Modification of the existing maximum residue levels for fluazifop-P in various products of plant and animal origin

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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 levels (MRL) for the active substance fluazifop-P in tomato, carrot and courgette. The data submitted in support of the request were found to be sufficient to derive MRL proposals for carrot and courgette. For tomato, data gaps were identified which precluded the derivation of MRL proposal. Adequate analytical methods for enforcement are available to control the residues of fluazifop-P in plant matrices under consideration. 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 on carrots and courgettes according to the reported agricultural practices and the products of animal origin under consideration is unlikely to present a risk to consumer health.

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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 levels (MRLs) for the active substance fluazifop-P in tomato, carrot and courgette. 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 2 August 2016. To accommodate for the intended uses of fluazifop-P, the EMS proposed to raise the existing MRL from 0.3 to 0.4 mg/kg in carrot and from 0.01 mg/kg (limit of quantification (LOQ)) to 0.2 mg/kg in tomato and to 0.03 mg/kg in courgette, respectively.

EFSA based its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its additional reports) prepared under Council Directive 91/414/EEC, the revised Commission review report on fluazifop-P, the conclusions on the peer review of the pesticide risk assessment of the active substance fluazifop-P, as well as previous EFSA reasoned opinions of which one opinion on the review of existing MRLs according to Article 12 (hereafter, MRL review).

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.

Sufficiently validated analytical methods based on high-performance liquid chromatography (HPLC) 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 (LOQ) in the crops assessed.

The available residue trials are sufficient to derive MRL proposals of 0.4 mg/kg for carrot and 0.03 mg/kg for courgette. The intended use on tomato is not adequately supported by residue data and therefore a MRL proposal cannot be derived.

Processing factors (PF) for tomatoes were derived from processing studies provided in the framework of this application and are recommended to be included in Annex VI of Regulation (EC) No 396/2005 as follows:

- Tomato/juice: 0.64  
- Tomato/puree: 2.06  
- Tomato/paste: 2.42  
- Tomato/canned: 0.66

The occurrence of residues of fluazifop-P in rotational crops had been investigated in the framework of the European Union (EU) pesticides peer review. Based on the available information on the nature and magnitude of residues, as for the intended uses in tomatoes, carrots and courgettes, 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 good agricultural practice (GAP).

As carrot culls can be used as feed product, a potential carry-over into food of animal origin was assessed. During the MRL review, the nature of fluazifop-P residues in livestock had been investigated and the residue definition proposed for enforcement and for risk assessment for fluazifop-P as the sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop is still applicable for the application under assessment. The currently implemented MRLs for animal commodities were based on the livestock dietary burden assessed during the MRL review. The previous assessment has been updated according to the latest OECD methodology. Based on the estimated dietary burdens and the results of livestock feeding studies, new MRLs are proposed for products of animal origin as outlined in the summary table below. This assessment outcome is driven by the existing uses while the new use of fluazifop-P on carrot does not have a significant impact on the estimated maximum livestock exposure. In the MRL review, a data gap was identified regarding sufficiently validated analytical methods for enforcement of residues in animal commodities. No new analytical methods have been provided with this application. The lack of such methods and the fact that the new MRL proposals are triggered solely by the use of a new methodology is highlighted for risk manager consideration.

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
Panel of experts on Plant Protection Products and their residues (PPR Panel) of the European Food Safety Authority (EFSA) evaluated the residue data for fluazifop-P in various products of plant and animal origin. 

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(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 did not exceed the ARFD for any of the crops assessed in this application. The long-term intake of residues resulting from the existing and the intended uses of fluazifop-P did not exceed the ADI. EFSA concluded that the proposed uses of fluazifop-P on carrot and courgette and the products of animal origin under consideration are unlikely to pose a risk to consumer's health.

EFSA proposes to amend the existing MRLs as reported in the summary table below. Due to the deficiencies of the dossier related to tomato, no MRL proposal could be derived. It is noted that no MRLs are proposed for ruminant fat and swine fat as with the new methodology calculated MRLs remained the same as set in Commission Regulation (EU) No 2017/171.

| Code(a) | Commodity    | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                      |
|---------|--------------|-------------------------|-------------------------|-----------------------------------------------------------|
| 213020  | Carrots      | 0.3                     | 0.4                     | The MRL proposal reflects the most critical residue situation of the NEU use. No consumer health concern was identified |
| 231010  | Tomatoes     | 0.01*                   | –                       | The submitted data are insufficient to derive a MRL proposal |
| 232030  | Courgette    | 0.01*                   | 0.03                    | The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified |
| 1011010 | Swine muscle | 0.02                    | 0.01*                   | Risk manager consideration required. Lower MRL resulting from use of the new OECD methodology |
| 1011030 | Swine liver  | 0.03                    | 0.06                    | Risk manager consideration required. Triggered by the new OECD methodology |
| 1011040 | Swine kidney | 0.06                    | 0.07                    | Risk manager consideration required. Triggered by the new OECD methodology |
| 1012010 | Bovine muscle| 0.02                    | 0.01*                   | Risk manager consideration required. Lower MRL resulting from use of the new OECD methodology |
| 1012030 | Bovine liver | 0.03                    | 0.05                    | Risk manager consideration required. Triggered by the new OECD methodology |
| 1012040 | Bovine kidney| 0.07                    | 0.06                    | Risk manager consideration required. Lower MRL resulting from use of the new OECD methodology |
| 1013010 | Sheep muscle | 0.02                    | 0.03                    | Risk manager consideration required. Triggered by the new OECD methodology |
| 1013020 | Sheep fat tissue | 0.04         | 0.08                    | Risk manager consideration required. Triggered by the new OECD methodology |
| 1013030 | Sheep liver  | 0.03                    | 0.04                    | Risk manager consideration required. Triggered by the new OECD methodology |
| 1013040 | Sheep kidney | 0.07                    | 0.2                     | Risk manager consideration required. Triggered by the new OECD methodology |
| 1014010 | Goat muscle  | 0.02                    | 0.03                    | Extrapolated from sheep. Risk manager consideration required. Triggered by the new OECD methodology |
| 1014020 | Goat fat tissue | 0.04         | 0.08                    | Extrapolated from sheep. Risk manager consideration required. Triggered by the new OECD methodology |

**Enforcement residue definition:** sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop.
| Code\(^{(a)}\) | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/Justification |
|------------|-----------------|-------------------------|-------------------------|------------------------|
| 1014030    | Goat liver      | 0.03                    | 0.04                    | Extrapolated from sheep Risk manager consideration required. Triggered by the new OECD methodology |
| 1014040    | Goat kidney     | 0.07                    | 0.2                     | Extrapolated from sheep Risk manager consideration required. Triggered by the new OECD methodology |
| 1015010    | Equine muscle   | 0.02                    | 0.01\(^{*}\)            | Extrapolated from bovine Risk manager consideration required Lower MRL resulting from use of the new OECD methodology |
| 1015030    | Equine liver    | 0.03                    | 0.05                    | Extrapolated from bovine Risk manager consideration required. Triggered by the new OECD methodology |
| 1015040    | Equine kidney   | 0.07                    | 0.06                    | Extrapolated from bovine Risk manager consideration required Lower MRL resulting from use of the new OECD methodology |
| 1016010    | Poultry muscle  | 0.02                    | 0.04                    | Risk manager consideration required. Triggered by the new OECD methodology |
| 1016020    | Poultry fat tissue | 0.02                   | 0.04                    | Risk manager consideration required. Triggered by the new OECD methodology |
| 1016030    | Poultry liver   | 0.04                    | 0.09                    | Risk manager consideration required. Triggered by the new OECD methodology |
| 1020010    | Milk cattle     | 0.08                    | 0.07                    | Risk manager consideration required Lower MRL resulting from use of the new OECD methodology |
| 1020020    | Milk sheep      | 0.08                    | 0.15                    | Risk manager consideration required. Triggered by the new OECD methodology |
| 1020030    | Milk goat       | 0.08                    | 0.15                    | Extrapolated from sheep Risk manager consideration required. Triggered by the new OECD methodology |
| 1020040    | Milk horse      | 0.08                    | 0.07                    | Extrapolated from bovine Risk manager consideration required Lower MRL resulting from use of the new OECD methodology |
| 1030010    | Birds eggs      | 0.02                    | 0.03                    | Risk manager consideration required. Triggered by the new OECD methodology |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; OECD: Organisation for Economic Co-operation and Development.

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

\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Background

Regulation (EC) No 396/2005¹ (hereinafter referred to as 'the MRL regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the MRL regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC², repealed by Regulation (EC) No 1107/2009³, shall submit an application to a Member State to modify a MRL in accordance with the provisions of Article 7 of the MRL regulation.

The applicant Syngenta Crop Protection AG⁴ submitted an application to the competent national authority in Portugal, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRLs for the active substance fluazifop-P in tomato, carrot and courgette. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA on 2 August 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00500 and the following subject:

*Fluazifop-P – MRLs in tomato, carrot and courgette*

Portugal proposed to raise the existing MRLs of fluazifop-P from 0.01 mg/kg (limit of quantification (LOQ)) to 0.2 mg/kg in tomato and to 0.03 mg/kg in courgette and from 0.3 to 0.4 mg/kg in carrot.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which were requested to the EMS. On August 2016, the EMS submitted a revised evaluation report (Portugal, 2016), which replaced the previously submitted evaluation report. Further original studies were provided to the EMS on tomato.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated LOQ for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within three months from the date of receipt of the application.

The evaluation report submitted by the EMS (Portugal, 2016) 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. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

The active substance and its use pattern

The detailed description of the intended uses of fluazifop-P in tomato, carrot and courgette, which are the basis for the current MRL application, is reported in Appendix A.

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¹ 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.
² 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.
³ 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.
⁴ Syngenta Crop Protection AG, Schwarzwaldallee 215, CH-4058 Basel, Switzerland.
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 B.

Fluazifop-P was evaluated in the framework of Directive 91/414/EEC 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 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. A resubmission application was subsequently made in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No 201/2013. Following this second peer review, which was carried out by EFSA, fluazifop-P is deemed to have been approved under Regulation (EU) No 1107/2009 in accordance with Regulation (EU) No 540/2011. This decision was published by means of Commission Implementing Regulation (EU) No 788/2011, 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.

The EU MRLs for fluazifop-P are established in Annexes II of Regulation (EC) No 396/2005. The review of existing 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. After completion of the MRL review, EFSA has issued one reasoned opinion on the modification of MRLs for fluazifop-P in pumpkin seeds (EFSA, 2016). The proposals from this reasoned opinion have been considered in recent Regulation for EU MRL legislation.

**Assessment**

EFSA has based its assessment on the evaluation report submitted by the EMS (Portugal, 2016), the DAR prepared under Council Directive 91/414/EEC (France, 2007), 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).

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.

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5 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.

6 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.

7 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.

8 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 pacing 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.

9 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.

10 Commission Regulation (EU) No 2016/1015 of 17 June 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluazifop-P, fuberidazole, meipquat and tralkoxydim in or on certain products. OJ L 172, 29.6.2016, p. 1–21.

11 Commission Regulation (EU) 2017/171 of 30 January 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, azoxystrobin, cyantraniliprole, cyflufenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxypin, isofetamid, metalaxyl, prohexadione, propaziquafop, pyrimethanil, Trichoderma atroviride strain SC1 and xamadoxim in or on certain products. OJ L 30, 3.2.2017, p. 45–111.

12 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.
(European Commission, 1997a–g, 2000, 2010a,b, 2016 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 the MRL review, including the end points of studies submitted in support of the current MRL application, are presented in Appendix B.

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 in primary crops belonging to the group of fruit crops, root crops, leafy crops and pulses/oilseeds has been investigated with the variant fluazifop-P-butyl in the framework of EU pesticides peer review and the MRL review (EFSA, 2012, 2015b).

Fluazifop-P-butyl was recovered in lettuce and cotton plants (up to 50% and 24% of total radioactive residue (TRR), respectively) but was not detected in the root crops, or at a trace level in celery leaves (2% of TRR). The predominant compound of the total residues in all crops was fluazifop, free and conjugated (20–70% of TRR). Overall, a similar metabolic pattern was observed in all crops investigated and a general residue definition could be derived. 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).

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Metabolism was investigated in three different crop groups (root crops, leafy crops and cereals) by means of a confined rotational crop metabolism study (France, 2010). 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, the residue definition for the rotational crops can be set as the same as for the primary crops (EFSA, 2015b).

1.1.3. Nature of residues in processed commodities

Nature of residues in processed commodities was not investigated under standardised hydrolytic conditions. 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 is not expected to differ significantly from the metabolic pattern observed in raw commodities (EFSA, 2012, 2015b).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of fluazifop-P residues as fluazifop, its esters and its conjugates were assessed during the EU pesticides peer review (EFSA, 2012).

The methods are sufficiently validated for the determination of residues of fluazifop-P as fluazifop, its esters and its conjugates in the crops under consideration. The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg for the total residue (fluazifop, its esters and its conjugates) in crops belonging to the group of high water content.

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13 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.
1.1.5. 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 (EFSA, 2012). The findings for fluazifop-P-butyl were applied also to the sum of all constituent isomers of fluazifop, its esters and its conjugates (France, 2010; EFSA, 2012).

It was demonstrated that in crops assessed in the framework of this application belonging to the high water content commodities, residues were 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:

- 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 set as fluazifop-P (sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop) and is considered as having identical meaning.

Taking into account the proposed uses assessed in this application, EFSA concluded 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 residue trials performed on tomato, carrot and courgette. The samples were analysed for all constituents of the residue definitions for enforcement and risk assessment upon hydrolysis to fluazifop. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Portugal, 2016).

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

1.2.1.1. Tomato

In support of the southern Europe (SEU) outdoor use, residue trials on tomato were provided. The trials were conducted in Greece, Spain, Italy and south of France, over five growing seasons in the years 1996, 1997, 1999, 2001 and 2002. A total of 11 residue trials were provided.

The intended GAP for tomato refers to one application at 312.5 g/ha at a growth stage earlier than growth stages of mono- and dicotyledonous plants (BBCH) 51, i.e. before flower bud is visible. Only one of the 11 submitted residue trials complies with the intended GAP in terms of the growth stage and thus all other trials were disregarded by EFSA.

Since in the framework of the MRL review, a similar GAP for tomato was assessed (although the residue values at preharvest interval (PHI) 30 were considered instead of the growth stage at last application). EFSA consulted available residue data and selected four trials which can be considered compliant with the intended GAP (last treatment done when inflorescence is not visible (~BBCH 51)). According to the EU guidance document (European Commission, 2016), tomato is a major crop for which at least eight GAP-compliant residue trials are required. Therefore, the number of available trials is not sufficient to support the intended SEU outdoor use and to derive a MRL proposal for tomato. Furthermore, the PHI of the residue trials provided under this assessment and in the MRL review ranged from 18 to 94 days. Considering that this active substance is systemic, and the final residue may be influenced not only by the growth stage of the last application, but also by the time elapsed between the last application and the harvest, EFSA is of the opinion that a PHI should be defined in the GAP.

14 In tomato, BBCH 51 corresponds to first inflorescence visible (first bud erect). If the growth stage is below 51, EFSA understands that the inflorescence should not be seen.
1.2.1.2. Carrot

In support of the northern Europe (NEU) and SEU GAPs, the applicant submitted eight GAP-compliant residue trials on carrot for the NEU use and 10 GAP-compliant residue trials for the SEU use. The trials were conducted in France, Germany, Poland, Italy and Spain over six growing seasons in 1983, 1997, 1998, 1999, 2013 and 2014.

The northern use results in a more critical residue situation in the crop and was therefore used to derive a MRL proposal of 0.4 mg/kg for carrot.

1.2.1.3. Courgette

In support of the SEU GAP, eight GAP-compliant residue trials on cucumber and one GAP-compliant residue trial on courgette were provided. The trials were conducted in Italy and Spain over three growing seasons over the years 1996, 1997 and 1999. In accordance with the EU extrapolation rules (European Commission, 2016), the applicant proposed to combine the available residue data on cucumber and courgettes and to extrapolate the results to courgettes. The number and quality of the trials are sufficient to support the proposed extrapolation and to derive a MRL proposal of 0.03 mg/kg for courgettes.

1.2.2. Magnitude of residues in rotational crops

Carrots, tomatoes and courgettes 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

New studies to investigate the effect of processing on the magnitude of residues according to the residue definitions in processed tomato products have been submitted in the framework of the current application (Portugal, 2016). Tomatoes were processed into juice, puree, canning and ketchup.

The studies demonstrated that except for puree, other processing techniques such as juicing, peeling and canning lead to a reduction of the residues in the processed product. Due to a loss of the water content in puree and ketchup, the residue is concentrated. Processing factors were derived for juice, puree, ketchup and canned tomato and are summarised in Appendix B.1.2.3. These processing factors for tomato are proposed for the inclusion in Annex VI of Regulation (EC) No 396/2005.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for carrot and courgette, but not for tomato (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on carrot and courgette resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Carrot culls may be used for feed purposes. Hence, it was necessary to update the previous livestock dietary burden which was calculated in the framework of the MRL review (EFSA, 2015b) to estimate whether the residues of fluazifop-P in carrot from the intended use would have an impact on the existing livestock dietary exposure. As the livestock dietary burden calculated in the MRL review did not consider several feed items (sugar beet dried pulp/ensiled pulp/molasses, lupin seed meal, dried pulp of potato, potato process waste, soybean hulls) and new processing factors (for apple pomace and citrus dried pulp) according to the latest OECD methodology (OECD, 2013), it has been updated in the framework of the current assessment. The updated livestock dietary burden results in a higher exposure from the one in the MRL review for poultry (0.274 mg/kg body weight (bw) per day against 0.099 mg/kg bw per day) and for ruminants (0.596 mg/kg bw per day, against 0.259 mg/kg bw per day). Further, the main contributing commodities are different (soybean hulls and sugar beet tops).
The input values for the exposure calculations for livestock (EFSA, 2015b), are presented in Appendix D. The results of the dietary burden calculation are presented in Appendix B.2 and demonstrated that the calculated dietary burdens exceeded the trigger values for all livestock species. Although the livestock exposure is driven by the existing uses and the new use of fluazifop-P on carrot would not have significant impact on the estimated exposure, the use of the new OECD methodology triggers the recalculation of the MRLs for product of animal origin. Furthermore, during the MRL review a gap was identified on the lack of a sufficiently validated analytical method for animal commodities.

2.1. Nature of residues and methods of analysis in livestock

2.1.1. Nature of residues in livestock

Metabolism studies in livestock (lactating goats and laying hens) with the variant fluazifop-P-butyl have been assessed previously in the framework of the EU pesticides peer review and the MRL review (France, 2010, EFSA, 2012, 2015b). The highest total residue levels were observed in ruminant liver and kidney, and in eggs and poultry fat, and were shown to be principally constituted of fluazifop and its conjugates (50–74% of the TRR, except in goat liver 20–25% of the TRR). Unchanged fluazifop-P-butyl was detected in trace levels in poultry liver only (0.7% of TRR). Other minor components were identified but not considered relevant. Metabolic patterns between goats and hens were found to be similar and no significant difference was observed compared to the rat metabolism (EFSA, 2015b).

2.1.2. Method of analysis in products of animal origin

An analytical method using gas chromatography with mass spectrometry (GC–MS) was validated for the enforcement of the residue definition with an LOQ of 0.01 mg/kg in muscle, fat, liver, kidney, milk and eggs (France, 2010). This method is also supported by independent laboratory validation (ILV). However, the method was validated for only one fragment ion and the efficiency of the derivatisation, extraction and hydrolysis steps were not demonstrated. Further validation of the method is therefore still required.

2.1.3. Stability of residues in products of animal origin

Stability of total fluazifop was demonstrated at −20°C for a period of 12 months in bovine muscle, fat, liver, kidney, milk and in poultry eggs (France, 2010).

2.1.4. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the toxicological significance of metabolites and/or degradation products, the capabilities of enforcement analytical methods the following residue definitions for products of animal origin were proposed:

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

The residue is not fat-soluble.

The residue definition set in Regulation (EC) No 396/2005 for enforcement is set as fluazifop-P (sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop) and is considered as having identical meaning.

2.2. Magnitude of residues in livestock

Feeding studies with lactating cows and laying hens were assessed previously (France, 2010). In ruminants (0.028, 0.108 and 0.445 mg/kg bw per day) and in hens (0.021, 0.124 and 0.553 mg/kg bw per day) different dose levels were tested. All samples were stored in compliance with the conditions for which storage stability was demonstrated in Section 2.1.3, and a decline of residues during storage of the samples is therefore not expected. Samples were analysed in compliance with the proposed residue definitions for animal commodities. The results were used to propose MRLs and risk assessment values for ruminant, poultry and swine products.
## 2.2.1. Proposed MRLs

The proposed MRLs and risk assessment values for livestock were derived according to the OECD guidance which was agreed upon at the European level (OECD, 2013). The overview of the study results used to derive the risk assessment values and the MRL proposals are summarised in Appendix B.2.2. According to the OECD guidance, MRLs and risk assessment values derived from cattle feeding study data can be extrapolated to all ruminants (e.g. goats and sheep), and other animals such as horses, pigs and rabbits.

## 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. ADI and 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.

### 3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for carrots and courgettes assessed in this application in accordance with the internationally agreed methodology (EFSA, 2007). The calculations were based on the highest residue (HR) derived from supervised field trials, the HRs or supervised trials median residue (STMR) (milk and milk products) for certain products of animal origin derived using the updated methodology (OECD, 2013). The complete list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for any the crops assessed in this application (see Appendix B.3).

### 3.2. Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level (EFSA, 2015b). EFSA updated the calculation with the relevant STMR values derived from the residue trials submitted in support of this MRL application for carrot and courgette and the STMRs for certain products of animal origin derived using the updated methodology (OECD, 2013). In addition, for pumpkin seed the STMR value derived in the previous EFSA opinion published after the MRL review was used as an input value (EFSA, 2016). The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake was in the range of 1–42% of the ADI. 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.

EFSA concluded that the long-term intake of residues resulting from the existing uses of fluazifop-P and the intended new uses of fluazifop-P on carrots and courgettes and the products of animal origin under consideration is unlikely to present a risk to consumer health.

## Conclusions and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for carrot and courgettes.

For tomato, a data gap was identified which precluded the derivation of a MRL proposal due to an insufficient number of trials.

As the use in carrots is relevant for animal feeding, the livestock dietary burdens were reassessed according to the latest OECD methodology. The assessment outcome is driven by the existing uses while the new use of fluazifop-P on carrot does not have a significant impact on the estimated maximum livestock exposure. The new MRLs proposed for products of animal origin are resulting from the assessment with the new methodology and this was highlighted for risk manager consideration.

Adequate analytical methods for enforcement are available to control the residues in carrots and courgettes in line with the residue definition for enforcement. Sufficiently validated analytical methods for enforcement are still not available for animal products.
Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the intended uses of flazifop-P on carrots and courgettes according to the reported agricultural practices and the products of animal origin under consideration is unlikely to present a risk to consumer 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
CF conversion factor for enforcement to risk assessment residue definition
DAR draft assessment report
DAT days after treatment
DM dry matter
EC emulsifiable concentrate
EMS evaluating Member State
GAP Good Agricultural Practice
GC–MS gas chromatography with mass spectrometry
HPLC high-performance liquid chromatography
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 Member States
MS/MS tandem mass spectrometry detector
NEU northern Europe
NOAEL no observed adverse effect level
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SEU southern Europe
STMR supervised trials median residue
TMDI theoretical maximum daily intake
TRR total radioactive residue
WHO World Health Organization
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | FG or I\(^{(a)}\) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)\(^{(d)}\) | Remarks |
|-----------------------|-------------------------|------------------|-----------------------------------|-------------|-----------------|-----------------------------|------------------|----------|
|                       |                         |                  |                                   | Type\(^{(b)}\) | Conc. a.s. | Method | Range of growth stages & season\(^{(c)}\) | Number min-max | Interval between application (min) | L product/ha | Water L/ha min-max | g a.s./ha min-max |          |
| Carrot                | NEU                     | F                | Annual and perennial grasses      | EC 125 g/L  | Foliar | –     | 1 | – | 0.75-2 | 100-400 | 93.75-250 | 49 | – |
| Carrot                | SEU                     | F                | Annual and perennial grasses      | EC 125 g/L  | Foliar | –     | 1 | – | 0.625-2.5 | 100-400 | 78.125-312.5 | 28 | – |
| Tomato                | SEU                     | F                | Annual and perennial grasses      | EC 125 g/L  | Foliar | Preflowering before flower bud visible (<BBCH 51) | 1 | – | 0.625-2.5 | 100-400 | 78.125-312.5 | \(^{(e)}\) | – |
| Courgette             | SEU                     | F                | Annual and perennial grasses      | EC 125 g/L  | Foliar | –     | 1 | – | 0.625-2.5 | 100-400 | 78.125-312.5 | 28 | – |

NEU: northern European Union; SEU: southern European Union; MS: Member State; EC: emulsifiable concentrate; a.s.: active substance.

\(^{(a)}\): 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.

\(^{(c)}\): 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.

\(^{(e)}\): Determined by growth stage at last application.
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

| Crop groups (available studies) | Crop(s) | Application(s) | Sampling (DAT) |
|--------------------------------|---------|----------------|---------------|
| **Primary crops** | | | |
| Fruit crops | Grapes | Soil, 670 + 160 g a.s./ha | 14, 30 |
| Root crops | Carrot | Foliar, 1 × 250 g a.s./ha | 45 |
| | | Foliar, 1 × 500 g a.s./ha | 45 |
| | Sugar beet | Foliar, 1 × 250 g a.s./ha | 90 |
| | | Foliar, 1 × 500 g a.s./ha | 90 |
| Leafy crops | Celery | Foliar, 2 × 420 g a.s./ha | 30 |
| | Lettuce | Foliar, 1 × 450 g a.s./ha | 27 |
| Pulses/oilseeds | Soya bean | Foliar, 1 × 560 g a.s./ha | BBCH 61 & Maturity |
| | | Foliar, 560 × 211 g a.s./ha | Maturity |
| | Cotton | Foliar, 1 × 450 g a.s./ha | 27 |

Studies on grapes, celery and soya beans were carried out with fluazifop-P-butyl, labelled on both the phenyl and pyridyl moieties.

Studies on lettuce and cotton were carried out with fluazifop-butyl (R and S enantiomers separately), labelled on the phenyl moiety.

Studies on carrots and sugar beet included 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) (France, 2010; EFSA, 2012).

| Crop groups (available studies) | Crop(s) | Application(s) | PBI (DAT) |
|--------------------------------|---------|----------------|-----------|
| **Rotational crops** | | | |
| Root/tuber crops | Carrot | Soil, 1 × 470 g a.s./ha | 30 |
| | | Soil, 1 × 970 g a.s./ha | 90, 270 |
| Leafy crops | Lettuce | Soil, 1 × 470 g a.s./ha | 30 |
| | | Soil, 1 × 970 g a.s./ha | 90, 270 |
| Cereal (small grain) | Wheat | Soil, 1 × 470 g a.s./ha | 30 |
| | | Soil, 1 × 970 g a.s./ha | 90, 270 |

All crops: C14-phenyl and C14-pyridinyl fluazifop-P (France, 2010; EFSA, 2012).

| Conditions | Investigated? |
|------------|---------------|
| Pasteurisation (20 min, 90°C, pH 4) | No |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | No |
| Sterilisation (20 min, 120°C, pH 6) | No |

Investigations under severe hydrolytic conditions used in the analytical enforcement methods (EFSA, 2015b).

PBI: plant back interval; DAT: days after treatment; a.s.: active substance.
Can a general residue definition be proposed for primary crops?  
Yes

Rotational crop and primary crop metabolism similar?  
Yes. Although compound X was found to be much more predominant in rotational crops, this compound is not more toxic than the parent compound and residue levels observed in rotational crop field trials were very low

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

Conversion factor (monitoring to risk assessment)  
Not applicable

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)  
Matrices with high water content, high oil content, high acid content and dry matrices: HPLC–MS/MS, 0.01 mg/kg, and highly specific (France, 2014). ILV available. Analytical method is not available for hops, herbal infusions and spices (EFSA, 2012)

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity   | T (°C) | Stability (months/years) |
|-----------------------------------|----------|-------------|--------|-------------------------|
| **Fluazifop-butyl**               | High water content | Sugar beet  | −18    | 12 months               |
|                                   |          | Fresh beans | −18    | 12 months               |
|                                   |          | Cauliflower | −18    | 9 months                |
|                                   |          | Tomatoes    | −18    | 4 months                |
|                                   | High oil content | Oilseed rape | −18   | 9 months                |
|                                   | High acid content | Strawberries | −18  | 9 months                |
| **Fluazifop-P-butyl**             | High water content | Onions     | −18    | 28 months               |
|                                   |          | Potatoes    | −18    | 18 months               |
|                                   |          | Lettuce     | −18    | 18 months               |
|                                   |          | Cabbage     | −18    | 18 months               |
|                                   |          | Tomatoes    | −18    | 18 months               |
|                                   | High oil content | Soya bean   | −18    | 18 months               |
|                                   | Dry/high protein | Dry beans  | −18    | 18 months               |

Findings for fluazifop-P-butyl can be applied to the sum of all constituent isomers of fluazifop, its esters and its conjugates. Residue is also considered stable for 18 months in acidic commodities, spices, hops and herbal infusions. 

Source: France (2010), EFSA (2015a).
B.1.2. Magnitude of residues in plants

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

| Crop                     | Region/Indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments (OECD calculations) | MRL proposals (mg/kg) | HR\(_{\text{OECD}}\)\(^{(b)}\) (mg/kg) | STMR\(_{\text{OECD}}\)\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|--------------------------|--------------------------|-----------------------------------------------------------------|-------------------------------|----------------------|----------------------------------------|----------------------------------------|--------|
| Carrots                  | NEU                      | 0.02, 03 × 0.03, 2 × 0.06, 0.08, 0.24                            | NEU use more critical         | 0.4                  | 0.24                                   | 0.05                                   | 1      |
|                          | SEU                      | 2 × 0.02; 2 × 0.03, < 0.04, < 0.05, 0.05, 2 × 0.07, 0.19         |                              | MRL\(_{\text{OECD}}\) = 0.26 | 0.3                                    | 0.19                                   | 0.05   |
| Cucumbers, Courgettes    | SEU                      | Cucumbers: 6 × < 0.01, 0.01, 0.02 Courgettes: < 0.01             | Data set on cucumbers already assessed (EFSA, 2015b). Residue data combined and extrapolated to courgettes | MRL\(_{\text{OECD}}\) = 0.02 | 0.03                                   | 0.02                                   | 0.01   |
| Tomatoes                 | SEU                      | 0.05\(^{(e)}\)                                                 | Number of trials insufficient to derive a MRL proposal |                      |                                        |                                        |        |

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development.

(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 according to the residue definition for monitoring.

(c): Supervised trials median residue according to the residue definition for monitoring.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment

(e): Mean of replicate trial.
### B.1.2.2. Residues in succeeding crops

**Confined rotational crop study (quantitative aspect)**

Measurable residues of fluazifop-P or fluazifop-P-butyl are not expected in any rotational crop but the study indicated some potential for Compound X to occur at measurable levels in all rotational crops, except carrot roots.

Source: EFSA, 2012

**Field rotational crop study**

Rotational crop field trials were submitted with wheat, lettuce and carrot (rotated with oilseed rape treated at 375 g a.s./ha, or with bare soils treated at 375–475 g a.s./ha of fluazifop-P-butyl, plant back intervals of 1, 2, 4 and 6 months). Residue levels of total fluazifop and total Compound X (free and conjugated) were below the limit of quantification in all crops, except carrot foliage where Compound X amounted to 0.03–0.13 mg/kg. However, Compound X did not raise any particular toxicological concerns and no measurable levels of relevant residues are expected to occur in rotational crops.

Source: EFSA, 2012

### B.1.2.3. Processing factors

| Processed commodity | Number of valid studies | Processing factor (PF) | CF<sub>P</sub>(a) |
|---------------------|-------------------------|------------------------|-----------------|
|                     |                         | Individual values      | Median PF       |                 |
| **Robust processing factors (sufficiently supported by data)** | | | | |
| Tomato, juice       | 3                       | 0.49; 0.64; 0.79       | 0.64            | 1               |
| Tomato, puree       | 3                       | 1.36; 2.04; 2.80       | 2.06            | 1               |
| Tomato, paste/ketchup | 3                  | 2.10; 2.10; 3.07       | 2.42            | 1               |
| Tomato, washed      | 3                       | 0.43; 0.56; 0.98       | 0.66            | 1               |
| Tomato, canned      | 3                       | 0.50; 0.51; 0.97       | 0.66            | 1               |
| **Indicative processing factors (limited data set)** | | | | |
| Tomato, peeled      | 2                       | 0.41; 0.71             | 0.56            | 1               |

(a): Conversion factor for risk assessment in the processed commodity is the same as derived from the raw commodities.

### B.2. Residues in livestock

| Relevant groups | Dietary burden expressed in mg/kg bw per day | Most critical commodity(a) | Trigger exceeded (Y/N) | Previous assessment maximum burdens(c) (mg/kg bw per day) |
|-----------------|---------------------------------------------|-----------------------------|------------------------|----------------------------------------------------------|
|                 | Median (b) Maximum | Median (b) Maximum (b) | Beef | Soybean; hulls | Y | 0.259 |
| Cattle (all diets) | 0.153 | 0.203 | 6.4 | 8.5 | 4.5 | Dairy | Sugar beet; tops | Y |
| Cattle (dairy only) | 0.093 | 0.175 | 2.4 | 4.5 | 4.5 | Dairy | Sugar beet; tops | Y |
| Sheep (all diets) | 0.517 | 0.596 | 12.2 | 14.0 | 14.0 | Lamb | Soybean; hulls | Y |
| Sheep (ewe only) | 0.392 | 0.453 | 11.8 | 13.6 | 13.6 | Ewe | Soybean; hulls | Y |
| Swine (all diets) | 0.191 | 0.223 | 6.2 | 7.7 | 7.7 | Finishing | Soybean; hulls | Y | 0.215 |
| Poultry (all diets) | 0.238 | 0.274 | 3.5 | 4.0 | 4.0 | Layer | Soybean; hulls | Y | 0.10 |
### Relevant groups

| Relevant groups | Dietary burden expressed in | Previous assessment maximum burdens (mg/kg bw per day) |
|----------------|-----------------------------|------------------------------------------------------|
|                | mg/kg bw per day            |                                                      |
|                | Median | Maximum | Median | Maximum | Most critical commodity | Trigger exceeded (Y/N) |
| Poultry (layer only) |       |         |       |         |                        |                       |
|                | 0.238 | 0.274   | 3.5   | 4.0     | Layer                  | Y                      |

bw: body weight; DM: dry matter.
(a): Calculated for the maximum dietary burden.
(b): The highest dietary burdens expressed in mg/kg DM result from swine, breeding.
(c): EFSA (2015b).

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

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

| Livestock (available studies) | Animal | Dose (mg/kg bw/day) | Duration (days) | N rate/comment |
|-------------------------------|--------|---------------------|-----------------|---------------|
| Laying hen                    | 0.84   | 10                  | 3.1 N rate      |
| Lactating goat                | 0.28   | 7                   | 1.4 N rate (beef) |
|                               |        |                     | 1.6 N rate      |

All studies were carried out with fluazifop-P-butyl, labelled on both the phenyl and pyridyl moieties
France (2010)

- Time needed to reach a plateau concentration in milk and eggs (days)
  - Milk: 48 h
  - Eggs: 24 h
- Metabolism in rat and ruminant similar (Yes/No)
  - Yes
- Animal residue definition for monitoring (RD-Mo)
  - Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop
- Animal residue definition for risk assessment (RD-RA)
  - Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop
- Conversion factor (monitoring to risk assessment)
  - Not applicable
- Fat soluble residues (Yes/No)
  - No
- Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)
  - Muscle, fat, liver, kidney, milk and eggs: GC–MS, LOQ 0.01 mg/kg (France, 2010)
  - Confirmatory method missing: only one fragment ion was validated and efficiency of the hydrolysis step was not demonstrated
  - ILV available

#### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (months/years) |
|-------------------------------------|--------|-----------|--------|-------------------------|
|                                     | Cow    | Muscle    | −20    | 12 months               |
|                                     | Fat    | −20       | 12 months|
|                                     | Liver  | −20       | 12 months|
|                                     | Kidney | −20       | 12 months|
|                                     | Milk   | −20       | 12 months|
| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (months/years) |
|-------------------------------------|--------|-----------|--------|-------------------------|
|                                     | Hen    | Egg       | ~20    | 12 months               |

Study performed with fluazifop. Since the analytical method included a hydrolytic step, findings can be applied to the sum of all constituent isomers of fluazifop, its esters and its conjugates.

Source: France, 2010

### B.2.2. Magnitude of residues in livestock

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

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF<sup>(c)</sup> |
|------------------|-----------------------------------------------|-----------------------|----------------------|-------------------|
|                  | Mean, Highest                                 | STMR<sup>(a)</sup> (mg/kg), HR<sup>(b)</sup> (mg/kg) |                      |                   |
| Cattle (all diets) |                                              |                       |                      |                   |
| Muscle           | 0.02, 0.02                                   | 0.01<sup>(g)</sup>    | 0.01<sup>(g)</sup>   | 0.01<sup>*</sup>  |
| Fat              | 0.02, 0.02                                   | 0.02                  | 0.03                | 0.04             |
| Liver            | 0.02, 0.03                                   | 0.03                  | 0.05                | 0.05             |
| Kidney           | 0.02, 0.02                                   | 0.04                  | 0.06                | 0.06             |
| Cattle (dairy only) |                                              |                       |                      |                   |
| Milk             | 0.04, 0.06                                   | 0.04                  | 0.07                | 0.07             |
| Sheep (all diets) |                                              |                       |                      |                   |
| Muscle           | 0.02, 0.02                                   | 0.02<sup>(g)</sup>    | 0.03                | 0.03             |
| Fat              | 0.04, 0.06                                   | 0.04                  | 0.07                | 0.08             |
| Liver            | 0.03, 0.03                                   | 0.03                  | 0.04                | 0.04             |
| Kidney           | 0.09, 0.13                                   | 0.11                  | 0.17                | 0.2              |
| Sheep (dairy only) |                                              |                       |                      |                   |
| Milk             | 0.14, 0.18                                   | 0.12                  | 0.14                | 0.15             |
| Swine (all diets) |                                              |                       |                      |                   |
| Muscle           | 0.02, 0.02                                   | 0.01<sup>(g)</sup>    | 0.01<sup>(g)</sup>   | 0.01<sup>*</sup>  |
| Fat              | 0.02, 0.02                                   | 0.02                  | 0.03                | 0.04             |
| Liver            | 0.02, 0.03                                   | 0.04                  | 0.05                | 0.06             |
| Kidney           | 0.02, 0.02                                   | 0.04                  | 0.06                | 0.07             |
| Poultry (all diets) |                                              |                       |                      |                   |
| Muscle           | 0.02, 0.02                                   | 0.03                  | 0.04                | 0.04             |
| Fat              | 0.02, 0.02                                   | 0.03                  | 0.04                | 0.04             |
| Liver            | 0.02, 0.04                                   | 0.04                  | 0.08                | 0.09             |
| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF(c) |
|------------------|-----------------------------------------------|-----------------------|----------------------|-------|
|                  | Mean | Highest | STMR(a) (mg/kg) | HR(b) (mg/kg) |               |           |
| Poultry (layer only) |          |          |                      |               |           |
| Egg              | 0.02 | 0.02    | 0.03               | 0.03          | 0.03      | 1       |

STMR: supervised trials median residue; HR: highest residue; bw: body weight.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): Mean residue level, recalculated at the 1N rate for the median dietary burden.
(b): The mean residue level in milk and the highest residue levels in eggs and tissues were recalculated at the 1N rate for the maximum dietary burden.
(c): CF: conversion factor for risk assessment.
(d): Closest feeding level and N dose rate related to the maximum dietary burden.
(e): Only the milk samples collected from day 3 to day 28 were considered (plateau level).
(f): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
(g): Alternative value based on expert judgement.

### B.3. Consumer risk assessment

**ARfD**

|                | 0.017 mg/kg bw (EFSA, 2012) |
|----------------|-------------------------------|

Highest IESTI, according to EFSA PRIMo

| Commodity | % of ARfD |
|-----------|-----------|
| Carrot    | 89.5%     |
| Milk and milk products: Cattle | 29.2%     |
| Milk and milk products: Goat | 17.1%     |
| Courgettes | 5.5%     |
| Poultry: Meat | 2.7%     |
| Remaining products: < 2.5% of ARfD |

Assumptions made for the calculations

The calculation is based on the highest residue levels expected in raw agricultural commodities and the products of animal origin for which a MRL change is proposed.

**ADI**

|                | 0.01 mg/kg bw per day (EFSA, 2012) |
|----------------|-----------------------------------|

Highest IEDI, according to EFSA PRIMo

| Commodity | % of ADI |
|-----------|----------|
| Carrot    | 1.3%     |
| Milk and milk products, cattle | 11.7     |
| Milk and milk products, goat | 11.7     |

Assumptions made for the calculations

The calculation is based on the median residue levels derived for raw agricultural commodities for the crops under consideration and the products of animal origin for which a MRL change is proposed, for poppy seeds (art 10 issued after the MRL review) and for the authorised uses assessed in the MRL review. The contributions of commodities where a GAP was reported in the framework of the MRL review and the MRL application on poppy seeds were not included in the calculation.
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity      | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------------|----------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 213020            | Carrots        | 0.3                     | 0.4                     | The MRL proposal reflects the most critical residue situation of the NEU use. No consumer health concern was identified |
| 231010            | Tomatoes       | 0.01*                   | --                      | The submitted data are insufficient to derive a MRL proposal                           |
| 232030            | Courgettes     | 0.01*                   | 0.03                    | The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified |
| 1011010           | Swine muscle   | 0.02                    | 0.01*                   | Risk manager consideration required. Lower MRL resulting from use of the new OECD methodology |
| 1011030           | Swine liver    | 0.03                    | 0.06                    | Risk manager consideration required. Triggered by the new OECD methodology            |
| 1011040           | Swine kidney   | 0.06                    | 0.07                    | Risk manager consideration required. Triggered by the new OECD methodology            |
| 1012010           | Bovine muscle  | 0.02                    | 0.01*                   | Risk manager consideration required. Lower MRL resulting from use of the new OECD methodology |
| 1012030           | Bovine liver   | 0.03                    | 0.05                    | Risk manager consideration required. Triggered by the new OECD methodology            |
| 1012040           | Bovine kidney  | 0.07                    | 0.06                    | Risk manager consideration required. Triggered by the new OECD methodology            |
| 1013010           | Sheep muscle   | 0.02                    | 0.03                    | Risk manager consideration required. Triggered by the new OECD methodology            |
| 1013020           | Sheep fat tissue | 0.04                | 0.08                    | Risk manager consideration required. Triggered by the new OECD methodology            |
| 1013030           | Sheep liver    | 0.03                    | 0.04                    | Risk manager consideration required. Triggered by the new OECD methodology            |
| 1013040           | Sheep kidney   | 0.07                    | 0.2                     | Risk manager consideration required. Triggered by the new OECD methodology            |
| 1014010           | Goat muscle    | 0.02                    | 0.03                    | Extrapolated from sheep. Risk manager consideration required. Triggered by the new OECD methodology |
| 1014020           | Goat fat tissue | 0.04                | 0.08                    | Extrapolated from sheep. Risk manager consideration required. Triggered by the new OECD methodology |
| 1014030           | Goat liver     | 0.03                    | 0.04                    | Extrapolated from sheep. Risk manager consideration required. Triggered by the new OECD methodology |
| 1014040           | Goat kidney    | 0.07                    | 0.2                     | Extrapolated from sheep. Risk manager consideration required. Triggered by the new OECD methodology |
| 1015010           | Equine muscle  | 0.02                    | 0.01*                   | Extrapolated from bovine. Risk manager consideration required. Lower MRL resulting from use of the new OECD methodology |
| 1015030           | Equine liver   | 0.03                    | 0.05                    | Extrapolated from bovine. Risk manager consideration required. Triggered by the new OECD methodology |

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

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| Code<sup>(a)</sup> | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|------------------|-----------------|-------------------------|-------------------------|----------------------------------------------------------------------------------------|
| 1015040          | Equine kidney   | 0.07                    | 0.06                    | Extrapolated from bovine Risk manager consideration required Lower MRL resulting from use of the new OECD methodology |
| 1016010          | Poultry muscle  | 0.02                    | 0.04                    | Risk manager consideration required. Triggered by the new OECD methodology             |
| 1016020          | Poultry fat tissue | 0.02                 | 0.04                    | Risk manager consideration required. Triggered by the new OECD methodology             |
| 1016030          | Poultry liver   | 0.04                    | 0.09                    | Risk manager consideration required. Triggered by the new OECD methodology             |
| 1020010          | Milk cattle     | 0.08                    | 0.07                    | Risk manager consideration required Lower MRL resulting from use of the new OECD methodology |
| 1020020          | Milk sheep      | 0.08                    | 0.15                    | Risk manager consideration required. Triggered by the new OECD methodology             |
| 1020030          | Milk goat       | 0.08                    | 0.15                    | Extrapolated from sheep Risk manager consideration required. Triggered by the new OECD methodology |
| 1020040          | Milk horse      | 0.08                    | 0.07                    | Extrapolated from bovine Risk manager consideration required Lower MRL resulting from use of the new OECD methodology |
| 1030010          | Birds eggs      | 0.02                    | 0.03                    | Risk manager consideration required. Triggered by the new OECD methodology             |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; OECD: Organisation for Economic Co-operation and Development.

*: 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)**

### Flauzifop-P

| Pesticide Residue Intake Model (PRIMo) | Status of the active substance | Code no. | LOQ (mg/kg bw): Proposed LOQ: | ADI (mg/kg bw per day): | ARfD (mg/kg bw): |
|----------------------------------------|-------------------------------|----------|--------------------------------|-------------------------|-----------------|
|                                        | Approved                      | Code no. |                                | 0.01                    | 0.017           |
|                                        | Toxological and points        |          |                                |                         |                 |
|                                        | ADI (mg/kg bw per day):       |          |                                |                         |                 |
|                                        | Source of ADI:                |          |                                | EFSA                    | EFSA            |
|                                        | Year of evaluation:           |          |                                | 2012                    | 2012            |
|                                        | No of diets exceeding ADI:    |          |                                |                         |                 |
|                                        |                                  |          |                                |                         |                 |
|                                        | Highest calculated TMDI values in % of ADI | Commodity/ group of commodities | 2nd contributor to MS diet | 3rd contributor to MS diet |
|                                        | TMDI range in % of ADI:       |          |                                |                         |                 |
|                                        | minimum – maximum             |          |                                |                         |                 |
| WHO Cluster diet B                     | 31.3% Sugar beet             |          |                                |                         |                 |
| WHO Cluster diet F                     | 26.6% Soybean                |          |                                |                         |                 |
| WHO Cluster diet D                     | 21.7% Sugar beet (dest)      |          |                                |                         |                 |
| NL child                               | 11.7% Milk and milk products Cattle |          |                                |                         |                 |
| WHO Cluster diet D                     | 10.3% Soybean                |          |                                |                         |                 |
| UK Infant                              | 9.6% Sugar beet (dest)       |          |                                |                         |                 |
| PT General population                  | 11.4% Soybean                |          |                                |                         |                 |
| WHO national European diet             | 2.9% Rapeseed                |          |                                |                         |                 |
| DE adult                               | 5.7% Milk and milk products Cattle |          |                                |                         |                 |
| IE adult                               | 3.5% Linseed                 |          |                                |                         |                 |
| ES infant                              | 5.0% Milk and milk products Cattle |          |                                |                         |                 |
| SE general population/50th percentile | 5.0% Milk and milk products Cattle |          |                                |                         |                 |
| FR toddler                             | 3.0% Beans (with pods)       |          |                                |                         |                 |
| UK vegetable                           | 3.6% Sugar beet (dest)       |          |                                |                         |                 |
| NL general                             | 2.6% Milk and milk products Cattle |          |                                |                         |                 |
| ES adult                               | 2.0% Milk and milk products Cattle |          |                                |                         |                 |
| FR population                          | 1.1% Milk and milk products Cattle |          |                                |                         |                 |
| LT autumn                              | 1.6% Milk and milk products Cattle |          |                                |                         |                 |
| IT toddler                             | 0.5% Beans                   |          |                                |                         |                 |
| OK adult                               | 0.7% Carrots                 |          |                                |                         |                 |
| IT adult                               | 0.4% Beans (with pods)       |          |                                |                         |                 |
| PL general population                  | 0.3% Potatoes                |          |                                |                         |                 |
| FI adult                               | 0.3% Soybean (dest)          |          |                                |                         |                 |
| OK adult                               | 0.2% Carrots                 |          |                                |                         |                 |

### Chronic risk assessment – refined calculations

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

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**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Flauzifop-P is unlikely to present a public health concern.
### Acute risk assessment/children – refined calculations

The acute risk assessment is based on the ARfD.

#### Highest % of ARfD/ADI Commodities

| Commodity                          | pTMRL (mg/kg) | threshold MRL (mg/kg) |
|------------------------------------|---------------|-----------------------|
| Carrots                           | 89.5          | 0.24/-                |
| Milk and milk products: Cattle     | 29.2          | 0.04/-                |
| Milk and milk products: Goat       | 17.1          | 0.12/-                |
| Courgettes                        | 5.5           | 0.02/-                |
| Poutry Meat                       | 2.7           | 0.04/-                |
| Bovine Liver                      | 1.6           | 0.02/-                |
| Bovine Kidney                     | 1.3           | 0.02/-                |
| Milk and milk products: Sheep      | 1.3           | 0.02/-                |
| Bovine Meat                       | 0.8           | 0.01/-                |
| Bovine Meat                       | 0.5           | 0.01/-                |
| Bovine Kidney                     | 0.5           | 0.01/-                |
| Bovine Kidney                     | 0.4           | 0.01/-                |
| Bovine Kidney                     | 0.3           | 0.01/-                |

#### No of critical MRLs (IESTI 1)

| Commodity                          | pTMRL (mg/kg) | threshold MRL (mg/kg) |
|------------------------------------|---------------|-----------------------|
| Carrots                            |               |                       |
| Milk and milk products: Cattle     |               |                       |
| Milk and milk products: Goat       |               |                       |
| Courgettes                         |               |                       |
| Poutry Meat                        |               |                       |
| Bovine Liver                       |               |                       |
| Bovine Kidney                      |               |                       |
| Milk and milk products: Sheep      |               |                       |
| Bovine Meat                        |               |                       |
| Bovine Meat                        |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |

### Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

#### Highest % of ARfD/ADI Commodities

| Commodity                          | pTMRL (mg/kg) | threshold MRL (mg/kg) |
|------------------------------------|---------------|-----------------------|
| Carrots                            | 89.5          | 0.24/-                |
| Milk and milk products: Cattle     | 29.2          | 0.04/-                |
| Milk and milk products: Goat       | 17.1          | 0.12/-                |
| Courgettes                         | 5.5           | 0.02/-                |
| Poutry Meat                        | 2.7           | 0.04/-                |
| Bovine Liver                       | 1.6           | 0.02/-                |
| Bovine Kidney                      | 1.3           | 0.02/-                |
| Milk and milk products: Sheep      | 1.3           | 0.02/-                |
| Bovine Meat                        | 0.8           | 0.01/-                |
| Bovine Meat                        | 0.5           | 0.01/-                |
| Bovine Kidney                      | 0.5           | 0.01/-                |
| Bovine Kidney                      | 0.4           | 0.01/-                |
| Bovine Kidney                      | 0.3           | 0.01/-                |

#### No of critical MRLs (IESTI 2)

| Commodity                          | pTMRL (mg/kg) | threshold MRL (mg/kg) |
|------------------------------------|---------------|-----------------------|
| Carrots                            |               |                       |
| Milk and milk products: Cattle     |               |                       |
| Milk and milk products: Goat       |               |                       |
| Courgettes                         |               |                       |
| Poutry Meat                        |               |                       |
| Bovine Liver                       |               |                       |
| Bovine Kidney                      |               |                       |
| Milk and milk products: Sheep      |               |                       |
| Bovine Meat                        |               |                       |
| Bovine Meat                        |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |
| Bovine Kidney                      |               |                       |

### 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.

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*The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.*

**pTMRL: provisional temporary MRL.**

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Modification of existing MRLs for fluazifop-P in various products of plant and animal origin

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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                | Input value (mg/kg)   | Comment    |
| Fodder (mangel) beet\(^\text{a}\) | 0.10                  | STMR                   | 0.32                  | HR         |
| Tops sugar beet\(^\text{a}\)   | 0.47                  | STMR                   | 1.7                   | HR         |
| Leaves head cabbage\(^\text{a}\) | 0.09                  | STMR                   | 0.56                  | HR         |
| Culls carrot                    | 0.05                  | STMR                   | 0.24                  | HR         |
| Culls potato\(^\text{a}\)      | 0.01                  | STMR                   | 0.1                   | HR         |
| Root Swede\(^\text{a}\)        | 0.03                  | STMR                   | 0.29                  | HR         |
| Root turnip\(^\text{a}\)       | 0.03                  | STMR                   | 0.29                  | HR         |
| Dry seed bean\(^\text{a}\)     | 0.61                  | STMR                   | 0.61                  | HR         |
| Seed lupin\(^\text{a}\)        | 0.61                  | STMR                   | 0.61                  | HR         |
| Dry seed field pea\(^\text{a}\)| 0.61                  | STMR                   | 0.61                  | HR         |
| Seed soybean\(^\text{a}\)      | 3.75                  | STMR                   | 3.75                  | HR         |
| Wet pomace apple\(^\text{a}\)  | 0.15 STMR \times 5    | 0.15 STMR \times 5     |
| Dried pulp sugar beet\(^\text{a}\)| 1.80 STMR \times 18   | 1.80 STMR \times 18    |
| Meal canola (rape seed)\(^\text{a}\)| 3.76 STMR \times 1.6 | 3.76 STMR \times 1.6   |
| Dried pulp citrus\(^\text{a}\) | 0.10 STMR \times 10   | 0.10 STMR \times 10    |
| Meal flaxseed/linseed\(^\text{a}\)| 3.76 STMR \times 1.6 | 3.76 STMR \times 1.6   |
| Meal lupin seed\(^\text{a}\)   | 0.67 STMR \times 1.1  | 0.67 STMR \times 1.1   |
| Process waste potato\(^\text{a}\)| 0.20 STMR \times 20   | 0.20 STMR \times 20    |
| Dried pulp potato\(^\text{a}\) | 0.38 STMR \times 38   | 0.38 STMR \times 38    |
| Meal rape\(^\text{a}\)         | 3.76 STMR \times 1.6  | 3.76 STMR \times 1.6   |
| Meal soybean\(^\text{a}\)      | 4.88 STMR \times 1.3  | 4.88 STMR \times 1.3   |
| Hulls soybean\(^\text{a}\)     | 48.75 STMR \times 13  | 48.75 STMR \times 13   |
| Meal sunflower\(^\text{a}\)    | 0.04 STMR \times 2    | 0.04 STMR \times 2     |

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

\(^{\text{a}}\): STMR, HR and PF taken from MRL review (EFSA, 2015b).

#### D.2. Consumer risk assessment

| Commodity       | Chronic risk assessment | Acute risk assessment |
|-----------------|-------------------------|-----------------------|
|                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment   |
| Carrots         | 0.05 STMR               | 0.24 HR               |
| Courgettes      | 0.01 STMR               | 0.02 HR               |
| Swine muscle    | 0.01 STMR               | 0.01 HR               |
| Swine liver     | 0.04 STMR               | 0.05 HR               |
| Swine kidney    | 0.04 STMR               | 0.06 HR               |
| Bovine muscle   | 0.01 STMR               | 0.01 HR               |
| Bovine liver    | 0.03 STMR               | 0.05 HR               |
| Bovine kidney   | 0.04 STMR               | 0.06 HR               |
| Sheep muscle    | 0.02 STMR               | 0.03 HR               |
| Sheep fat tissue| 0.04 STMR               | 0.07 HR               |
| Sheep liver     | 0.03 STMR               | 0.04 HR               |
| Sheep kidney    | 0.11 STMR               | 0.17 HR               |
| Goat muscle     | 0.02 STMR               | 0.03 HR               |
| Goat fat tissue | 0.04 STMR               | 0.07 HR               |
| Commodity                  | Chronic risk assessment | Acute risk assessment |
|---------------------------|-------------------------|-----------------------|
| Goat liver                | 0.03 STMR               | 0.04 HR               |
| Goat kidney               | 0.11 STMR               | 0.17 HR               |
| Equine muscle             | 0.01 STMR               | 0.01 HR               |
| Equine liver              | 0.03 STMR               | 0.05 HR               |
| Equine kidney             | 0.04 STMR               | 0.06 HR               |
| Poultry muscle            | 0.03 STMR               | 0.04 HR               |
| Poultry fat tissue        | 0.03 STMR               | 0.04 HR               |
| Poultry liver             | 0.04 STMR               | 0.08 HR               |
| Milk cattle               | 0.04 STMR               | 0.04 STMR             |
| Milk sheep                | 0.12 STMR               | 0.12 STMR             |
| Milk goat                 | 0.12 STMR               | 0.12 STMR             |
| Milk horse                | 0.04 STMR               | 0.04 STMR             |
| Bird eggs chicken         | 0.03 STMR               | 0.03 HR               |
| Pumpkin seed              | 1.60 STMR (EFSA, 2016)  | Acute risk assessment conducted only for the products for which a MRL is proposed |
| Products of plant origin, except spring onions, tomatoes, peppers head cabbages, leeks, beans (without pods) cotton seeds | STMR Refer to Table C.2. of the Reasoned opinion on MRL review (EFSA, 2015b) |
| Other commodities of animal origin | MRL Regulation (EU) No 2017/171 |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
*: Indicates that the input value is proposed at the limit of quantification.
### Appendix E – Used compound code(s)

| Code/trivial name     | Chemical name/SMILES notation                                                                 | Structural formula |
|-----------------------|-----------------------------------------------------------------------------------------------|--------------------|
| Fluazifop-P           | (R)-2-\{4-\{5-(trifluoromethyl)-2-pyridyloxy\}phenoxy\}propionic acid \(O=C(O)[C@@H](C)Oc1ccc(cc1)Oc2ccc(cn2)C(F)(F)F\) | ![Structural formula for Fluazifop-P](image) |
| Fluazifop             | (RS)-2-\{4-\{5-(trifluoromethyl)-2-pyridyloxy\}phenoxy\}propionic acid \(O=C(O)(C)Oc1ccc(cc1)Oc2ccc(cn2)C(F)(F)F\) | ![Structural formula for Fluazifop](image) |
| Fluazifop-butyl       | butyl \((RS)-2-\{4-\{5-(trifluoromethyl)-2-pyridyloxy\}phenoxy\}propionate \(O=C(OCCCC)C(C)Oc1ccc(cc1)Oc2ccc(cn2)C(F)(F)F\) | ![Structural formula for Fluazifop-butyl](image) |
| Code/trivial name | Chemical name/SMILES notation                                                                 | Structural formula |
|------------------|-----------------------------------------------------------------------------------------------|-------------------|
| Fluazifop-P-butyl| butyl (R)-2-\{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy\}propionate                         | ![Structural formula](image) |
|                  | \(O=\text{C}(\text{OCCC})[[\text{C}@@\text{H}](\text{C})\text{O}c1\text{ccc}2\text{ccc}3\text{cn}2)\text{C}(\text{F})(\text{F})\text{F}\) |                   |
| Compound III R118106 | (RS)-2-(4-hydroxyphenoxy)propanoic acid                                                      | ![Structural formula](image) |
| Compound X       | 5-(trifluoromethyl)-2(1H)-pyridinone                                                          | ![Structural formula](image) |

SMILES: simplified molecular-input line-entry system.