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REASONED OPINION

Reasoned opinion on the modification of the existing maximum residues levels (MRLs) for fluazifop-P in several commodities[1]

European Food Safety Authority[2]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, hereafter referred to as the evaluating Member State (EMS-DE), received an application from LELF to modify the existing MRLs for the active substance fluazifop-P in lupins and linseeds. Afterwards, France, hereafter referred to as the evaluating Member State (EMS-FR), received an application from Syngenta Agro SAS to modify, according to the above regulation, the existing MRLs for fluazifop-P in several commodities, including lupins and linseeds. Amendments of the existing MRLs of fluazifop-P in several vegetables, pulses, oilseeds and in roots of herbal infusions (dried) and roots or rhizome of spices were proposed. Both EMS-DE and EMS-FR drafted evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005 which were submitted to the European Commission and forwarded to EFSA. According to EFSA, data are sufficient to derive MRL proposals of 0.4 mg/kg on celeriac, 0.5 mg/kg on Jerusalem artichokes, 1.5 mg/kg on peas (without pods), 0.9 mg/kg on globe artichokes, 4 mg/kg on beans, lentils, lupins (pulses), herbal infusions (dried roots) and spices (roots or rhizome), 9 mg/kg on linseeds, poppy seeds and safflower seeds. Adequate analytical enforcement methods are available to control the residues of fluazifop-P in the crops under consideration. Based on the risk assessment results, EFSA concludes that the proposed uses of fluazifop-P on celeriac, Jerusalem artichokes, peas (without pods), globe artichokes, beans, lentils, lupins, linseeds, poppy seeds, safflower seeds, herbal infusions (dried roots) and spices (roots and rhizome) is unlikely to pose a consumer health risk.

KEY WORDS

fluazifop-P, various crops, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, herbicide

[1] On request from the European Commission, Question No EFSA-Q-2014-00137 and EFSA-Q-2014-00603, approved on 17 March 2015.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, hereafter referred to as the evaluating Member State (EMS-DE), received an application from LELF to modify the existing MRLs for the active substance fluazifop-P in lupins and linseeds. Afterwards, France, hereafter referred to as the evaluating Member State (EMS-FR), received an application from Syngenta Agro SAS to modify, according to the above regulation, the existing MRLs for fluazifop-P in several commodities, including lupins and linseeds. Amendments of the existing MRLs of fluazifop-P in several vegetables, pulses, oilseeds and in roots of herbal infusions (dried) and roots or rhizome of spices were proposed. Both EMS-DE and EMS-FR drafted evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005 which were submitted to the European Commission and forwarded to EFSA on 27 February 2014 and 1 September 2014, respectively. For efficiency EFSA combined both applications in one reasoned opinion.

EFSA bases its assessment on the evaluation reports, the Draft Assessment Report (DAR) and its Additional Reports, the revised Commission Review Report on fluazifop-P and the EFSA conclusions on the peer review of the pesticide risk assessment of the active substance fluazifop-P.

The toxicological profile of fluazifop-P was assessed in the framework of the peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an ADI of 0.01 mg/kg bw per day and an ARfD of 0.017 mg/kg bw for fluazifop.

The metabolism of fluazifop-P in plants has been studied in the leafy, root and oilseed/pulse crop groups after foliar applications. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as "sum of all constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers)". For the use on the crops under consideration, EFSA concludes that the metabolism of fluazifop-P in primary crops is sufficiently addressed and that the derived residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.4 mg/kg on celeriac, 0.5 mg/kg on Jerusalem artichokes, 1.5 mg/kg on peas (without pods), 0.9 mg/kg on globe artichokes, 4 mg/kg on beans, lentils, lupins (pulses), herbal infusions (dried roots) and spices (roots or rhizome), 9 mg/kg on linseeds, poppy seeds and safflower seeds. Adequate analytical enforcement methods are available to control the residues of fluazifop-P in the crops under consideration at the validated LOQ of 0.01-0.05 mg/kg.

Standard hydrolysis studies investigating the nature of fluazifop-P residues in processed commodities were not provided in the framework of the peer review, but based on the available information, it was concluded that the active substance is not expected to be degraded beyond fluazifop (acid). Thus, the same residue definition as for raw agricultural commodities (RAC) is applicable. The following processing factors, recommended for inclusion in Annex VI of Regulation (EC) No 396/2005, were derived from studies on peas submitted in the framework of this MRL application:

- Pea without pods/washed	0.95	- Dry pea/washed	1.8
- Pea without pods/cooked	0.90	- Dry pea/cooked	0.78
- Pea without pods/canned	0.76	- Dry pea/canned	0.39

The occurrence of fluazifop-P residues in rotational crops was investigated in the framework of the peer review. Based on the available information, EFSA confirms the conclusion of the peer review that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on the crops under consideration according to the proposed Good Agricultural Practice (GAP).

Having regards to the wide range of existing uses of fluazifop-P on plant commodities used as feed items and considering that the contribution of the crops under consideration in this MRL application to the overall animal intakes will be negligible, EFSA proposes that the assessment of the potential carry-

over of residues in animal commodities is performed in the framework of the Article 12 MRL review under Regulation (EC) No 396/2005, when all authorised uses of fluazifop-P and residue data are available.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic exposure, EFSA used the supervised trials median residue (STMR) derived from the trials conducted on the crops under consideration. Additional STMRs and processing factors (PF), proposed in the framework of the peer review or in the framework of the establishment of temporary MRLs under Regulation (EC) No 396/2005, were also included in these calculations. The validity of these input values could not be verified by EFSA, but a more realistic assessment will be available by end 2015, when full information on authorised uses and additional data will be available to EFSA under the on-going Article 12 MRL review. Based on the available information, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The maximum chronic intake was estimated to be 88 % of the ADI (Dutch child).

Using the internationally agreed standard methodology based on the highest residue (HR) or the STMR for bulk commodities (i.e. pulses) no acute consumer risk was identified, the maximum acute exposure being 63 % of the ARfD of for globe artichokes (Spanish child). However, it is noted that for beans, lentils and safflowers, calculations exceed the ARfD when residues are considered at the proposed MRL levels. Nevertheless, an effective exceedance of the acute toxicological reference value can be excluded with an acceptable probability.

EFSA concludes that the proposed uses of fluazifop-P on celeriac, Jerusalem artichokes, peas (without pods), globe artichokes, beans, lentils, lupins, linseeds, poppy seeds, safflower seeds, herbal infusions (dried roots) and spices (roots and rhizome) is unlikely to pose a consumer health risk.

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

SUMMARY TABLE

Code number (a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Fluazifop-P-butyl (fluazifop acid (free and conjugate))				
0213030	Celeriac	0.3	0.4	NEU (optional, 0.5 mg/kg by extrapolation from NEU trials on carrots).
0213050	Jerusalem artichokes	0.2	0.5	NEU (extrapolated from NEU trials on carrots).
0260040	Peas (without pods)	1	1.5	NEU and SEU.
0270050	Globe artichokes	0.5	0.9	NEU and SEU
0300010	Beans	2	4	NEU and SEU (trials on peas and beans).
0300020	Lentils	2	4	Extrapolation from NEU and SEU trials on peas and beans.
0300040	Lupins	2	4	
0401010	Linseeds	3	9	Extrapolation from NEU and SEU trials on oilseed rape.
0401030	Poppy seeds	5	9	
0401110	Safflower seeds	0.2	9	
0633000	H. infusion (dried roots)	0.1	4	Extrapolation from NEU trials on carrots (applying a default dehydration factor of 8).
0840000	Spices (roots or rhizome)	0.1	4	

(a): According to Annex I of Regulation (EC) No 396/2005.

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that 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/EEC,[4] repealed by Regulation (EC) No 1107/2009,[5] shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Germany, hereafter referred to as the evaluating Member State (EMS-DE), received an application from the Ländliche Entwicklung, Landwirtschaft und Flurneuordnung (LELF)[6] to modify the existing MRLs for the active substance fluazifop-P in lupins and linseeds. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

France, hereafter referred to as the evaluating Member State (EMS-FR), received an application from the company Syngenta Agro SAS[7] to modify the existing MRLs for fluazifop-P in several commodities, including lupins and linseeds. This application was notified to the European Commission and EFSA and was subsequently evaluated in accordance with Article 8 of the Regulation.

After completion, both evaluation reports were submitted to the European Commission who forwarded the applications, the evaluation reports and the supporting dossiers to EFSA on 27 February 2014 and 1 September 2014, respectively.

The applications were included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00137 and EFSA-Q-2014-00603 and the following subjects:

Fluazifop-P – Application to modify the existing MRLs in lupins and linseeds.

Fluazifop-P – Application to modify the existing MRLs in various crops.

The EMS-DE concluded that an amendment of the existing MRL of 2 mg/kg for lupins was not required and proposed a MRL of 3 mg/kg for the intended use on linseeds. The EMS-FR proposed to raise the existing MRLs of fluazifop-P in Jerusalem artichokes and celeriac to 0.5 mg/kg, in herbal infusions (dried roots) and spices (roots or rhizome) to 4 mg/kg, in fresh peas without pods to 2 mg/kg, in globe artichokes to 1.5 mg/kg, in beans, lentils, lupins (pulses) to 5 mg/kg and linseeds, poppy seeds and safflower seeds to 15 mg/kg.

EFSA proceeded with the assessment of the applications and the evaluation reports as required by Article 10 of the Regulation. Considering that both applications refer to the modification of existing MRLs for active substance fluazifop-P, to optimise the evaluation work, EFSA addressed the MRL applications in one reasoned opinion.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.
[5] 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.
[6] Ländliche Entwicklung, Landwirtschaft und Flurneuordnung (LELF), Steinplatz 1, 15806 Zossen OT Wünsdorf, Germany.
[7] Syngenta Agro SAS, Avenue des Prés 1, CS 10537, 78286 Guyancourt, France.

TERMS OF REFERENCE

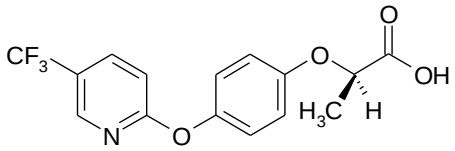
In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinions are 27 May 2014 and 1 December 2014.

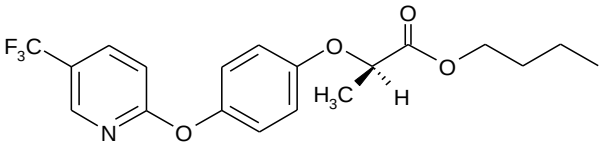
THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Fluazifop-P is the ISO common name for (*R*)-2-{4-[5-(trifluoromethyl)-2- pyridyloxy]phenoxy} propionic acid (IUPAC). Fluazifop-P-butyl is a variant ester of the active substance fluazifop-P, evaluated in the peer review. The chemical structure of both compounds is reported below.



Fluazifop-P

Molecular weight: 327.4 g/mol



Fluazifop-P-butyl

Molecular weight: 383.4 g/mol

Fluazifop-P belongs to the class of aryloxyphenoxypropionate herbicides (commonly called "FOPs"), such as diclofop, quizalofop-P and propaquizafop. They are absorbed by foliage and translocated into the plant. They interfere with the synthesis of fatty acids by competitively binding to the enzyme acetyl-coenzyme A carboxylase (ACCase).

Fluazifop-P was evaluated according to the transitory measures of Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC, with France designated as rapporteur Member State (RMS). It has been approved by Commission Implementing Regulation (EU) No 788/2011[8] which entered into force on 1 January 2012 and included in Commission Implementing Regulation (EU) No 540/2011[9] for use as herbicide in orchards (basal application) with one application every year. Then, an amendment to the restriction of the approval to allow other uses as herbicide has been granted by Commission Implementing Regulation (EU) No 201/2013[10]. The representative uses evaluated in the peer review were a single foliar application on pome fruits, peas without pods, beans with pods, pulses, potatoes and rapeseeds. The Draft Assessment Report (DAR) of fluazifop-P and its Additional Reports have been peer reviewed by EFSA (EFSA, 2010, 2012).

[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 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC. OJ L 203, 06.08.2011, p. 21–25.

[9] Commission Implementing Regulation (EU) No 540/2011 of 23 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, 11.06.2011, p. 1–186.

[10] 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, 09.03.2013, p. 6–9.

The EU MRLs for fluazifop-P are established in Annex IIIA of Regulation (EC) No 396/2005. Codex Alimentarius has not established CXLs for fluazifop-P or its variant fluazifop-P-butyl.

The details of the intended GAPs for fluazifop-P are given in Appendix A. It is pointed out that the intended uses on peas without pods and on pulses are comparable to the representative NEU uses assessed during the peer review (EFSA, 2012).

ASSESSMENT

EFSA bases its assessment on the evaluation reports submitted by the EMSs (Germany, 2013; France, 2014a), the Draft Assessment Report (DAR) and its Additional Reports (France, 2007, 2010, 2012), the revised Commission Review Report on fluazifop-P (EC, 2013) and the EFSA conclusions on the peer review of the pesticide risk assessment of the active substance fluazifop-P (EFSA, 2010, 2012). 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[11] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 2011; OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

The analytical methods assessed during the peer review were accepted for the monitoring of total fluazifop residues (as sum of isomers, its esters and its conjugates) in plant commodities. Both the capillary gas chromatography equipped with mass spectrum detection (GC-MSD) and the liquid chromatography coupled with tandem mass spectrometry or ultraviolet detection (LC-MS/MS or LC-UV) quantifications were considered validated at LOQs ranging from 0.01 to 0.05 mg/kg, depending on the matrix (EFSA, 2010, 2012).

In the framework of one of the MRL applications, the EMS-FR assessed a LC-MS/MS and its Independent Laboratory Validation (ILV). Data were validated in high water, high acid and high oil content and dry/protein commodities at the LOQ of 0.01 to 0.05 mg/kg, depending on the matrix. This method includes a hydrolysis step which covers all constituents of the residue definition (France, 2014a). No validation data were presented demonstrating that the proposed method is also suitable for roots of herbal infusions and spices as required by the current guidance document (EC, 2010b).

Since the commodities under consideration belong to the group of high water (artichokes, celeriac, peas), high oil (linseed, poppy seed, safflower seed) content and dry/protein (pulses) commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs are available. Further validation data on the suitability of the proposed analytical method on the roots of herbal infusions and spices would be required. However, due to the fact that they are very minor crops (EC, 2011), the lack of validation data is of minor relevance.

1.2. Methods for enforcement of residues in food of animal origin

The analytical method assessed during the peer review (GC-MSD) was accepted for the control and monitoring of fluazifop residues in milk, eggs, liver, muscle, fat and kidney with an LOQ validated at 0.01 mg/kg (EFSA, 2010, 2012). Nevertheless, it should be confirmed that the method covers all compounds included in the residue definition (France, 2014a).

EFSA concludes that an analytical method for enforcing the proposed MRLs for fluazifop-P in food of animal origin is available. However, confirmation of the compliance to the residue definition is necessary.

[11] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127–175.

2. Mammalian toxicology

The toxicological profile of the active substance fluazifop-P was assessed in the framework of the peer review under Regulation (EC) No 1107/2009 (EFSA, 2012; EC, 2013). The data were sufficient to derive toxicological reference values for fluazifop which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Fluazifop					
ADI	EC	2013	0.01 mg/kg bw per day	2-yr rat with fluazifop acid	100
ARfD	EC	2013	0.017 mg/kg bw	Rat, developmental toxicity with fluazifop-P-butyl, corrected for molecular weight (supported by the 90-d rat study)	100

The metabolite Compound X (5-trifluoromethyl-2(1*H*)-pyridinone), which was observed in the plant and soil metabolism but not in the rat metabolism, was considered of no toxicologically relevance (EFSA, 2012; EC, 2013).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of fluazifop-P in primary crops was investigated after foliar application of the butyl ester in the leafy crop group (celery, lettuce), root crop group (carrot, sugar beet) and pulse/oilseed crop group (soya bean, cotton plant). The details of the studies are reported in the DAR and the EFSA conclusion (France, 2007, 2010; EFSA, 2012). The overview of the metabolism study designs is presented in the table below.

Table 3-1: Summary of available metabolism studies after foliar applications in plants

Crop group	Crops	Application	Sampling[(b)]
Leafy	Celery	Foliar, 2 × 420 g a.s./ha[(a)], 15 days interval	30 DALA
	Lettuce	Foliar, 1 × 450 g a.s./ha, phenyl label	27 DAT
Root	Carrots	Foliar, 1 × 250 g a.s./ha, phenyl label	45 DAT
	Sugar beet	Foliar, 1 ×250 g a.s./ha, phenyl label	90 DAT
Pulses/ oilseeds	Soya bean	Foliar, 1 × 560 g a.s./ha, at BBCH 15 Foliar, 2 × 560 and 210 kg a.s./ha, at BBCH 15 & 69	Forage, maturity Maturity
	Cotton	Foliar, 1 × 450 g a.s./ha, phenyl label	45 DAT

(a): The actual application rate of fluazifop-P-butyl used in the second application was lower: 0.18 kg a.s./ha (phenyl label) and 0.36 kg a.s/ha (pyridyl label).
(b): DALA: day(s) after last application; DAT: day(s) after treatment.

The metabolism of fluazifop-P-butyl showed to be similar in all crops with a rapid degradation of the parent ester to fluazifop, free and conjugated, which was the predominant compound of the total residues (20 to 70 % of the TRR). Minor metabolites, containing either the phenyl or the pyridyl ring, were formed from the hydrolysis of the acid fluazifop. The *R/S* isomer ratio of fluazifop remained unchanged in plants suggesting no enantiomeric conversion (EFSA, 2012).

From these studies the peer review concluded on a residues definition for monitoring and risk assessment as "sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers)". This residue definition is almost similar to the definition set in Regulation (EC) No 396/2005 as "fluazifop-P-butyl (fluazifop acid (free and conjugate)" but with a more precise wording. Although mentioning fluazifop free and conjugate, EFSA cannot verify if all existing MRLs have been really set including all the compounds of the residue definition as established during the peer review.

For the uses on the crops under consideration, EFSA concludes that the metabolism of fluazifop-P is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

a. Jerusalem artichokes, herbal infusions (roots dried) and spices (roots or rhizome).

Nine residue trials on carrots conducted in the United Kingdom according to the proposed NEU GAP (1 × 375 g/ha, PHI 49 days) were submitted to support the intended use by extrapolation. These trials, conducted prior to the Good Laboratory Practice (GLP) requirements, are poorly documented and the description of the analytical method and validation data were not provided. Moreover, results seem inconsistent, as residue levels are all below the LOQ (<0.03 mg/kg) in the seven 1984 trials, while at a levels of 0.21 mg/kg and 0.29 mg/kg in the two 1989 trials.

However, additional trials on carrots conducted in SEU according to a similar GAP (1× 321 g/ha, PHI 28 days) submitted in the framework of the on-going Article 12 MRL review, confirm such an erratic residue profile on carrots. These trials, conducted in 1997 and 1998 according to the requested standards (GLP, validated analytical methods) show the following residue levels in roots: 2 × 0.02; 2 × 0.03, <0.04, <0.05, 0.05, 2 × 0.07 and 0.19 mg/kg (France, 2014b).

Considering that the contribution of the crops under considerations to the overall consumer intake is limited and that the results of the NEU 1984/1989 trials are confirmed by the SEU 1997/1998 trials conducted according to the requested standards, EFSA proposes to derive a MRL of 0.5 mg/kg from the NEU trials conducted on carrots. This MRL is extrapolated to Jerusalem artichokes. For the groups "herbal infusions (dried roots)" and "spices (roots or rhizome)", since the MRL applies to the dried commodity, a MRL of 4 mg/kg is proposed, considering the residues in carrots (fresh roots) and a default dehydration factor of 8 (based on a dry matter content of 12 % in fresh carrots (FAO, 2009) and of 90 % in dried root).

b. Celeriac

A MRL proposal of 0.4 mg/kg is derived from four NEU residue trials conducted on celeriac in 1997 and 1998. According to the EU guideline (EC, 2011) an extrapolation from residue trials on carrots to celeriac is also possible, and therefore an alternative MRL of 0.5 mg/kg may be proposed for celeriac, by extrapolation from carrots (see point a above).

c. Peas without pods

Seventeen GAP-compliant residue trials (nine NEU and eight SEU) on peas without pods were submitted. All trials were performed over more than two growing seasons and part of them were already assessed to support the representative use during the peer review (EFSA, 2012). Since not significantly different (U-test, 5 %), EFSA combined the NEU and SEU datasets to derive a more robust MRL proposal of 1.5 mg/kg.

d. Globe artichokes

Eight GAP-compliant residue trials (four NEU and four SEU) on globe artichokes were submitted. All were designed as decline trials and performed in various European countries during 2008 and 2009.

Since not significantly different (U-test, 5 %), EFSA combined the NEU and SEU datasets to derive a more robust MRL proposal of 0.9 mg/kg.

e. Beans, lentils, lupins (dry pulses)

Twenty-eight GAP-compliant residue trials (sixteen NEU and twelve SEU) on dry peas and dry beans were submitted. Except one, all trials were already submitted and assessed to support the representative use on pulses during the peer review (EFSA, 2012). Since not significantly different (U-test, 5 %), EFSA combined the NEU and SEU datasets to derive a more robust MRL proposal of 4 mg/kg for beans. Since the GAPs are identical and the number of trials per each region is sufficient, the extrapolation of the residue trials conducted on peas and beans to lentils and lupins is possible (EC, 2011).

It is noted that the residue trials on peas submitted by the EMS-DE and conducted with a less critical GAP (1 × 161 g/ha) result in significant lower residue levels. Therefore, the MRL for lupins is derived from the residue trials on peas conducted with the GAP proposed by the EMS-FR (1 × 375 g/ha).

f. Linseeds, poppy seeds and safflower seeds (oilseeds)

Eighteen GAP-compliant trials on oilseed rapes (ten NEU and eight SEU) were submitted to support an extrapolation to linseeds, poppy seeds and safflower seeds. Except the three 2012 and 2013 trials, all trials were already submitted and assessed during the peer review (EFSA, 2012). Since not significantly different (U-test, 5 %), EFSA combined the NEU and SEU datasets to derive a more robust MRL proposal of 9 mg/kg. Since the GAPs are identical and the number of trials per each region sufficient, the proposed extrapolation to linseeds, poppy seeds and safflower seeds is possible (EC, 2011).

As previously for lupins (see point e above), the residue trials on linseeds submitted by the EMS-DE and conducted with a less critical GAP (1 × 161 g/ha) result in significant lower residue levels. Therefore, the MRL for lupins is extrapolated from the residue trials conducted on rapeseeds according to the GAP proposed by the EMS-FR (1 × 375 g/ha).

The results of the residue trials, the related risk assessment input values (HR, STMR) and the MRL proposals are summarised in Table 3-2.

The storage stability of fluazifop-P in primary crops was investigated during the peer review and residues as total fluazifop were found to be stable at ≤ -18 °C for up to 18 months in matrices with high water and high oil content as well as in dry/protein matrices (EFSA, 2012). No information was available on the six samples of the 1984 trials on carrots. The other residue trial samples were stored (up to 17 months) under conditions for which integrity of the samples was demonstrated, thus EFSA concludes that these residue data are valid with regard to storage stability.

The analytical methods used to analyse the supervised residue trial samples were either accepted during the peer review or considered as sufficiently validated by the EMS-FR. Details on the method used to analyses the six samples from the 1984 trials on carrots and the four samples from the trials on celeriac have not been provided. According to the EMS-FR, all results were expressed as total fluazifop (France, 2014a).

EFSA concludes that the data are sufficient to derive following MRL proposals:[12]

- 0.5 mg/kg Jerusalem artichokes
- 0.4 mg/kg celeriac (optional, 0.5 mg/kg)
- 1.5 mg/kg peas (without pods)

[12] The EMS-FR proposed for certain crops different MRLs, which were derived from the single dataset leading to the higher residues (France, 2014a).

- 0.9 mg/kg globe artichokes
- 4 mg/kg beans, lentils, lupins, herbal infusion (dried roots) and spices (roots or rhizome)
- 9 mg/kg linseeds, poppy seeds and safflower seeds

Table 3-2: Overview of the available residues trials data

Commodity (trial GAP)	**Region** [(a)]	**Individual trial results** (mg/kg)[(b)] (data already submitted and considered in a previous assessment are underlined)	**Comments**[(c)]	**MRL proposal** (mg/kg)	**HR** (mg/kg) [(d)]	**STMR** (mg/kg) [(e)]
Carrots (1 × 375 g/ha, PHI 49 days)	NEU	7 × <0.03; 0.21; 0.29	**Extrapolation to Jerusalem artichokes.** MRL_{OECD}: 0.48/0.5	0.5	0.29	0.03
			Extrapolation to herbal infusions (dried roots) and spices (roots or rhizome) considering a default drying factor of 8.	4.0	2.32	0.24
Celeriac (1 × 375 g/ha, PHI 49 days)	NEU	2 × <0.01; 0.11; 0.17	MRL_{OECD} = 0.39/0.4 (optionally, MRL 0.5 mg/kg by extrapolation from trials on carrots)	0.4 (0.5)	0.17	0.06
Peas (without pods) (1 × 375 g/ha, PHI 35 days)	NEU	<0.03; 0.18; 0.19; 0.26; 0.27; 0.41; 0.47; 0.48; 0.8	NEU and SEU datasets not significantly different (U-test; 5 %). MRL derived from the merged data MRL_{OECD} = 1.4/1.5	1.5	1.0	0.26
	SEU	0.03; 0.04; 0.07; 0.09; 0.2; 0.36; 0.37; 1.0				
Artichokes (1× 250 g/ha, PHI 42 days)	NEU	2 × <0.01; 0.02; 0.11	NEU and SEU datasets not significantly different (U-test; 5 %). MRL derived from the merged data MRL_{OECD} = 0.8/09	0.9	0.53	0.02
	SEU	2 × <0.01; 0.13; 0.53				
Beans, peas (pulses) (1× 375 g/ha, PHI 90 days)	NEU	0.02; 0.08; 0.09; 0.10; 0.11; 0.18; 0.26; 0.34; 0.57; **0.61**; **0.64**; **0.72**; 0.79; **0.97**; 1.1; 2.8	Results from trials on beans are in **bold.** NEU and SEU datasets not significantly different (U-test; 5 %). MRL derived from the merged data MRL_{OECD} = 3.7/4 **Extrapolation to lentils, lupins (dry pulses**).	4	3.1	0.22
	SEU	**2 × <0.01**; **<0.05**; 0.06; 0.08; **0.09**; **0.19**; 0.20; **0.23**; 0.54; **1.8**; **3.1**				
Peas (pulses) (1 × 161 g/ha)	NEU	3 × <0.05; 2 × 0.19, 0.22	GAP proposed by EMS-DE less critical. MRL for **lupins** derived from GAP proposed by EMS-FR.	-		
Rapeseeds (1 × 375 g/ha, PHI 90 days)	NEU	2 × 1.5; 1.7; 2.1; 2.2; 2.4; 2.6; 2.9; 3.2; 3.3	NEU and SEU datasets not significantly different (U-test; 5 %). MRL derived from the merged data MRL_{OECD} = 8.5/9 **Extrapolation to linseed, poppy seed, safflower.**	9	6.3	2.25
	SEU	0.36; 0.49; 2 × 2.3; 3.52; 4.23; 4.7; 6.3				
Linseeds (1 × 161 g/ha)	NEU	0.1; 0.52, 0.58; 0.61, 0.89, 1.5	GAP proposed by EMS-DE less critical. MRL for linseeds derived by extrapolation from rapeseeds.	-		

(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 (EC, 2011).
(b): Individual residue levels considered for MRL calculation are reported in ascending order.
(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values).
(d) STMR: Median value of the individual trial results according to residue definition for risk assessment.
(e): HR: Highest value of the individual trial results according to the residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

It should be noted that the nature of fluazifop-P residues in processed commodities has not been investigated under standard hydrolysis conditions, according the current requirements. It was however agreed in the conclusion of the peer review that fluazifop-P-butyl is not expected to be degraded beyond fluazifop (acid) and therefore that same residue definition as for the RAC is applicable to processed commodities (EFSA, 2012). The need for further hydrolysis studies will be considered in the framework of the Article 12 MRL review.

The applicant submitted two processing studies investigating the magnitude of fluazifop-P residues in processed fresh peas without pods and dry peas. Samples were collected in two trials conducted at exaggerated application rates (about 2 or 5 times). Raw samples were washed and either cooked or canned. Both, balance and follow-up studies were carried out in each study. The storage of samples prior to analysis did not exceed the demonstrated storage stability period (France, 2014a). Proposed processing factors (PFs) are reported in Table 3-3.

In addition, PFs derived on rapeseeds during the peer review (EFSA, 2012) and considered in the consumer risk assessment (see section 4) by both EMSs (Germany, 2013; France, 2014a) are reminded in this table.

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF[(a)]	Comments (individual PF values)
Enforcement residue definition: sum of all constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers) (EFSA, 2012)			
Pea without pods/washed	6	0.95	0.76; 0.91; 0.94; 0.96; 0.99; 1.06
Pea without pods/cooked	4	0.90	0.83; 0.86; 0.94; 1.21
Pea without pods/canned	4	0.76	0.57; 0.71; 0.81; 0.93
Dry pea/washed	2	1.8	1.45; 2.15
Dry pea/cooked	4	0.78	2 × 0.75; 0.80; 0.85
Dry pea/canned	4	0.39	0.33; 0.34; 0.44; 0.7
Rapeseed/press cake	2	1.79	PFs derived during the peer review (EFSA, 2012).
Rapeseed/crude oil	2	0.10	
Rapeseed/refined oil	2	0.05	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

EFSA recommends the inclusion of the PFs derived for fresh and dry processed peas in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

The crops under consideration can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil studies demonstrated that the degradation rate of fluazifop-P is moderate; the maximum DT_{90lab} was 128 days for fluazifop-P-butyl which is above the trigger value of 100 days; the soil metabolite Compound X appeared to be quite persistent, with a maximum DT_{90} of 255 days (EFSA, 2012). Thus, further studies investigating the nature and magnitude of the compound uptake in rotational crops are required (EC, 1997c).

3.1.2.2. Nature of residues

The metabolism of fluazifop-P in rotational crops was assessed during the peer review (EFSA, 2012). Fluazifop-P was intensively degraded and Compound X, the main soil metabolite, was shown to be the predominant component of the residue in rotational crops, due to its uptake from the soil. However, since Compound X was concluded to be of no toxicological relevance (see Section 2), the residue definition for monitoring and risk assessment proposed for primary crops was concluded to be applicable to rotational crops as well (EFSA, 2012).

3.1.2.3. Magnitude of residues

Field crop rotational studies were assessed during the peer review (EFSA, 2012). After application to bare soil or to oilseed rapes as primary crop of fluazifop-P-butyl at a dose rate of 375 or 475 g/ha, residue levels of total fluazifop and Compound X (free and conjugated) were below the limit of quantification in lettuce, carrot root and wheat, planted at the plant back intervals of 1, 2, 4 and 6 months.

Considering that the maximum application rate proposed for the crops under consideration in this MRL application is 375 g/ha, EFSA is of the opinion that the conclusions of the peer review are applicable and that significant residue levels are unlikely to occur in rotational crops, provided that fluazifop-P is applied according to the proposed GAPs.

3.2. Nature and magnitude of residues in livestock

Since pulses and oilseed by-products are normally fed to livestock, the nature and magnitude of fluazifop-P residues in livestock should be considered (EC, 1996).

Based on the goat and hen metabolism studies, the residue definitions for monitoring and risk assessment were proposed as the sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers) in the conclusion of the peer review (EFSA, 2012).

Having regards to the wide range of existing uses of fluazifop-P on plant commodities used as feed items and considering that the contribution of the crops under consideration in this MRL application to the overall animal intakes will be negligible, EFSA proposes that the comprehensive assessment of the potential carry-over of residues into products of animal origin and the modification of the existing MRLs is performed in the framework of Article 12 MRL review under Regulation (EC) No 396/2005 when all residue data are available. Article 12 MRL review is expected to be finalised by end 2015.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population[13] (EFSA, 2007).

For the calculation of the chronic exposure, EFSA used the STMR as derived from the residue trials on the crops under consideration (see Table 3-2). To refine the calculation, EFSA used the STMR peer review derived for beans with pods, dry peas and potatoes (EFSA, 2012), assuming that they represent the current uses as the existing MRLs correspond to the MRLs derived for the representative uses. By analogy, EFSA disregarded the STMR derived for pome fruits and rapeseeds because the MRL proposed for the representative uses are lower than the existing MRLs in Regulation (EC) No

[13] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

396/2005. For the remaining plant and animal commodities, the existing MRLs as listed in Regulation (EC) 839/2008[14] were used as input values.

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the HR or the STMR as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation for celeriac and globe artichokes (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment (Scenario 1)

Commodity	Chronic exposure assessment		Acute exposure assessment	
	value (mg/kg)	**Comment**	**value** (mg/kg)	**Comment**
Risk assessment residue definition: sum of all constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop				
Celeriac	0.06	STMR	0.17	HR
Jerusalem artichokes	0.03	STMR	0.29	HR
Peas without pods	0.26	STMR	1	HR
Globe artichokes	0.02	STMR	0.53	HR
Beans, lentils, lupins (pulses)	0.22	STMR	0.22	STMR
Linseed, poppy seed, safflower	2.25	STMR	2.25	STMR
Herbal infusion (dried roots)	0.24	STMR	2.32	HR
Spices (roots or rhizome)	0.24	STMR	2.32	HR
Beans with pods	0.27	STMR (EFSA, 2012)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Peas (dry)	0.46	STMR (EFSA, 2012)		
Potatoes	0.01	STMR (EFSA, 2012)		
Other commodities of plant and animal origin	MRL	See Regulation (EC) No 839/2008		

With regard to the **long-term exposure**, an exceedance of the ADI was identified for four European diets (**Scenario 1**): 163 % (WHO Cluster E), 141 % (British Toddler), 116 % (WHO Cluster B) and 112 % (WHO Cluster F). The contribution of residues in the crops under consideration in this MRL application to the total consumer exposure accounted for 8 % of the ADI. The existing EU MRLs for rapeseeds, sugar beet and soya beans were identified as the three major contributors to the chronic exposure.

A refined calculation (**Scenario 2**) was focused on the main contributors identified in Scenario 1, considering the STMR and PFs derived in the framework of the establishment of temporary MRLs in Annex III of Regulation (EC) No 396/2005, which were reported to be associated with the temporary MRLs established at national level for soya beans and rapeseeds (EC, 2008). In addition, the yield factor for wine grape was also applied. For rapeseeds, EFSA used the more conservative STMR of 2.91 mg/kg derived from SEU trials (see Table 3-2) since more closely associated to the existing MRL value of 15 mg/kg.

[14] Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products. OJ L 234, 30.08.2008, p. 1–216.

The input values used to refine the chronic dietary exposure calculation are summarised in Table 4-2. It is noted that the validity of these input values could not be verified by EFSA.

Table 4-2: Additional input values for the chronic consumer dietary exposure assessment (Scenario 2)

Commodity	Chronic exposure assessment	
	Input value (mg/kg)	**Comment**
Grapes, wine grape	0.14 (0.2 × 0.7)	MRL × YF[(a)]
Soya beans	0.17 (2.1 × 0.08)	STMR (rapeseed) × PF oil (EC, 2008)
Rapeseeds	0.29 (2.91 × 0.1)	STMR (SEU, see Table 3-2) × PF crude oil (see Table 3-3)
Sugar beet	0.02 (0.5 × 0.04)	MRL × PF oil (EC, 2008)

(a): Consumption in EFSA PRIMo are expressed as wine grapes. A yielding factor of 0.7 is applied to refine the intake calculations, assuming that 100 kg of grapes produce 70 kg of wine.

According to Scenario 2, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 88 % of the ADI (Dutch child).

Taking into account the uncertainties regarding the input values used in the refinement of the consumer risk assessment (Scenario 2) and the lack of detailed information on the approved uses of fluazifop-P, the result of the exposure assessment might underestimate/overestimate the actual consumer exposure. A more realistic consumer risk assessment will be performed in the framework of the on-going Article 12 MRL review, when full information on authorised uses of fluazifop-P and additional residue data will be available to EFSA.

Using the internationally agreed standard methodology based on the HR and the STMR for bulk commodities (pulses) (FAO, 2009), no **acute consumer risk** was identified for the crops under consideration in this MRL application, the maximum acute exposure being 63 % of the ARfD for globe artichokes (Spanish child).

EFSA notes that the short term exposure related to beans (430 %), safflower seeds (195 %) and lentils (145 %) exceed the ARfD if calculations are made using the MRL levels. These exceedances should however be considered as theoretical since the assumptions that residues are present at MRL levels are very conservative. Furthermore, these crops are usually eaten cooked or processed (i.e. as oils). For this reasons, an effective exceedance of the acute toxicological reference value can be excluded with an acceptable probability.

EFSA concludes that the intended use of fluazifop-P on celeriac, Jerusalem artichokes, peas without pods, globe artichokes, beans, lentils, lupins, linseeds, poppy seeds, safflower seeds, herbal infusion (dried roots) and spices (roots or rhizome) is unlikely to pose a consumer health risk.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of fluazifop-P was assessed in the framework of the peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an ADI of 0.01 mg/kg bw per day and an ARfD of 0.017 mg/kg bw for fluazifop.

The metabolism of fluazifop-P in plants has been studied in the leafy, root and oilseed/pulse crop groups after foliar applications. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as "sum of all constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers)". For the use on the crops under

consideration, EFSA concludes that the metabolism of fluazifop-P in primary crops is sufficiently addressed and that the derived residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.4 mg/kg on celeriac, 0.5 mg/kg on Jerusalem artichokes, 1.5 mg/kg on peas (without pods), 0.9 mg/kg on globe artichokes, 4 mg/kg on beans, lentils, lupins (pulses), herbal infusions (dried roots) and spices (roots or rhizome), 9 mg/kg on linseeds, poppy seeds and safflower seeds. Adequate analytical enforcement methods are available to control the residues of fluazifop-P in the crops under consideration at the validated LOQ of 0.01-0.05 mg/kg.

Standard hydrolysis studies investigating the nature of fluazifop-P residues in processed commodities were not provided in the framework of the peer review, but based on the available information, it was concluded that the active substance is not expected to be degraded beyond fluazifop (acid). Thus, the same residue definition as for raw agricultural commodities (RAC) is applicable. The following processing factors, recommended for inclusion in Annex VI of Regulation (EC) No 396/2005, were derived from studies on peas submitted in the framework of this MRL application:

- Pea without pods/washed	0.95	- Dry pea/washed	1.8
- Pea without pods/cooked	0.90	- Dry pea/cooked	0.78
- Pea without pods/canned	0.76	- Dry pea/canned	0.39

The occurrence of fluazifop-P residues in rotational crops was investigated in the framework of the peer review. Based on the available information, EFSA confirms the conclusion of the peer review that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on the crops under consideration according to the proposed Good Agricultural Practice (GAP).

Having regards to the wide range of existing uses of fluazifop-P on plant commodities used as feed items and considering that the contribution of the crops under consideration in this MRL application to the overall animal intakes will be negligible, EFSA proposes that the assessment of the potential carry-over of residues in animal commodities is performed in the framework of the Article 12 MRL review under Regulation (EC) No 396/2005, when all authorised uses of fluazifop-P and residue data are available.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic exposure, EFSA used the supervised trials median residue (STMR) derived from the trials conducted on the crops under consideration. Additional STMRs and processing factors (PF), proposed in the framework of the peer review or in the framework of the establishment of temporary MRLs under Regulation (EC) No 396/2005, were also included in these calculations. The validity of these input values could not be verified by EFSA, but a more realistic assessment will be available by end 2015, when full information on authorised uses and additional data will be available to EFSA under the on-going Article 12 MRL review. Based on the available information, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The maximum chronic intake was estimated to be 88 % of the ADI (Dutch child).

Using the internationally agreed standard methodology based on the highest residue (HR) or the STMR for bulk commodities (i.e. pulses) no acute consumer risk was identified, the maximum acute exposure being 63 % of the ARfD of for globe artichokes (Spanish child). However, it is noted that for beans, lentils and safflowers, calculations exceed the ARfD when residues are considered at the proposed MRL levels. Nevertheless, an effective exceedance of the acute toxicological reference value can be excluded with an acceptable probability.

EFSA concludes that the proposed uses of fluazifop-P on celeriac, Jerusalem artichokes, peas (without pods), globe artichokes, beans, lentils, lupins, linseeds, poppy seeds, safflower seeds, herbal infusions (dried roots) and spices (roots and rhizome) is unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code number (a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Fluazifop-P-butyl (fluazifop acid (free and conjugate))				
0213030	Celeriac	0.3	0.4	NEU (optional, 0.5 mg/kg by extrapolation from NEU trials on carrots).
0213050	Jerusalem artichokes	0.2	0.5	NEU (extrapolated from NEU trials on carrots).
0260040	Peas (without pods)	1	1.5	NEU and SEU.
0270050	Globe artichokes	0.5	0.9	NEU and SEU
0300010	Beans	2	4	NEU and SEU (trials on peas and beans).
0300020	Lentils	2	4	Extrapolation from NEU and SEU trials on peas and beans.
0300040	Lupins	2	4	
0401010	Linseeds	3	9	Extrapolation from NEU and SEU trials on oilseed rape.
0401030	Poppy seeds	5	9	
0401110	Safflower seeds	0.2	9	
0633000	H. infusion (dried roots)	0.1	4	Extrapolation from NEU trials on carrots (applying a default dehydration factor of 8).
0840000	Spices (roots or rhizome)	0.1	4	

(a): According to Annex I of Regulation (EC) No 396/2005.

REFERENCES

EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95-rev.4.

EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.

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

EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.

EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.

EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.

EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.

EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95.

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

EC (European Commission), 2008. Experts meeting Annexes Reg. 396/2005 – May, June, September 2007 and 2nd round 28-31 January 2008. Expert meeting report (unpublished), January, 2008, pp. 80.

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

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

EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9.

EC (European Commission), 2013. Review report for the active substance fluazifop-P. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 17 June 2011 in view of the approval of fluazifop-P as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/11238/2011 rev 4, revised on 1 February 2013, 10 pp.

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2008. Addendum to the reasoned opinion published on 15 March 2007 on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) 396/2005 on maximum residue levels of pesticides in food and feed of plant and animal origin. EFSA Scientific Report (2008) 132r, 1–317, doi:10.2903/j.efsa.2008.132r

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance fluazifop-P. EFSA Journal 2010;8(11):1905, 76 pp. doi:10.2903/j.efsa.2010.1905

EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment of the active substance fluazifop-P. EFSA Journal 2012;10(11):2945, 77 pp. doi:10.2903/j.efsa.2012.2945

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

France, 2007. Draft Assessment Report on the active substance fluazifop-P-butyl prepared by the rapporteur Member State France in the context of the possible inclusion of the active substance in Annex I of Council Directive 91/414/EEC, April, 2007.

France, 2010. Final Addendum to the Draft Assessment Report (DAR) and Additional Report on the active substance fluazifop-P provided by the rapporteur Member State France upon resubmission in the framework of the accelerated procedure as laid down in Commission Regulation (EC) No 33/2008, October, 2010.

France, 2012. Final Addendum to the Additional Report on the active substance fluazifop-P prepared by the rapporteur Member State France as referred to in Regulation (EC) No 1107/2009, September 2012.

France, 2014a. Evaluation report on the modification of MRLs for fluazifop-P in various commodities prepared by the evaluating Member State France (EMS-FR) under Article 8 of Regulation (EC) No 396/2005, 24 June 2014, 96 pp.

France, 2014b. Evaluation report on the review of the existing MRLs for fluazifop-P prepared by the rapporteur member state France under Article 12.1 of Regulation (EC) No 396/2005, September 2014, 125 pp.

Germany, 2013. Evaluation report on the modification of MRLs for fluazifop-P in lupins and linseed prepared by the evaluating Member State Germany (EMS-DE) under Article 8 of Regulation (EC) No 396/2005, 5 November 2013, 29 pp.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues.

APPENDICES

Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	MS NEU SEU or Country	F G I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. a.s. (g/L) (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	inter-val	g as /hL min max	water L/ha min max	g a.s /ha min max		
Celeriac, Jerusalem artic. Root/herbal infu. Roots/spices	NEU	F	weeds	EC	125	broadcast		1				375	49	
Peas without pods (fresh)	NEU	F	weeds	EC	125	broadcast	Pre-flowering (before BBCH 50)	1				375	35	
	SEU													
Globe artichokes	NEU	F	weeds	EC	125	broadcast		1				250	42	
	SEU													
Beans, Lentils	NEU	F	weeds	EC	125	broadcast	Pre-flowering (before BBCH 50)	1				375	90	
	SEU													
Lupins	DE	F	weeds	EC	107	foliar spray	BBCH 13-49	1		50-100	200-400	214	n.a.	Less cGAP
	NEU	F	weeds	EC	125	broadcast	Pre-flowering (before BBCH 50)	1				375	90	
	SEU													
Linseeds	DE	F	weeds	EC	107	foliar spray	Before BBCH 51	1		50-100	200-400	214	n.a.	Less cGAP
	NEU	F	weeds	EC	125	broadcast	By BBCH 50	1				375	90	
	SEU													
Poppy seeds, Safflower seeds	NEU	F	weeds	EC	125	broadcast	By BBCH 50	1				375	90	
	SEU													

Remarks:

(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
(f) All abbreviations used must be explained Method, e.g. high volume spraying, low
(g) volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

Appendix B. Pesticide Residue Intake Model (PRIMo)

SCENARIO 1

Fluazifop-P			
Status of the active substance:	**approved**	Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.017**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
11	163
No of diets exceeding ADI:	4

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
163.1	WHO cluster diet E	89.3	Rape seed	29.0	Soya bean	3.9	Wheat	2.2
141.0	UK Toddler	114.3	Sugar beet (root)	3.9	Wheat	3.4	Apples	0.8
116.4	WHO Cluster diet B	30.3	Soya bean	9.3	Tomatoes	8.5	Wheat	2.9
112.4	WHO Cluster diet F	46.8	Rape seed	32.6	Soya bean	4.0	Milk and milk products: Cattle	2.0
91.1	NL child	29.3	Milk and milk products: Cattle	12.7	Apples	4.7	Wheat	2.9
88.0	DE child	24.1	Apples	14.3	Milk and milk products: Cattle	4.1	Wheat	1.6
83.3	IE adult	10.6	Sweet potatoes	4.0	Brussels sprouts	3.6	Sesame seed	1.8
80.2	UK Infant	50.4	Sugar beet (root)	4.0	Carrots	3.7	Brussels sprouts	1.1
62.2	WHO regional European diet	18.3	Rape seed	4.8	Milk and milk products: Cattle	3.6	Soya bean	2.7
61.6	WHO cluster diet D	18.4	Soya bean	6.5	Wheat	4.7	Milk and milk products: Cattle	1.4
60.5	FR infant	25.7	Milk and milk products: Cattle	7.9	Carrots	5.0	Apples	1.3
48.0	FR all population	18.3	Other oilseeds	8.0	Wine grapes	3.3	Wheat	1.1
47.6	SE general population 90th percentile	12.4	Milk and milk products: Cattle	3.6	Bananas	3.2	Wheat	0.9
47.2	FR toddler	7.3	Carrots	7.1	Spinach	5.2	Apples	2.3
45.6	PT General population	15.3	Soya bean	5.0	Wine grapes	3.9	Wheat	0.5
43.3	ES child	12.5	Milk and milk products: Cattle	4.4	Wheat	2.9	Tomatoes	2.8
36.9	UK vegetarian	18.9	Sugar beet (root)	2.0	Wheat	1.9	Tomatoes	0.3
34.3	IT kids/toddler	6.6	Wheat	6.4	Other oilseeds	4.3	Tomatoes	0.1
33.8	UK Adult	20.0	Sugar beet (root)	2.2	Wine grapes	1.7	Wheat	0.3
33.8	DK child	5.5	Wheat	4.6	Apples	4.4	Rye	0.7
33.5	NL general	6.6	Milk and milk products: Cattle	2.4	Apples	2.1	Wheat	1.5
28.8	IT adult	5.8	Other oilseeds	4.1	Wheat	3.5	Tomatoes	0.1
28.3	ES adult	4.9	Milk and milk products: Cattle	2.4	Tomatoes	2.3	Wheat	1.6
18.6	LT adult	4.0	Milk and milk products: Cattle	3.7	Apples	1.9	Tomatoes	1.3
17.7	PL general population	4.1	Apples	2.6	Tomatoes	1.1	Beetroot	0.3
16.1	DK adult	2.8	Wine grapes	2.0	Wheat	1.6	Apples	0.6
11.3	FI adult	1.3	Tomatoes	1.0	Wheat	1.0	Oranges	0.2

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 11.3 % to 163 % of the ADI.

For 4 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

SCENARIO 2

Fluazifop-P			
Status of the active substance:	**approved**	Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.017**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
11	88
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
87.5	NL child	29.3	Milk and milk products: Cattle	12.7	Apples	4.7	Wheat	2.9
84.5	DE child	24.1	Apples	14.3	Milk and milk products: Cattle	4.1	Wheat	1.6
83.1	IE adult	10.6	Sweet potatoes	4.0	Brussels sprouts	3.6	Sesame seed	1.8
79.6	WHO Cluster diet B	9.3	Tomatoes	8.5	Wheat	4.2	Other tropical root and tuber	3.1
60.5	FR infant	25.7	Milk and milk products: Cattle	7.9	Carrots	5.0	Apples	1.3
47.6	SE general population 90th percentile	12.4	Milk and milk products: Cattle	3.6	Bananas	3.2	Wheat	0.9
47.0	FR toddler	7.3	Carrots	7.1	Spinach	5.2	Apples	2.3
47.0	WHO cluster diet E	3.9	Wheat	3.2	Wine grapes	3.0	Milk and milk products: Cattle	2.3
46.0	FR all population	18.3	Other oilseeds	8.0	Wine grapes	3.3	Wheat	1.1
43.2	ES child	12.5	Milk and milk products: Cattle	4.4	Wheat	2.9	Tomatoes	2.8
40.7	WHO cluster diet D	6.5	Wheat	4.7	Milk and milk products: Cattle	3.0	Tomatoes	1.5
40.6	WHO regional European diet	4.8	Milk and milk products: Cattle	3.3	Tomatoes	3.0	Wheat	2.7
35.0	WHO Cluster diet F	4.0	Milk and milk products: Cattle	3.6	Wheat	2.0	Tomatoes	2.0
34.0	IT kids/toddler	6.6	Wheat	6.4	Other oilseeds	4.3	Tomatoes	0.1
33.7	DK child	5.5	Wheat	4.6	Apples	4.4	Rye	0.7
32.5	NL general	6.6	Milk and milk products: Cattle	2.4	Apples	2.1	Wheat	1.5
31.8	UK Infant	4.0	Carrots	3.7	Brussels sprouts	3.1	Apples	3.1
31.1	UK Toddler	4.6	Sugar beet (root)	3.9	Wheat	3.4	Apples	5.4
30.7	PT General population	5.0	Wine grapes	3.9	Wheat	2.7	Tomatoes	0.5
28.6	IT adult	5.8	Other oilseeds	4.1	Wheat	3.5	Tomatoes	0.1
28.2	ES adult	4.9	Milk and milk products: Cattle	2.4	Tomatoes	2.3	Wheat	1.6
18.7	UK vegetarian	2.0	Wheat	1.9	Tomatoes	1.6	Wine grapes	1.1
18.6	LT adult	4.0	Milk and milk products: Cattle	3.7	Apples	1.9	Tomatoes	1.3
17.4	PL general population	4.1	Apples	2.6	Tomatoes	1.1	Beetroot	0.3
15.9	DK adult	2.8	Wine grapes	2.0	Wheat	1.6	Apples	0.6
14.6	UK Adult	2.2	Wine grapes	1.7	Wheat	1.3	Tomatoes	1.1
10.8	FI adult	1.3	Tomatoes	1.0	Wheat	1.0	Oranges	0.2

Conclusion:

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

Acute risk assessment /children - refined calculations

Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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

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

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

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
62.6	Globe artichokes	0.53 / -	55.3	Celeriac	0.17 / -	33.1	Globe artichokes	0.53 / -	23.6	Globe artichokes	0.53 / -
55.3	Celeriac	0.17 / -	48.8	Safflower	2.25 / -	22.4	Peas (without pods)	1 / -	22.4	Peas (without pods)	1 / -
48.8	Safflower	2.25 / -	48.2	Peas (without	1 / -	16.8	Celeriac	0.17 / -	16.8	Celeriac	0.17 / -
48.2	Peas (without pods)	1 / -	44.7	Globe artichokes	0.53 / -	9.7	Jerusalem artichokes	0.29 / -	8.1	Beans	0.22 / -
23.7	Beans	0.22 / -	23.7	Beans	0.22 / -	8.1	Beans	0.22 / -	7.8	Jerusalem artichokes	0.29 / -
14.2	Linseed	2.25 / -	14.2	Linseed	2.25 / -	6.3	Linseed	2.25 / -	6.3	Linseed	2.25 / -
13.1	Poppy seed	2.25 / -	13.1	Poppy seed	2.25 / -	4.2	Poppy seed	2.25 / -	4.2	Poppy seed	2.25 / -
8.0	Lentils	0.22 / -	8.0	Lentils	0.22 / -	4.0	Lentils	0.22 / -	4.0	Lentils	0.22 / -
1.1	Ginger	2.32 / -	1.1	Ginger	2.32 / -	0.13	Horseradish, root	2.32 / -	0.13	Horseradish, root spices	2.32 / -
0.25	Turmeric (Curcuma)	2.32 / -	0.25	Turmeric	2.32 / -						
No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		---			**No of commodities for which ARfD/ADI is exceeded:**		---		
		*****)**					*****)**		
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		

*) 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

***) pTMRL: provisional temporary MRL for unprocessed commodity

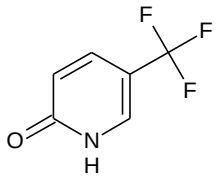
Conclusion:

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

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

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

Appendix C. List of metabolites and related structural formula

Code/Trivial name	Chemical name*	Structural formula*
Compound X, (Compound 10; R154719)	5-trifluoromethyl-2(1*H*)-pyridinone	

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DT90	period required for 90 % dissipation (define method of estimation)
EC	emulsifiable concentrate
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
GLP	Good Laboratory Practice
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
i.e.	that is (id est, Latin)
ILV	independent laboratory validation
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MSD	mass spectrometry detector
MS/MS	tandem mass spectrometry
NEU	northern European Union

OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residue Overview File
RAC	raw agricultural commodity
RMS	rapporteur Member State
SEU	southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultraviolet (detector)
WHO	World Health Organization
YF	yield factor
yr	year