------------------|------------------|
| When considering the intended use, measurable residues of fluazifop-P or fluazifop-P-butyl are not expected in any rotational crop. However, the study indicated some potential for compound X to occur at measurable levels in all rotational crops, except carrot roots (EFSA, 2012). |

| Residues in rotational and succeeding crops expected based on field rotational crop study? | No |
|----------------------------------|------------------|
| Results from rotational crop field trials submitted during the peer review confirmed that no measurable levels of relevant residues are expected to occur in rotational crops, provided that the active substance is applied according to the intended use. |

B.1.2.3. Processing factors

No new processing studies were submitted in the framework of this application but robust processing factors for juice, paste, puree and canned tomatoes were evaluated in previous reasoned opinion (EFSA, 2017).

B.2. Residues in livestock

Not relevant

B.3. Consumer risk assessment

| ARfD | 0.017 mg/kg bw (EFSA, 2012) |
|----------------------------------|------------------|
| Highest IESTI, according to EFSA PRIMo | Tomato: 10.3% of ARfD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities |

| ADI | 0.01 mg/kg bw per day (EFSA, 2012) |
|----------------------------------|------------------|
| Highest IEDI, according to EFSA PRIMo | 40.6% ADI (WHO cluster diet E) |
| Contribution of crop assessed: | Tomato: 0.308% of ADI |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for the crop under consideration and for all other uses assessed in previous reasoned opinions (EFSA, 2015b, 2017) |

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------------------------|------------------|------------------|------------------|------------------|
| Enforcement residue definition: sum of all constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop |
| 231010 | Tomatoes | 0.01* | 0.06 | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely The MRL proposal is affected by non-standard uncertainties, resulting from the fact that the residue trials were not exactly reflecting the most critical application conditions |

MRL: maximum residue level; SEU: southern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
Appendix C – Pesticide Residue Intake Model (PRIMo)

Fluazifop-P

| Toxicological end points | ADI (mg/kg bw per day): 0.01 | ARfD (mg/kg bw): 0.017 |
|--------------------------|-------------------------------|------------------------|
| Source of ADI:           | EFSA                           | Source of ARfD: EFSA    |
| Year of evaluation:      | 2012                           | Year of evaluation: 2012|

Status of the active substance: Approved

- Code no.
- LOQ (mg/kg bw): Proposed LOQ

| Year of evaluation: 2012 | Year of evaluation: 2012 |
---------------------------|---------------------------|
| ADI (mg/kg bw per day): 0.01 | ARfD (mg/kg bw): 0.017 |

| Source of ADI: | EFSA | Source of ARfD: EFSA |
----------------|------|----------------------|
| Year of evaluation: | 2012 | Year of evaluation: 2012 |

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI | 2nd contributor to MS diet in % of ADI | 3rd contributor to MS diet in % of ADI | Commodity/group of commodities |
|---------------------------------|--------------------------|----------------------------------------|----------------------------------------|--------------------------------|
| 40.6 WHO cluster diet E         | 21.8 Soya bean           | 14.6 Raps seed                         | 0.8 Beans                               |
| 35.0 WHO Cluster diet F         | 24.4 Soya bean           | 7.3 Raps seed                          | 0.5 Beans                               |
| 30.4 WHO Cluster diet B         | 22.8 Soya bean           | 0.9 Beans (with pods)                  | 0.7 Peas                                |
| 29.7 UK Toddler                 | 22.9 Sugar beet (root)   | 4.7 Beans                              | 0.7 Peas (without pods)                 |
| 17.8 WHO Cluster diet D         | 13.8 Soya bean           | 0.6 Beans                              | 0.5 Peas                                |
| 16.0 UK Infant                  | 15.1 Sugar beet (root)   | 3.0 Beans                              | 1.3 Peas (without pods)                 |
| 14.6 PT General population      | 11.4 Soya bean           | 1.0 Beans                              | 0.5 Peas (without pods)                 |
| 11.8 WHO regional European diet | 2.9 Raps seed            | 2.7 Soya bean                          | 1.0 Peas (with pods)                    |
| 10.8 IE adult                   | 3.5 Linseed              | 1.7 Peas                               | 0.9 Lentils                             |
| 7.5 UK vegetarian               | 3.6 Sugar beet (root)    | 2.2 Beans                              | 0.3 Peas                               |
| 7.5 NL child                    | 1.8 Soya bean            | 1.4 Beans (with pods)                  | 1.0 Peas (without pods)                 |
| 7.1 FR toddler                  | 3.0 Beans (with pods)    | 1.2 Carrots                            | 0.8 Peas (without pods)                 |
| 6.4 UK Adult                    | 4.0 Sugar beet (root)    | 1.3 Beans                              | 0.3 Peas (without pods)                 |
| 5.6 FR infant                   | 2.3 Beans (with pods)    | 1.3 Carrots                            | 0.6 Peas (without pods)                 |
| 5.4 ES Jini                     | 1.4 Lentils              | 0.8 Beans                              | 0.7 Peas                               |
| 4.4 DE child                    | 1.4 Soya bean            | 0.5 Carrots                            | 0.3 Strawberries                        |
| 3.4 NL general                  | 0.7 Beans (with pods)    | 0.5 Soya bean                          | 0.4 Peas (without pods)                 |
| 3.3 ES adult                    | 0.6 Beans (with pods)    | 0.6 Lentils                            | 0.4 Peas                               |
| 2.5 SE general population 90th percentile | 0.4 Carrots | 0.4 Peas (without pods) |
| 2.4 IT kid/toddler              | 0.5 Beans                | 0.3 Beans (with pods)                  | 0.2 Peas (without pods)                 |
| 2.0 IT adult                    | 0.4 Beans                | 0.2 Beans (with pods)                  | 0.2 Peas (without pods)                 |
| 1.7 FR all population           | 0.4 Beans (with pods)    | 0.3 Raps seed                          | 0.2 Carrots                            |
| 1.5 DK child                    | 0.7 Carrots              | 0.2 Potatoles                          | 0.2 Onions                             |
| 1.4 PL general population       | 0.3 Potatoes             | 0.2 Potatoles                          | 0.2 Beans                              |
| 1.2 FI adult                    | 0.3 Soya bean            | 0.3 Beans                              | 0.1 Potatoles                          |
| 1.1 DK adult                    | 0.2 Peas (without pods)  | 0.2 Potatoles                          | 0.1 Potatoles                          |
|                                |                          |                                        |                                        |
| Conclusion:                    |                          |                                        |                                        |

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Fluazifop-P is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, the calculation was performed with a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3. Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For Fluazifop-P, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

**Conclusion:**

For Fluazifop-P, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.
### Appendix D – Input values for the exposure calculations

#### D.1. Consumer risk assessment

| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------|-------------------------|-----------------------|
|                                                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Tomato                                         | 0.01                    | STMR                  | 0.03                | HR                    |
| Strawberries, peas (with pods) and cotton seeds| STMR                    | FAO (2016)            |                     |                       |
| Other products of plant and animal origin       | STMR                    | EFSA (2017)           |                     |                       |

**Risk assessment residue definition:** sum of all constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop.

STMR: supervised trials median residue; HR: highest residue.
### Appendix E – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|-------------------|-------------------------------------------------|--------------------------------|
| Fluazifop-P       | (R)-2-\{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy\} propionic acid | ![Structural formula](image)
|                   | O=C(O)[C@@H](C)Oc1ccc(cc1)Oc2ccc(cn2)C(F)(F)F YUVKUEAFVKLW-SECBINFHSA-N | ![Structural formula](image) |
| Fluazifop         | (RS)-2-\{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy\} propionic acid | ![Structural formula](image)
|                   | O=C(O)C(C)Oc1ccc(cc1)Oc2ccc(cn2)C(F)(F)F YUVKUEAFVKLW-UHFFFAOYSA-N | ![Structural formula](image) |
| Fluazifop-butyl   | butyl (RS)-2-\{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy\} propionate | ![Structural formula](image)
|                   | O=C(OC=CC)C(C)Oc1ccc(cc1)Oc2ccc(cn2)C(F)(F)F VAIZTNZGPYBOGF-UHFFFAOYSA-N | ![Structural formula](image) |
| Fluazifop-P-butyl | butyl (R)-2-\{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy\} propionate | ![Structural formula](image)
|                   | O=C(OC=CC)[C@@H](C)Oc1ccc(cc1)Oc2ccc(cn2)C(F)(F)F VAIZTNZGPYBOGF-CYBMUJFWSA-N | ![Structural formula](image) |
| Compound X        | 5-(trifluoromethyl)-2(1H)-pyridinone | ![Structural formula](image) |

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

<sup>(a)</sup>: ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(b)</sup>: ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).