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Modification of the existing maximum residue levels for fluxapyroxad in grapes and potatoes

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Netherlands received an application from BASF SE to modify the existing maximum residue levels (MRLs) for the active substance fluxapyroxad in grapes and potatoes. In order to accommodate for the intended uses of fluxapyroxad, the Netherlands proposed to raise the existing MRLs to 0.5 mg/kg in table and wine grapes and 0.07 mg/kg in potatoes. The Netherlands 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 EFSA. According to EFSA, the submitted supervised residue trials are sufficient to derive MRL proposals of 0.5 mg/kg on table and wine grapes and 0.07 mg/kg on potatoes. Alternatively, risk managers may consider the MRL of 0.1 mg/kg for potatoes to cover potential residues in rotational crops as proposed in the conclusion of the peer review. Adequate analytical enforcement methods are available to monitor the residues of fluxapyroxad on the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed uses of fluxapyroxad on table and wine grapes and potatoes will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

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Keywords: fluxapyroxad, grapes, potatoes, MRL application, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Netherlands received an application from BASF SE to modify the existing maximum residue levels (MRLs) for the active substance fluxapyroxad in grapes and potatoes. In order to accommodate for the intended uses of fluxapyroxad, the Netherlands proposed to raise the existing MRLs to 0.5 mg/kg in table and wine grapes and 0.07 mg/kg in potatoes. The Netherlands 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 1 September 2014.

EFSA bases its assessment on the revised evaluation report, the draft assessment report (DAR) and its addendum prepared according to Directive 91/414/EEC, the Commission review report on fluxapyroxad, the conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad, the JMPR evaluation report as well as the conclusions from previous EFSA opinions on fluxapyroxad.

The toxicological profile of fluxapyroxad was assessed in the framework of the peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.02 mg/kg bw per day and an acute reference dose (ARfD) of 0.25 mg/kg bw.

The metabolism of fluxapyroxad in primary crops was investigated in three crop groups following foliar application and the general residue definition for enforcement and risk assessment as parent compound was established during the peer review. A metabolism study on wheat following the treatment of the seeds was made available by the Netherlands and confirmed that fluxapyroxad is the appropriate marker to estimate residues in cereals after seed treatment. Since the metabolic pattern of the active substance was seen to be similar after foliar application or seed treatment and on primary and rotational crops, EFSA concludes that the residue definitions for enforcement and risk assessment set as fluxapyroxad in the conclusion of the peer review are applicable to the uses under consideration in this MRL application.

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.5 mg/kg on table and wine grapes and 0.07 mg/kg on potatoes. Adequate analytical enforcement methods are available to monitor the residues of fluxapyroxad on the commodities under consideration at the validated LOQ of 0.01 mg/kg.

Under standard hydrolysis processing conditions fluxapyroxad showed to be stable. Therefore for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable. The results of the processing studies provided in this MRL application allow deriving the following processing factors (PF), which are recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- Grape/juice: 0.3
- Grape/red wine: 0.2
- Grape/raisins: 2.9

The occurrence of fluxapyroxad residues in rotational crops was investigated in the framework of the peer review. It was concluded that the metabolic patterns in primary and succeeding crops are similar but that fluxapyroxad exhibits high persistence in soil and significant residues are expected to be present in rotational crops. Based on field rotational crop studies assessed during the peer review a default MRL of 0.1 mg/kg was proposed for potatoes and other root and tuber vegetables, including sugar beets, and for leaves/sprouts of brassica. EFSA would recommend reconsidering the proposed MRL once a guidance document on the setting of MRLs in rotational crops is available.

Potatoes are usually fed to livestock therefore the possible carry-over of residues in food of animal origin has to be considered. Based on the revised dietary burden calculations, a modification of the existing MRLs for fluxapyroxad on commodities of animal origin is not required.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). To calculate the chronic exposure, EFSA used the median residue (STMR) derived from the residue trials conducted on grapes and the default MRL of 0.1 mg/kg for potatoes and other root and tuber vegetables and for leaves/sprouts of brassica as proposed for rotational crops during

the peer review. The existing MRLs as established for fluxapyroxad in Regulation (EC) No 491/2014 were used as input values for the remaining commodities of plant and animal origin. The acute exposure assessment was performed only with regard to the commodities under consideration.

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic intake calculated accounted for 83 % of the ADI (German child). An acute consumer concern was not identified in relation to the MRL proposals.

EFSA concludes that the proposed uses of fluxapyroxad on table and wine grapes and potatoes will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a health risk to consumers.

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

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Fluxapyroxad ^{(F)(b)}				
0151010	Table grapes	0.01*	0.50	NEU and SEU use supported.
0161030	Wine grapes	0.01*	0.50	
0211000	Potatoes	0.03	0.07 (0.1)	Supported by NEU/SEU combined data. Alternatively, risk managers may consider the default MRL of 0.1 mg/kg on potatoes which was proposed for rotational crops in the conclusion of the peer review.

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

(b): Since fluxapyroxad was designated as fat-soluble by the peer review, EFSA proposes to add this classification in the preparation of EU legislation.

(c): NEU (Northern Europe) SEU (Southern Europe)

(F): Fat-soluble.

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

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Background

Regulation (EC) No 396/2005¹ establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the 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 Directive 91/414/EEC,² repealed by Regulation (EC) No 1107/2009,³ shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

The Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company BASF SE⁴ to modify the existing MRLs for the active substance fluxapyroxad in table and wine grapes and in potatoes. 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 Regulation.

After completion, the evaluation report was submitted to the European Commission and to EFSA on 1 September 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00602 and the following subject:

Fluxapyroxad: Application to modify MRLs in grapevine and potato

The Netherlands proposed to raise the existing MRLs of fluxapyroxad from the LOQ of 0.01 mg/kg to 0.5 mg/kg in grapes (table and wine) and from the existing MRL of 0.03 mg/kg to 0.07 mg/kg in potatoes. EFSA identified some data requirements and the assessment of the application was suspended. On 8 June 2015 the EMS submitted the reply in a revised evaluation report, which replaces the original document. EFSA proceeded with the assessment of the application and the revised evaluation report as required by Article 10 of the Regulation.

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

In accordance with Article 11 of the 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 if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

Fluxapyroxad is the ISO common name for 3-(difluoromethyl)-1-methyl-*N*-(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix C. Fluxapyroxad has been approved for the uses as a fungicide.

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, 16.03.2005, 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, 19.08.1991, 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 BASF SE Agricultural Center Limburgerhof – Speyerer Straße 2 – Limburgerhof D-67114, Germany.

Fluxapyroxad is a new active substance approved in accordance with Regulation (EC) No 1107/2009 and included in the Annex of Commission Implementing Regulation (EU) No 540/2011⁵ by Commission Implementing Regulation (EU) No 589/2012⁶ which entered into force on 25 July 2012 for use as a fungicide. Decision 2010/672/EU⁷ confirmed that the dossier was complete and according to the transitional measures provided for in Regulation (EC) No 1107/2009, repealing Directive 91/414/EEC, the procedure of Directive 91/414/EEC was applied for the assessment. The representative uses supported in the peer review were two spray applications at 125 g/ha on cereals in northern Europe (NEU) and southern Europe (SEU). The Draft Assessment Report (DAR) of fluxapyroxad has been peer reviewed by EFSA (EFSA, 2012).

The EU MRLs for fluxapyroxad are established in Annex IIIA of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued a reasoned opinion on the modification of MRLs for fluxapyroxad (EFSA, 2011). The proposals from this reasoned opinion has been considered together with the proposal to adopt certain maximum residue limits (CXLs) in the preparation of EU legislation. The MRL changes that were reported in the EU legislation since the entry into force of the Regulation are summarised in Table 1.

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure ^(a)	Considered by Regulation	Remarks
Art. 10 (EFSA, 2011)	(EU) No 978/2011	various commodities of plant and animal origin
Art. 43 (EFSA, 2013)	(EU) No 491/2014	CAC 2013

(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005.
Art. 43: EFSA opinion according to Article 43 of Regulation (EC) No 396/2005.

Codex Alimentarius has established CXLs for a wide range of commodities, including potatoes, for which the CXLs is set at 0.03 mg/kg.

The details of the intended GAPS for fluxapyroxad are given in Appendix A. The GAP highlighted in grey in the table was not assessed as less critical.

Assessment

EFSA bases its assessment on the revised evaluation report submitted by the EMS (Netherlands, 2015), the DAR and its final addendum prepared according to Directive 91/414/EEC (United Kingdom, 2011a, b), the Commission review report on fluxapyroxad (European Commission, 2012), the conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad (EFSA, 2012), the JMPR Evaluation report (FAO, 2012) as well as the conclusions from previous EFSA opinions on fluxapyroxad (EFSA, 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 546/2011⁸ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2011; OECD, 2011).

⁵ 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.

⁶ Commission Implementing Regulation (EU) No 589/2012 of 4 July 2012 approving the active substance fluxapyroxad, 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. OJ L 175, 05.07.2012, p. 7–10.

⁷ 2010/672/EU: Commission Decision of 5 November 2010 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of penflufen and fluxapyroxad in Annex I to Council Directive 91/414/EEC. OJ L 290, 06.11.2010, p. 51–52.

⁸ 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.

1. Method of analysis

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

Analytical methods for the determination of fluxapyroxad residues in plant commodities were assessed during the peer review, which concluded that the LC-MS/MS method has been adequately validated to enforce fluxapyroxad residues in high water, high acid, high oil content commodities and in dry matrices at the LOQ of 0.01 mg/kg (EFSA, 2012).

As the commodities under consideration belong to the high water and high acid content commodity groups, EFSA concludes that sufficiently validated analytical methods are available to enforce the proposed MRLs for fluxapyroxad.

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

Analytical methods for the determination of fluxapyroxad residues in commodities of animal origin were assessed during the peer review, which concluded that the LC-MS/MS method has been adequately validated to enforce fluxapyroxad residues in tissue matrices at the LOQ of 0.01 mg/kg and in milk and eggs at 0.001 mg/kg (EFSA, 2012).

2. Mammalian toxicology

The toxicological profile of the active substance fluxapyroxad was assessed in the framework of the peer review under Regulation (EC) No 1107/2009 (EFSA, 2012; European Commission, 2012). The data were sufficient to derive toxicological reference values compiled in Table 2.

Table 2: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Fluxapyroxad					
ADI	European Commission	2012	0.02 mg/kg bw per day	Rat, 2-year study	100
ARfD		2012	0.25 mg/kg bw	Rabbit and rat, developmental toxicity ^(a)	100

(a): Rabbits, developmental effects; rats, maternal effects (EFSA, 2012).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

During the peer review the metabolism of fluxapyroxad in primary crops was investigated in the fruit, pulses/oilseeds and cereals crop groups following foliar applications. The details of these studies are reported in a previous EFSA reasoned opinion and in the conclusion of the peer review (EFSA, 2011, 2012). An additional metabolism study on spring wheat after seed treatment was provided to support the uses following soil or seed application and was assessed by the EMS (Netherlands, 2015) and JMPR (FAO, 2012; EFSA, 2013). An overview of the available metabolism studies is presented in Table 3.

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application ^(a)	Sampling ^(b)	Comments
Fruit	Tomato	Foliar, 3× 100 g/ha, interval 7 d	3 DALA	1.6N rate on grape
Pulses /Oilseeds	Soyabean	Foliar, 3x 60 g/ha, BBCH 16/17, 51-59, 71-75	0 DAT ₁ , 34 DALA	
Cereals	Wheat	Foliar, 2x 125 g/ha, BBCH 30/35, 69	36 DAT ₁ , 4, 34-35 DALA	
		Seed treatment, 75 g/100 kg ^(c)	93, 112 161 DAT	Not peer reviewed

(a): Fluxapyroxad was radio-labelled in both the aniline and the pyrazole moieties.

(b): DALA: days after last application; DAT: day after treatment; DAT₁: day after first treatment.

(c): According to the evaluating Member State, it corresponds to an application rate of 135 g/ha (Netherlands, 2015).

Alter foliar applications, fluxapyroxad represented the main component of the total radioactive residues (TRR) in tomato, wheat and the soyabean plant parts, except soyabean seeds. The metabolism showed to be more extensive in soyabean seeds with the toxicological relevant metabolites M700F002 and M700F048⁹ being the predominant part of the total residues.

The peer review concluded on a general residue definition for monitoring as parent compound following foliar application. The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

For risk assessment, the inclusion of the metabolites observed in soyabean seeds in the residue definition was discussed and it was concluded to limit the residue definition to parent compound only (EFSA, 2012).

After seed treatment, fluxapyroxad was identified as the major component of the total residue, accounting for 58–79 % of the TRR in forage, hay, straw and chaff and 17 % of the TRR in grains (Netherlands, 2015). Globally, the metabolic pattern found in wheat after seed application was found comparable to the pathway observed in wheat after foliar application, which in turn had been found to be comparable to pathways after foliar application in other crops (soyabean and tomato). Therefore, it is concluded that the residue definition for enforcement and risk assessment limited to fluxapyroxad is also applicable to the use of fluxapyroxad on cereals after seed treatment.

A metabolism study after seed/soil treatment on roots/tubers crops is not available. However, based on the metabolic profile observed in wheat after seed treatment and having regard to the metabolic profile observed in rotational crops where fluxapyroxad was also identified as the major component of the residues (see Section 3.1.2.), EFSA concludes that the residue definitions proposed for primary crops are also applicable to the uses of the active substance on potatoes as soil/seed treatments. Moreover, the metabolites identified in the primary or rotational crop metabolism studies (M700F002, M700F008 and M700F048) and analysed for in the supervised residue trials submitted were never observed at levels above the limit of quantification.

In conclusion, for the intended uses on grapes and potatoes, the residue definition for enforcement and risk assessment as fluxapyroxad proposed during the peer review are applicable.

3.1.1.2. Magnitude of residues

In support of the MRL application, residue trials on grapes and potatoes were submitted. All samples were analysed for fluxapyroxad and metabolites M700F048, M700F008 and M700F002. Fluxapyroxad metabolites were always below the LOQ in all samples at all sampling points.

a. Table and wine grapes

NEU. Eight residue trials conducted on table and wine grapes in compliance with the northern critical GAP (3× 60 g/ha, PHI 35 d) were submitted. A MRL proposal of 0.4 mg/kg is derived from this residue dataset.

⁹ M700F002, a major soil metabolite, was considered to be less toxic than the parent compound, whilst M700F048 with similar toxicity as the parent fluxapyroxad (EFSA, 2012).

SEU. Ten residue trials on table and wine grapes conducted according to the southern GAP (3× 45 g/ha, PHI 35 d) were submitted. Although less critical than the northern GAP, since defined with a lower application rate of 45 g/ha per application, a higher MRL proposal of 0.5 mg/kg is derived from the southern dataset.

As proposed by the EMS, the MRL of 0.5 mg/kg derived from the southern data set is recommended by EFSA for the use of fluxapyroxad on table and wine grapes in northern and southern EU.

b. Potatoes

Eight NEU and eight SEU residue trials using in furrow applications at planting at the dose rate of ca. 240 g/ha were submitted. The in-furrow application was split into two runs of 50 % the intended total application rate each, prior and after the seeding of the tubers. The splitting practice is not expected to have a relevant impact on the overall residue levels as the soil surrounding the seed and its surface were actually treated with the total amount of the fungicide. Since the NEU and SEU residue datasets belong to similar populations (U-test, 5 %) and the GAPs are the same, the data were pooled together to derive a MRL proposal of 0.07 mg/kg.

Two northern and two southern residue trials using seed treatment (6 g/100 g seeds) were provided. Potato seeds were treated before planting according to the intended dressing rate. This phase was not performed under Good Laboratory Practice (GLP) however, since the accurate dosing of the seeds was checked, this deviation is considered acceptable. Dressed potatoes were planted at a seeding rate of 2500 kg/ha, equivalent to 150 g fluxapyroxad/ha. At harvest, no residues (< 0.01 mg/kg) were observed in the northern trials and low detectable residues (0.02; 0.04 mg/kg) were present in the southern trials (use not proposed by the applicant).

The limited number of trials using the seed dressing is not sufficient to conclude that the use of fluxapyroxad as seed dressing is equivalent to the use of the active substance by in furrow application at planting. When granting authorisation, Member states should consider the submission of additional residue trials using the seed dressing treatment.

The results of the residue trials, the related risk assessment input values (HR, STMR) and the MRL proposals are summarised in Table 4. When more than one use has been assessed for a crop, EFSA proposed the MRL derived from the more critical residue situation, highlighted in bold in Table 4.

Residues of fluxapyroxad were found to be stable at –20°C for up to 24 months in all matrices (EFSA, 2012). As the trial samples were stored for a maximum period of 7 months (grapes) and 5 months (potatoes) under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability of fluxapyroxad.

Storage stability of the three metabolites analysed in the submitted residue trials was also investigated during the peer review (United Kingdom, 2011a,b; EFSA, 2012). In high water and high acid content matrices, M700F048 and M700F002 showed to be stable for up to 24 and 27 months, respectively. In high water content matrices M700F008 was stable for 4 months, whereas in high oil matrices and in wheat straw for 24 months (EFSA, 2012). Regarding high acid content matrices, JMPR is reporting a transitory decrease in stability of M700F008 after 3 months but not between the subsequent 4–24 months in lemon fruit (FAO, 2012). The period over which the samples from the residue trials on potatoes were stored is slightly exceeding the storage stability for the metabolite M700F008 in high water content matrices. Nevertheless, considering the overall stability profile of these metabolites in the different matrices, EFSA concludes that the results from residue trials are also valid with regard to storage stability of these fluxapyroxad metabolites.

According to the EMS, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proven to be fit for the purpose (Netherlands, 2015).

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

- 0.50 mg/kg table and wine grapes in NEU and SEU.
- 0.07 mg/kg potatoes in NEU and SEU (in-furrow).

Table 4: Overview of the available residues trials data

Crop (GAPs)	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials ^(b) (mg/kg)	Recommendations/comments ^(c)	MRL proposal (mg/kg)	HR ^(d) (mg/kg)	STMR ^(e) (mg/kg)
Grapes (3× 60 g/ha, PHI 35 d)	NEU	0.07; 0.08; <u>0.08</u> ; <u>0.09</u> ; 0.13; 2× 0.15; 0.27	<u>Underlined value:</u> Higher residue measured at a longer PHI of 41-42 days. MRL _{OECD} : 0.39/0.40 (NEU) MRL _{OECD} : 0.42/0.50 (SEU) Reverse extrapolation between table grapes and wine grapes.	0.40	0.27	0.11
	(3× 45 g/ha, PHI 35 d)	SEU		2× 0.03; 0.03; 0.04; <u>0.06</u> ; <u>0.07</u> ; 0.11; <u>0.15</u> ; 0.20; 0.26	0.50	0.26
Potatoes (1× 240 g/ha) in furrow application	NEU	2× <0.01; 0.01; <u>0.01</u> ; 2× 0.02; 2× 0.04	<u>Underlined value:</u> Slight overdosed (+34 %) trial. MRL proposal derived from the combined NEU and SEU datasets (U-test: 5 %). MRL _{OECD} : 0.07/0.07	0.07	0.04	0.02
	SEU	2× <0.01; 2× 0.01; 2× 0.02; 0.03; 0.04				
(6 g/100 kg seeds) seed treatment	NEU	2× <0.01	Number of trials not sufficient to conclude that the use of fluxapyroxad as seed dressing is equivalent to the application of the active substance in furrow at 240 g/ha.	-	-	-
	SEU	0.02, 0.04				

(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): 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): HR: Highest residue level according to the residue definition for risk assessment.

(e): STMR: Median residue level according to residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of fluxapyroxad residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed during the peer review and it was concluded that the compound is hydrolytically stable under the representative conditions. Thus, for processed commodities, the same residue definition as for RAC is applicable (EFSA, 2012).

Studies investigating the effect of processing on the magnitude of fluxapyroxad residues in processed potato products were assessed in a previous reasoned opinion (EFSA, 2011). A PF of 0.67 for potato flakes, chips and fried potatoes was proposed for inclusion in Annex VI of Regulation (EC) No 396/2005.

Two studies on grapes processed to produce juice, red wine and raisins following standard production practice were submitted and assessed in this MRL application (Netherlands, 2015). White and red grapes for juice and wine were harvested 13/14 days after three spray applications of fluxapyroxad at the exaggerated rate of 400 g/ha with a 9–11 day interval (about 6N the maximum intended rate, shorter PHI than the intended PHI of 35 days); grape for raisins was allowed to field dry until collection.

In unprocessed grape fruits, fluxapyroxad ranged from 0.4 to 0.8 mg/kg when harvested at PHI 13/14 days and from 0.5 to 1.5 mg/kg when kept longer on the plant. A reduction of fluxapyroxad residues is observed in grape juice, must and young (1–2 weeks) red/rose wine, whereas concentration occurs in wet pomace and raisins. Processing studies to produce also white wine were not provided and would be necessary under the OECD requirements (OECD, 2008). Samples from the processing studies on grapes were stored under frozen conditions for up to 5 months and analysed also for the metabolites M700F048, M700F008 and M700F002, which were never found (Netherlands, 2015).

The processing factors derived from these studies are summarised in Table 5.

Table 5: Overview of the available processing studies

Crop (RAC)/ Processed product	Number of studies	Processing Factor (PF)		Remarks
		Individual values	Median PF	
grape/pomace (wet)	4	4.00; 4.80; 5.70; 7.21	5.25	
grape/juice (pasteurised)	4	0.22; 0.27; 0.42; 0.46	0.34	
grape/red wine (young)	4	0.19; 0.21; 0.22; 0.24	0.22	
grape/raisins	4	1.98; 2.80; 2.93; 5.81	2.86	

EFSA recommends the inclusion of the derived PFs for grape juice, red wine and raisins in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

Potatoes 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 degradation studies demonstrated that the degradation rate of fluxapyroxad and its soil metabolite M700F002 is slow (EFSA, 2012). The DT_{90} value in soil exceeds one year ($DT_{90\text{field}} > 1000$ days) and fluxapyroxad is likely to accumulate in soils. The plateau concentration in soil following several years of consecutive applications could not be established during the peer review, but is expected to be reached after 13 years (EFSA, 2012).

3.1.2.1. Nature of residues

The metabolism of fluxapyroxad in rotational crops was assessed in the DAR and in the conclusion on the peer review of the active substance (United Kingdom, 2011a,b; EFSA, 2012). The overview of the confined rotational studies design is presented in Table 6.

Table 6: Overview of the available confined rotational crop studies

Crop group	Rotational crops	Application			Remarks
		Method	Rate (g/ha)	PBI ^(a) (days)	
Leafy	Spinach	Bare soil	250 ^(b)	30, 120/149, 365	About 1N the intended maximum application rate on potatoes
Roots	Radish				
Cereals	Wheat				

(a): Plant back interval (interval between the application of the a.s. and the sowing/planting of the rotational crop).

(b): Fluxapyroxad was radio-labelled in both the aniline and the pyrazole moieties.

At all three PBIs, translocation of radioactivity from soil into plants was observed. Fluxapyroxad was the major component in almost all matrices, except in spinaches and in radish plants, where the metabolite M700F002 was predominant. It is noted that M700F002 is common to three other active substances used as pesticides: bixafen, isopyrazam and sedaxane. Based on these studies, the peer review concluded that the residue definition proposed for primary crops is also applicable to rotational crops (EFSA, 2012).

3.1.2.2. Magnitude of residues

Field rotational crop trials on cereals (wheat), root group (carrots), leafy crops (cauliflower, broccoli and lettuce) were assessed in the framework of the peer review (United Kingdom, 2011a,b; EFSA, 2012). The trials were conducted on bare soil previously treated at a rate of 250 g/ha (1N intended dose rate on potatoes).

There is currently no guidance documents or agreement at EU or international levels, defining an approach for the setting of MRLs in rotational crops for persistent active substances. However, based on the fluxapyroxad residue levels observed in the rotational crop studies and summarised in Table 7, the peer review proposed to set a default MRL of 0.1 mg/kg for potatoes and other root and tuber vegetables, including sugar beets and for leaves/sprouts of Brassica¹⁰ (EFSA, 2012). This default value was based on the highest residue levels of 0.06 and 0.08 mg/kg observed in cauliflower and carrot roots respectively, bearing in mind that the studies were conducted at the annual seasonal application rate of 250 g/ha only, whilst an accumulation of the active substance in soil is expected following several years of consecutive applications.

Table 7: Summary of the field rotational crop studies (fluxapyroxad residue levels, mg/kg)

PBI (days)	Carrot	Cauliflower		Broccoli	Lettuce		Wheat	
	Root	immature	mature	mature	immature	mature	grain	straw
31	<0.01-0.08	<0.01-0.06	<0.01	<0.01	<0.01-0.03	<0.01	<0.01	0.04-0.42
120	<0.01-0.03	<0.01-0.02	<0.01	-	<0.01-0.01	<0.01	<0.01	0.03-0.07
365	<0.01-0.02	<0.01-0.02	<0.01	-	0.01-0.02	<0.01	<0.01	0.04-0.08

EFSA therefore proposes to the risk manager to consider the default MRL of 0.1 mg/kg which was set for certain rotational crops, including potatoes, in the conclusion of the peer review of the active substance (EFSA 2012) as an alternative to the MRL of 0.07 mg/kg derived from the residue trials conducted on potato as primary crop (see Table 4). Anyway, EFSA would recommend reconsidering the MRL of 0.1 mg/kg once a guidance document on the setting of MRLs in rotational crops is available.

¹⁰ Corresponding to the code "0251080 baby leaf crops (including Brassica species)" according to Commission Regulation (EU) No 725/2014.

3.2. Nature and magnitude of residues in livestock

As potatoes may be fed to livestock, the nature and magnitude of fluxapyroxad residues in livestock was assessed in the framework of this application (European Commission, 1996).

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology (European Commission, 1996). The input values for the dietary burden calculation were selected according to the current FAO recommendations (FAO, 2009) considering the livestock intake from the intended use on potatoes (see Table 4). EFSA revised and updated a previously estimated livestock exposure for fluxapyroxad via cereals, pulses, oilseeds, sugar beets and apple pomace (EFSA, 2011) to take into account the residue definition established for risk assessment on pulses and oilseeds (EFSA, 2012) and the CXLs adopted on the crops that might be fed to livestock (EFSA, 2013), when relevant.

The input values for the dietary burden calculation are summarised in Table 8.

Table 8: Input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Potatoes	0.02	STMR	0.07	HR
Sugar/Fodder beet tops	2.57	STMR (EFSA, 2011)	4.17	HR (EFSA, 2011)
Silage (maize)	0.01	LOQ (EFSA, 2011)	0.01	LOQ (EFSA, 2011)
Apple pomace	1.38 (0.3× 4.6)	STMR (EFSA, 2013)-P (EFSA, 2011)	2.16 (0.47× 4.6)	STMR-P (EFSA, 2011)
Wheat/Rye grain	0.12	STMR (EFSA, 2011)	0.12	STMR (EFSA, 2011)
Barley/Oat grain	0.54	STMR (EFSA, 2011)	0.54	STMR (EFSA, 2011)
Maize grain	0.01	LOQ (EFSA, 2011)	0.01	LOQ (EFSA, 2011)
Wheat/Rye bran	0.37 (0.12× 3.09)	STMR-P (EFSA, 2011)	0.37 (0.12× 3.09)	STMR-P (EFSA, 2011)
Wheat/Rye straw	2.13	STMR (EFSA, 2011)	8.32	HR (EFSA, 2011)
Barley/Oat straw	4.33	STMR (EFSA, 2011)	10.11	HR (EFSA, 2011)
Peas, Beans, Lupins (dry)	0.04 ^(a)	STMR (EFSA, 2011)	0.04	STMR (EFSA, 2011)
Sugar/Fodder beet	0.04	STMR (EFSA, 2011)	0.07	HR (EFSA, 2011)
Cotton meal	0.01	LOQ (EFSA, 2013)	HR not relevant	
Peanuts meal	0.001 ^(a) (0.01× 0.12)	STMR-P (EFSA, 2011)		
Rape seed meal	0.05 ^(a) (0.12× 0.44)	STMR-P (EFSA, 2011)		
Soyabean meal	0.013 ^(a) (0.01× 1.3)	STMR-P (EFSA, 2011)		
Sunflower seed meal	0.013 (0.09× 0.14)	STMR (EFSA, 2013)-P (EFSA, 2011)		
Linseed meal	0.04 ^(a) (0.09× 0.44)	STMR-P (EFSA, 2011)		

(a): The previous input value was multiplied by a conversion factor (CF) since the metabolite M700F048 was included in the provisional residue definition for risk assessment of pulses and oilseeds (EFSA, 2011).

The estimated animal dietary intakes taking into account the feed commodities listed in Table 8 are summarised in Table 9. The maximum animal intakes estimated in the previous EFSA opinion (EFSA, 2011) are reported in this table in the column "Previous assessment".

Table 9: Results of the dietary burden calculation

Animal	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	Maximum burden (mg/kg DM)	> 0.1 mg /kg DM (Y/N)	Highest contributing commodity ^(a)	Previous assessment ^(b) (Max. burden)
Dairy cattle	0.222	0.381	10.468	Y	10.468	10.456
Beef cattle	0.320	0.592	13.822	Y	13.822	13.822
Poultry	0.031	0.034	0.539	Y	0.539	0.526
Pigs	0.179	0.279	6.987	Y	6.987	6.987

(a): Considering the maximum dietary animal burden.

(b): See Table 3-6 of the reasoned opinion on the setting of new MRLs for fluxapyroxad (BAS 700 F) in various commodities of plant and animal origin (EFSA, 2011).

Based on the revised dietary burden calculations, EFSA conclude that the existing MRLs on commodities of animal origin cover the additional use on potatoes and a modification is not required.

Since the octanol-water partition coefficient (log Pow at pH 7 = 3.13) exceeds 3 and the feeding studies indicated highest residue level in fat, the compound was designated fat-soluble (EFSA, 2012). JMPR has also identified the residue as fat-soluble (FAO, 2012). Therefore, EFSA proposes to add this classification in the preparation of EU legislation.

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 population¹¹ (EFSA, 2007).

To calculate the chronic exposure, EFSA used the STMR derived from the residue trials conducted on grapes (see Table 4) and the default MRL of 0.1 mg/kg for potatoes and other root and tuber vegetables and for leaves/sprouts of brassica as proposed for rotational crops during the peer review (EFSA, 2012). The existing MRLs as established for fluxapyroxad in Regulation (EU) No 491/2014 were used as input values for the remaining commodities of plant and animal origin.

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 (grapes) or the alternative MRL proposal (potatoes). A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation for table grapes and potatoes (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 10.

¹¹ 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).

Table 10: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition: Fluxapyroxad				
Table grapes	0.11	STMR	0.27	HR
Wine grapes	0.11	STMR	0.27	HR
Potatoes	0.1	Default MRL proposed for rotational crops (EFSA, 2012)	0.1	Default MRL proposed for rotational crops (EFSA, 2012)
Other root & tuber vegetables, except sugar beet ^(a)	0.1	Default MRL proposed for rotational crops (EFSA, 2012)	Acute risk assessment was undertaken only with regard to the commodities for which a MRL is proposed.	
Leaves/sprouts of brassica	0.1	Default MRL proposed for rotational crops (EFSA, 2012)		
Other plant and animal commodities	MRL	MRLs in Regulation (EU) No 491/2014		

(a): For sugar beets, EFSA used the existing MRL value, which is higher than the default MRL proposed for rotational crops during the peer review.

The estimated exposure was then compared with the toxicological reference values derived for fluxapyroxad (see Table 2). The results of the intake calculation are presented in Appendix B of this reasoned opinion.

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic intake calculated accounted for 83 % of the ADI (German child). The contribution of residues in the crops under consideration to the total consumer exposure accounted for a maximum of 2.9 % of the ADI for potatoes (Dutch child).

An acute consumer risk was not identified in relation to the MRL proposals. The highest acute consumer exposure amounted for 7 % (table grapes), 6 % (potatoes) and less than 3 % (wine grapes) of the ARfD.

EFSA emphasises the worst case exposure calculation for potatoes, which was performed on the basis of the highest level of 0.1 mg/kg (alternative MRL proposal), without any refinement.

EFSA concludes that the intended uses of fluxapyroxad on table and wine grapes and potatoes will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a concern for public health.

Conclusions and recommendations

The information submitted was sufficient to propose the MRLs summarised in the table below:

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Fluxapyroxad ^{(F)(b)}				
0151010	Table grapes	0.01*	0.50	NEU and SEU use supported.
0161030	Wine grapes	0.01*	0.50	
0211000	Potatoes	0.03	0.07 (0.1)	Supported by NEU/SEU combined data. Alternatively, risk managers may consider the default MRL of 0.1 mg/kg on potatoes which was proposed for rotational crops in the conclusion of the peer review.

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

(b): Since fluxapyroxad was designated as fat-soluble by the peer review, EFSA proposes to add this classification in the preparation of EU legislation.

(c): NEU (Northern Europe) SEU (Southern Europe)

(F): Fat-soluble.

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

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Abbreviations

a.s.	active substance
ACD	Advanced Chemistry Development
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
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
DT ₉₀	period required for 90 % dissipation (define method of estimation)
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GLP	Good Laboratory Practice
HR	highest residue
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
LC	liquid chromatography
MRL	maximum residue level
MS/MS	tandem mass spectrometry detector
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PBI	plant back interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RAC	raw agricultural commodity
RMS	rapporteur Member State

SANCO	European Commission's Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation (a)	NEU /SEU	F G or 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. ⁽ⁱ⁾	Method kind ^(f-h)	Growth stage & season ^(j)	Number min-max ^(k)	Interval min-max	g/hL min-max	Water L/ha min-max	g/ha min-max		
Grapes	NEU	F	<i>Erysiphe necator</i>	SC	300 g/L	spraying	BBCH 11-83	3	10–21	4–30	158–1200	27–60	35	cGAP
								1–3	10–21	4–22.5	150–1200	45	35	
	SEU	F	<i>Erysiphe necator</i>	SC	300 g/L	spraying	BBCH 11-83	1–3	10–21	4–22.5	150–1200	45	35	
Potatoes	NEU	F	<i>Rhizoctonia solani</i>	SC	300 g/L	in-furrow	at planting	1	–	120–400	60–200	240	n.a.	
		F		SC	300 g/L	seed treatment	before planting	1	–	20/mL 100 kg tuber (maximum 0.67 L/ha)	3.5–6 60–200	6 g/100 kg tuber (maximum 200 g/ha)	n.a.	Water volume refers to roller table dilution: use either the upper or lower but not both. Max number application per year is 1.

Remarks:

- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage 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), water soluble granule (WG)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) all abbreviations must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants. type of equipment used must be indicated

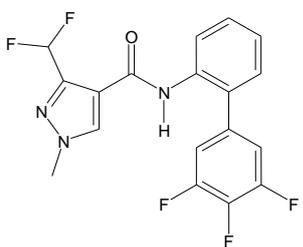
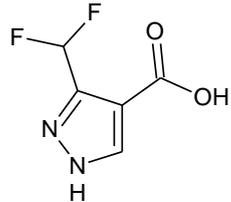
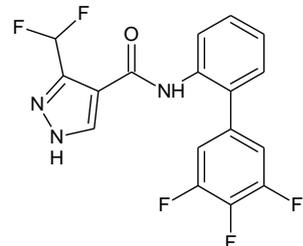
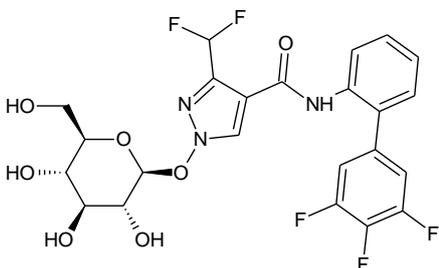
- (i) g/kg or µg/L
- (j) Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 2001), including where relevant, information on season at time of application
- (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

Appendix B – Pesticide Residue Intake Model (PRIMO)

Fluxapyroxad								
Status of the active substance:		approved		Code no.				
LOQ (mg/kg bw):				proposed LOQ:				
Toxicological end points								
ADI (mg/kg bw/day):		0.02		ARfD (mg/kg bw):		0.25		
Source of ADI:		EC		Source of ARfD:		EC		
Year of evaluation:		2012		Year of evaluation:		2012		
Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		10 - 83						
		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	pTMRs at LOQ (in % of ADI)
83.3	DE child	54.3	Apples	8.2	Wheat	2.9	Tomatoes	
60.0	NL child	28.5	Apples	9.5	Wheat	5.0	Beans (with pods)	
55.2	WHO Cluster diet B	17.1	Wheat	9.3	Tomatoes	4.5	Apples	
44.5	IE adult	12.4	Barley	4.6	Wheat	3.7	Apples	
44.3	DK child	11.0	Wheat	10.5	Apples	8.8	Rye	
43.3	UK Toddler	17.2	Sugar beet (root)	7.8	Wheat	7.7	Apples	
41.9	FR toddler	11.8	Apples	11.0	Beans (with pods)	5.2	Wheat	
40.3	WHO cluster diet E	8.1	Barley	7.9	Wheat	3.8	Apples	
33.8	UK Infant	7.6	Sugar beet (root)	7.0	Apples	5.2	Wheat	
32.0	WHO cluster diet D	13.0	Wheat	3.0	Tomatoes	3.0	Apples	
30.7	FR infant	11.3	Apples	8.4	Beans (with pods)	2.6	Milk and cream,	
30.0	WHO Cluster diet F	7.2	Wheat	6.0	Barley	3.0	Apples	
29.6	WHO regional European diet	5.9	Wheat	3.3	Tomatoes	3.3	Tomatoes	
28.9	IT kids/toddler	13.3	Wheat	4.3	Tomatoes	4.0	Apples	
28.1	ES child	8.9	Wheat	5.1	Apples	2.9	Tomatoes	
27.0	PT General population	7.8	Wheat	4.7	Apples	2.7	Tomatoes	
24.2	ES adult	4.9	Barley	4.7	Wheat	3.5	Apples	
24.1	SE general population 90th percentile	6.4	Wheat	4.7	Apples	2.3	Tomatoes	
23.1	NL general	5.3	Apples	4.1	Wheat	3.7	Barley	
22.8	IT adult	8.3	Wheat	3.6	Apples	3.5	Tomatoes	
20.0	LT adult	8.4	Apples	2.2	Rye	2.1	Wheat	
19.2	FR all population	6.6	Wheat	2.2	Wine grapes	2.1	Apples	
17.6	PL general population	9.2	Apples	2.6	Tomatoes	1.7	Potatoes	
16.8	UK vegetarian	4.1	Wheat	2.8	Sugar beet (root)	2.7	Apples	
16.0	DK adult	4.0	Wheat	3.5	Apples	1.4	Rye	
13.7	UK Adult	3.4	Wheat	3.0	Sugar beet (root)	1.8	Apples	
10.1	FI adult	2.0	Wheat	1.8	Apples	1.4	Rye	
<p>Conclusion: The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Fluxapyroxad is unlikely to present a public health concern.</p>								

Acute risk assessment /children - refined calculations			Acute risk assessment / adults / general population - refined calculations					
<p>The acute risk assessment is based on the ARfD.</p> <p>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.</p> <p>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.</p> <p>In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.</p> <p>Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.</p>								
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):	
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	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
7.1	Table grapes	0.27 / -	7.1	Table grapes	0.27 / -	3.4	Table grapes	0.27 / -
6.2	Potatoes	0.1 / -	4.4	Potatoes	0.1 / -	2.6	Wine grapes	0.27 / -
0.8	Wine grapes	0.27 / -	0.8	Wine grapes	0.27 / -	1.2	Potatoes	0.1 / -
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:		No of commodities for which ARfD/ADI is exceeded:		No of commodities for which ARfD/ADI is exceeded:	
	---		---		---		---	
	IESTI 1 ***)		IESTI 2 ***)		IESTI 1 ***)		IESTI 2 ***)	
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities
0.434	Grape juice	0.033 / -				0.052	Raisins	0.319 / -
0.146	Potato puree (flakes)	0.0268 / -				0.034	Wine	0.022 / -
0.015	Fried potatoes	0.0268 / -				0.005	Potato puree (flakes)	0.0134 / -
0.004	Wine	0.022 / -				0.004	Fried potatoes	0.0134 / -
<p>*) 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.</p> <p>**) pTMRL: provisional temporary MRL</p> <p>***) pTMRL: provisional temporary MRL for unprocessed commodity</p>								
<p>Conclusion:</p> <p>For Fluxapyroxad 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.</p> <p>For processed commodities, no exceedance of the ARfD/ADI was identified.</p>								

Appendix C – Used compound codes

Code/Trivial name	Chemical name ^(a)	Structural formula ^(a)
Fluxapyroxad (BAS 700 F)	3-(difluoromethyl)-1-methyl- <i>N</i> -(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide	
M700F002 (DMPac)	3-(difluoromethyl)-1 <i>H</i> -pyrazole-4-carboxylic acid	
M700F008	3-(difluoromethyl)- <i>N</i> -(3',4',5'-trifluorobiphenyl-2-yl)-1 <i>H</i> -pyrazole-4-carboxamide	
M700F048	3-(difluoromethyl)-1-(<i>b</i> - <i>D</i> -glucopyranosyloxy)- <i>N</i> -(3',4',5'-trifluorobiphenyl-2-yl)-1 <i>H</i> -pyrazole-4-carboxamide	

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