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Modification of the existing maximum residue levels for fluxapyroxad in various crops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member States (EMS), the Netherlands and the United Kingdom, received an application from BASF SE to modify the existing maximum residue levels (MRLs) for the active substance fluxapyroxad in several crops in order to accommodate for proposed new uses in Europe and for the import of crops. According to EFSA, the data are sufficient to derive MRL proposals for all the crops assessed, except for citrus fruits other than oranges and grapefruits. Adequate analytical enforcement methods are available to control the residues of fluxapyroxad on the commodities under consideration, but additional validation data on herbal infusion and spices would be desirable. Based on the risk assessment results, EFSA concluded that the proposed uses on various crops of fluxapyroxad and the use authorised in Brazil on oranges and grapefruits for which import of crops has been requested, will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

Keywords: fluxapyroxad, various crops, MRL application, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member States (EMS) the Netherlands and the United Kingdom, received an application from the company BASF SE to modify the existing maximum residue levels (MRLs) for the active substance fluxapyroxad in several crops in order to accommodate for proposed new uses in Europe and for the import of crops. Both the Netherlands and the United Kingdom drafted evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 2 August 2016 and 7 April 2017, respectively.

EFSA bases its assessment on the revised evaluation reports submitted by the EMSs, the draft assessment report (DAR) and its final addendum prepared under Directive 91/414/EEC, the Commission review report on fluxapyroxad, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) evaluation reports, the conclusions on the peer review of the pesticide risk assessment of the active substance fluxapyroxad as well as from previous EFSA opinions and scientific reports on fluxapyroxad.

The toxicological profile of fluxapyroxad was assessed in the framework of the peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.02 mg/kg body weight (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 the fruits, cereals/grass and pulses/oilseeds crop groups following foliar applications and in cereals/grass group after seed treatment. The peer review concluded on a residue definition after foliar use for enforcement and risk assessment as fluxapyroxad, which is applicable to the crops under assessment.

EFSA concluded that the submitted residue trials are sufficient to derive MRL proposals for all the crops assessed, except for citrus fruits other than oranges and grapefruits. Adequate analytical enforcement methods are available to control the residues of fluxapyroxad on the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. However, additional validation data on the roots of herbal infusions and spices would be desirable.

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 the import tolerance application allow deriving the following processing factors (PF) for oranges, which are recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- Orange juice: 0.05
- Orange, oil: 27

The peer review concluded that the metabolic patterns in primary and succeeding crops are similar. However, fluxapyroxad exhibited high persistence in soil and the possibility of residues of fluxapyroxad to be present in rotational crops cannot be excluded. Member States granting an authorisation should take the necessary risk mitigation measures in order to minimise residues in rotational crops. Additionally, EFSA would propose to risk managers, as an alternative to the MRL derived from the residue trials submitted, the default MRL of 0.1 mg/kg for the group of tropical root and tuber vegetables.

Although several crops under consideration and their by-products are used as feed products, EFSA concluded that the existing MRLs on commodities of animal origin cover the additional uses under consideration and a modification is not required.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the chronic exposure, both the uses under assessment and the uses previously assessed by EFSA were considered. For the remaining commodities of plant and animal origin, for which a median residue (STMR) to refine the calculation could not be retrieved, the existing MRLs were used as input values. The acute consumer exposure assessment was performed only with regard to the commodities under consideration. Potential residues in rotational through crops soil uptake and conversion factors for risk assessment were taken into account. A consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake accounted for 38% of the ADI (German child) and the highest acute exposure was calculated to be 69% of the ARfD for the post-harvest use on witloofs/Belgian endives.

EFSA concluded that the proposed uses of fluxapyroxad on various crops and the use authorised in Brazil on oranges and grapefruits for which import of crops has been requested, will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

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				
0110010	Grapefruits	0.01*	0.2	Import tolerance (BR GAP) supported by trials on oranges and unlikely to pose consumer health risk. Using OECD calculator the MRL of 0.4 mg/kg is derived. The MRL of 0.2 mg/kg set in country of origin is proposed by extrapolation for grapefruits. A change of the existing MRL is not required for oranges
0110020	Oranges	0.3	No change	
0212000	Tropical root and tuber vegetables, except potatoes	0.01*	0.02 or 0.1	NEU use supported by extrapolation from data on potatoes. Alternatively, risk managers may consider the default MRL of 0.1 mg/kg for rotational crops proposed in the conclusion of the peer review. Unlikely to pose consumer health risk
0213000	Other root and tuber vegetables except sugar beets and radishes	0.1	0.3	NEU and SEU uses supported by extrapolation from data on carrots MRL based on the most critical combined NEU/SEU data set of split applications. Unlikely to pose consumer health risk
0213080	Radishes	0.2	0.3	
0220040	Spring onions/green onions and Welsh onions	0.1	0.6	NEU and SEU uses supported by extrapolation from data on leeks. Unlikely to pose consumer health risk
0241010	Broccoli	0.2	No change	NEU and SEU uses supported by data on cauliflowers and broccoli. A change of the existing MRL is not required for broccoli. Unlikely to pose consumer health risk
0241020	Cauliflowers	0.07	0.15	
0241990	Others flowering brassica	0.07	0.15	
0242010	Brussels sprouts	0.07	0.3	NEU use supported. Unlikely to pose consumer health risk
0242020	Head cabbages	0.07	0.4	NEU and SEU uses supported. Unlikely to pose consumer health risk
0251000	Lettuces and salad plants, except lettuces	0.03	4	Indoor, NEU and SEU uses supported. MRL derived by extrapolation from the most critical indoor use on lettuces. A change of the existing MRL is not required for lettuces. Unlikely to pose consumer health risk
0251020	Lettuces	4	No change	
0252000	Spinaches and similar leaves	0.03	3	NEU and SEU uses supported by extrapolation from a combined data set of field trials on lettuces. Unlikely to pose consumer health risk
0255000	Witloofs/Belgian endives	0.03	6	Pre-harvest spraying and post-harvest dipping or spraying and post-harvest (dipping + spraying) uses supported. Unlikely to pose consumer health risk
0256000	Herbs and edible flowers	0.03	3	NEU and SEU uses supported by extrapolation from a combined data set on field trials on lettuces. Unlikely to pose consumer health risk
0270050	Globe artichokes	0.01*	0.3	NEU and SEU uses supported. Unlikely to pose consumer health risk
0270060	Leeks	0.01*	0.6	NEU and SEU uses supported. Unlikely to pose consumer health risk
0633000	Herbal infusions from roots	0.01*	0.3	NEU and SEU uses supported by extrapolation from data on carrots. Unlikely to pose consumer health risk

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0840000	Root and rhizome spices	0.01*	0.3	NEU and SEU uses supported by extrapolation from data on carrots. Unlikely to pose consumer health risk
0900030	Chicory roots	0.01	0.3	NEU use supported. Unlikely to pose consumer health risk

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; BR GAP: Brazil good agricultural practices; OECD: Organisation for Economic Co-operation and Development.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the Regulation') 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 set an import tolerance or to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

On one hand, the Netherlands, hereafter referred to as the evaluating Member State (EMS-NL), received from the company BASF SE[4] an import tolerance application to set MRLs for the active substance fluxapyroxad in citrus fruits, cranberries, papaya and cotton seeds. 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 forwarded to EFSA on 2 August 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00497 and the following subject:

Fluxapyroxad – IT MRLs in citrus fruits, cotton seeds, cranberry and papaya

The Netherlands proposed to raise the existing MRLs of fluxapyroxad from the limit of quantification (LOQ) of 0.01 to 0.3 mg/kg in grapefruits and oranges imported from Brazil (BR), 7 mg/kg in cranberries and 0.3 mg/kg in cotton seeds imported from the United States (US) and concluded that the import tolerance request for the other citrus fruits from Brazil and for citrus fruits and papaya from Mexico (MX) was not sufficiently supported by data. EFSA identified some data requirements for cranberries, which could not be addressed by the applicant. In the revised evaluation report submitted on 20 December 2016, the MRL for cranberries was not proposed any longer. In the meantime, the MRL of 0.3 mg/kg in cotton seeds has been implemented in the EU legislation. Hence, not only the requests for MRL modification in cranberries and papaya, but also in cotton seeds will not be assessed in this reasoned opinion.

On the other hand, the United Kingdom, hereafter referred to as the evaluating Member State (EMS-UK), received from the same company BASF SE, an application to modify the existing MRLs for the active substance fluxapyroxad in a large number of crops. 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. After completion, the evaluation report was submitted to the European Commission and forwarded to EFSA on 7 April 2017. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2017-00285 and the following subject:

Fluxapyroxad - MRLs in various crops

The United Kingdom proposed to raise the existing MRLs of fluxapyroxad to:

- 0.02 mg/kg in tropical roots and tubers vegetables (except potatoes);
- 0.3 mg/kg in other roots and tuber vegetables (except sugar beets), herbal infusions from roots, roots and rhizome spices, Brussels sprouts and chicory roots;
- 0.7 mg/kg spring onions and leeks;
- 0.15 mg/kg in flowering brassica (except broccoli);
- 0.4 mg/kg in head cabbages and globe artichokes;
- 4 mg/kg in lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers;
- 6 mg/kg in witloofs.

[1] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
[4] BASF SE, Agricultural Center Limburgerhof, Speyerer Strasse 2, 67114 Limburgerhof, Germany.

For strawberries, broccoli, cucurbits, cardoons, celeries, Florence fennels and rhubarbs, no change was proposed as equal or higher MRLs have been implemented in the EU legislation.

EFSA proceeded with the assessment of the application and the 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 3 months (which may be extended to 6 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 revised evaluations report submitted by the EMSs (Netherlands, 2016 and United Kingdom, 2017) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

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 B.

Fluxapyroxad is an active substance approved in accordance with Regulation (EC) No 1107/2009 and included in the Annex of Regulation (EU) No 540/2011[5] by Regulation (EU) No 589/2012[6] which entered into force on 1 January 2013 for use as a fungicide. Decision 2010/672/EU[7] 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 evaluated in the peer review were spray applications on cereals in Europe. The Draft Assessment Report (DAR) of fluxapyroxad has been peer reviewed by EFSA (2012).

The EU MRLs for fluxapyroxad are established in Annex IIIA of Regulation (EC) No 396/2005. The review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 has not yet been completed. EFSA has issued several reasoned opinions on the modification of MRLs for fluxapyroxad and assessed Codex MRLs. The proposals from these EFSA opinions have been considered in several regulations,[8,9,10,11] for EU MRL legislation.

[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, 11.6.2011, 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, 5. 7.2012, 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, 6.11.2010, p. 51–52.

[8] Commission Regulation (EU) No 978/2011 of 3 October 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, biphenyl, captan, chlorantraniliprole, cyflufenamid, cymoxanil, dichlorprop-P, difenoconazole, dimethomorph, dithiocarbamates, epoxiconazole, ethephon, flutriafol, fluxapyroxad, isopyrazam, propamocarb, pyraclostrobin, pyrimethanil and spirotetramat in or on certain products. OJ 258, 4.10.2011, p. 12–69.

[9] Commission Regulation (EU) No 491/2014 of 5 May 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, azoxystrobin, cycloxydim, cyfluthrin, dinotefuran, fenbuconazole, fenvalerate, fludioxonil, fluopyram, flutriafol, fluxapyroxad, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products. OJ 146, 16.5.2014, p. 1–91.

[10] Commission Regulation (EU) 2016/486 of 29 March 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, flupyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin in or on certain products. OJ 90, 6.4.2016, p. 1-66.

[11] Commission Regulation (EU) 2016/1902 of 27 October 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, ametoctradin, azoxystrobin, cyfluthrin, difluoroacetic acid, dimethomorph, fenpyrazamine, flonicamid, fluazinam, fludioxonil, flupyradifurone, flutriafol, fluxapyroxad, metconazole, proquinazid, prothioconazole, pyriproxyfen, spirodiclofen and trifloxystrobin in or on certain products. OJ 298, 4.11.2016, p. 1–60.

Fluxapyroxad use in citrus fruits is authorised in Brazil with a MRL of 0.2 mg/kg.[12] EFSA took note that in US the tolerance (MRL) of 0.3 mg/kg[13] is set in cotton seeds, but EFSA did not assess the notified use as a change of the existing MRL is not required. The notified use of fluxapyroxad in citrus is actually registered in Mexico,[14] but information if and which MRL value is set was not provided.

The detail description of the uses in Europe and in the non-European countries (for import tolerance request) of fluxapyroxad, which are the basis for the MRL applications, is given in Appendix A.

Assessment

EFSA has based its assessment on the revised evaluation reports submitted by the EMS-NL (Netherlands, 2016) and by the EMS-UK (United Kingdom, 2017), the DAR and its final addendum prepared under 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 reports (FAO, 2012, 2015) as well as the conclusions from previous EFSA opinions and scientific reports on fluxapyroxad (EFSA, 2011, 2013, 2015, 2016a,b). 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[15] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2016; OECD, 2009, 2011, 2013).

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 liquid chromatography with tandem mass spectrometry detector (LC–MS/MS) method has been adequately validated to enforce fluxapyroxad residues in all major category crop groups (high water, high acid, high oil content and dry matrices) at the limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2012).

Herbal infusions and spices are classified as difficult matrices to analyse for which separate validation data would be required to demonstrate the applicability of the analytical methods (European Commission, 2010b). Taking into account the successful validation in all four major matrix groups, the deficiency is noted as minor and additional validation data on these crops would be desirable.

EFSA concludes that sufficiently validated analytical methods are available to enforce the proposed MRLs for fluxapyroxad, but additional validation data on herbal infusions and spices would be desirable.

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

The analytical methods for the determination of fluxapyroxad residues in commodities of animal origin were not assessed in the framework of this reasoned opinion since a change of the existing MRLs is not proposed.

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 1.

[12] Resolution RE No 3594 of 24/09/2013, Official Journal of Brazilian Government (DOU) No 185 of 24/09/13, Section 1, p 44; Monograph F68 - Fluxapyroxad.
[13] US Code of Federal Regulations 40 CFR §180.666. Fluxapyroxad; Tolerances for residues.
[14] Federal Commission for the Protection against Sanitary Risk (COFEPRIS) website. Plant protection product 'Elmus' (http://www.cofepris.gob.mx).
[15] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

Table 1: 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	European Commission	2012	0.25 mg/kg bw	Rabbit (developmental effects) and rat (maternal effects), developmental toxicity	100

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

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 fluxapyroxad in primary crops was investigated in the fruits, pulses/oilseeds and cereals crop groups, following foliar applications under the peer review (EFSA, 2012). It is noted that an additional metabolism study on wheat following seed treatment was submitted in support to a previous MRL application (EFSA, 2015). An overview of the available metabolism studies is presented in Table 2.

Table 2: Summary of available metabolism studies in plants

Crop group	Crops	Applications	Sampling[(a)]	Comments
Fruits	Tomato	Foliar, 3 × 100 g/ha, interval 7 days	3 DALA	–
Pulses/ oilseeds	Soyabean	Foliar, 3 × 60 g/ha, BBCH 16/17, 51-59, 71-75	0 DAT_1, 34 DALA	–
Cereals	Wheat	Foliar, 2 × 125 g/ha, BBCH 30/35, 69	36 DAT_1, 4, 34–35 DALA	–
		Seed treatment, 75 g/100 kg[(b)]	93, 112, 161 DAT	Not peer reviewed

DALA: days after last application; DAT: day after treatment; DAT_1: day after 1st treatment; BBCH: growth stages of mono- and dicotyledonous plants.
(a): Fluxapyroxad was radiolabelled in both the aniline and the pyrazole moieties.
(b): According to the EMS, it corresponds to an application rate of 135 g/ha (EFSA, 2015).

After foliar applications, fluxapyroxad represented the main component of the total radioactive residues (TRR) in tomato, wheat and the soybean plant parts, except soybean seeds. The metabolism showed to be more extensive in soybean seeds with the metabolites M700F002 and M700F048[16] being the predominant part of the total residues.

The peer review concluded on a general residue definition for monitoring as parent compound following foliar applications. 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 potential inclusion of the metabolites observed in soybean seeds in the residue definition for the group of pulses/oilseeds was discussed during the peer review. It was concluded to limit the residue definition as parent compound and to set a general residue definition for risk assessment as fluxapyroxad for all crop groups (EFSA, 2012).

The intended uses of fluxapyroxad on witloofs concern post-harvest treatment of the active substance for which no metabolism study was submitted. Considering the metabolic behaviour observed in the three different crop groups after foliar applications, it is unlikely that a different or more extensive metabolism occurs after the post-harvest treatment and no further data are required.

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

For the uses under assessment, EFSA concludes that the metabolism of fluxapyroxad is sufficiently addressed and the residue definitions for enforcement and risk assessment as parent fluxapyroxad are applicable.

3.1.1.2. Magnitude of residues

In support of the MRL application, residue trials on oranges, lemons, potatoes, carrots, broccoli, cauliflowers, lettuces, lamb's lettuces, Brussels sprouts, head cabbages, artichokes, leeks, chicory roots and witloofs were provided.

a) Citrus fruits (import tolerance)

MX good agricultural practices (GAP): 2 × 67 g/ha, preharvest interval (PHI) 14 days
Residue data were not provided and the notified use was not assessed by the EMS-NL.

BR GAP: 3 × 50 g/ha, PHI 14 days

GAP-compliant residue trials on oranges (12 trials) and lemon (4 trials) conducted in Brazil and Argentina (2 in oranges, 2 in lemons) were provided. This data set is not sufficient to extrapolate results to the whole group of citrus fruits (European Commission, 2016). However, EFSA agrees with the EMS-NL proposal to extrapolate the residue data from oranges to other large fruits such as grapefruits.

Based on residues of fluxapyroxad in oranges ranging from 0.03 to 0.17 mg/kg and using the OECD MRL calculator, the MRL of 0.4 mg/kg is derived, which is higher than the MRL of 0.2 mg/kg set for citrus in Brazil. Therefore, EFSA proposes the MRL value of 0.2 mg/kg for grapefruits. On oranges, a change of the existing MRL of 0.3 mg/kg is not required.

b) Tropical root and tuber vegetables (northern (NEU) GAP: 4 × 56 g/ha, PHI 3 days)

Eight GAP-compliant residue trials on potatoes were provided and are sufficient to derive a MRL proposal by extrapolation to the whole group of tropical root and tuber vegetables. The MRL of 0.02 mg/kg is proposed for tropical root and tuber vegetables.

c) Other root and tuber vegetables, except sugar beets; herbal infusions from roots; roots rhizome spices

NEU/southern (SEU) GAP: 2 × 75 g/ha, PHI 7 days

GAP-compliant residue trials conducted on carrots in each northern (10 trials) and southern (8 trials) European region were provided. The results were combined (U-test, 5%) and the derived MRL of 0.3 mg/kg can be extrapolated to all three crop groups.

NEU/SEU GAP: 1 × 150 g/ha, PHI 7 days

GAP-compliant residue trials conducted on carrots in each northern (10 trials) and southern (8 trials) European region were provided. The results were combined (U-test, 5%) and the derived MRL of 0.2 mg/kg can be extrapolated to all three crop groups.

EFSA proposed the MRL of 0.3 mg/kg, based on the most critical split applications on carrots, for the groups of other root and tuber vegetables (except sugar beets), herbal infusions from roots and roots rhizome spices.

d) Spring onions, Leeks (NEU/SEU GAP: 2 × 75 g/ha, PHI 14 days)

GAP-compliant residue trials conducted on leeks in each northern (8 trials) and southern (8 trials) European region were provided. The results were combined (U-test, 5%) and the MRL of 0.6 mg/kg[17] derived can be extrapolate to spring onions.

e) Flowering brassica (NEU/SEU GAP: 3 × 75 g/ha, PHI 14 days)

GAP-compliant residue trials conducted on broccoli (4 trials) and cauliflowers (4 trials) in each northern and southern European region were provided and are sufficient to extrapolate results to the group of flowering brassica. Due to the large number of values below the LOQ, the statistical test for merging data sets (U-test) has limited power. Therefore, results from the NEU and SEU trials were assessed separately. Based on the most critical NEU use, the MRL of 0.15 mg/kg is proposed for

[17] The EMS-UK proposed the MRL of 0.7 mg/kg based on the single data set of NEU trials on leeks.

cauliflowers and other flowering brassica. On broccoli, a change of the existing MRL of 0.2 mg/kg is not necessary.

f) Brussels sprouts (NEU GAP: 3 × 75 g/ha, PHI 14 days)

Four GAP-compliant residue trials conducted in NEU support the MRL proposal of 0.3 mg/kg for Brussels sprouts.

g) Head cabbages (NEU/SEU GAP: 3 × 75 g/ha, PHI 14 days)

GAP-compliant residue trials conducted on head cabbages in each northern (8 trials) and southern (8 trials) European region were provided. Due to the large number of values below the LOQ, the statistical test for merging data sets (U-test) has limited power. Therefore, results from the NEU and SEU trials were assessed separately. Based on the most critical NEU use, the MRL of 0.4 mg/kg is proposed for head cabbages.

h) Lettuces and salad plants

Indoor GAP: 2 × 90 g/ha, PHI 14 days

Eight GAP-compliant residue trials conducted in greenhouses on open leaf lettuce varieties were provided. All trials were conducted at an application rate (75 g/ha), which is lower than the intended rate but within the acceptable range (25% of nominal application rate) and support a MRL proposal of 4 mg/kg for lettuces.

NEU/SEU GAP: 1 × 150 g/ha, PHI 14 days

GAP-compliant residue trials conducted in each northern (8 trials) and southern (8 trials) European region were provided. Open leaf lettuces varieties were used, except in one NEU trial. Results from the NEU and SEU trials were combined (U-test, 5%) and the MRL of 3 mg/kg derived for lettuces.

The extrapolation from lettuces to the whole group of lettuces and salad plants is supported for the indoor and the SEU use. For the NEU use, an additional trial conducted in an open leaf lettuce is required to fully support the single data set (European Commission, 2016). Taking into account that the residues from the seven NEU trials on open leaf lettuces provided sufficient evidence that the use is less critical for the MRL setting compared to the indoor and SEU uses, the deficiency identified is minor and not expected to impact on the validity of the proposed extrapolation.

Based on the most critical indoor use, the MRL of 4 mg/kg is proposed for the group of lettuces and salad plants. On lettuces, a change of the existing MRL of 4 mg/kg is not necessary.

i) Lamb's lettuces (indoor GAP: 2 × 90 g/ha – NEU/SEU GAP: 1 × 150 g/ha, PHI 14 days)

Two indoor and three NEU GAP-compliant residue trials were submitted. The number of trials is not sufficient to derive a MRL proposal based on residue trials on this crop. However, the extrapolation from open leaf lettuces to the whole group of lettuces and salad plants, which includes lamb's lettuces, as proposed in point (h) is acceptable.

j) Spinaches and similar leaves, herbs and edible flowers (NEU/SEU GAP: 1 × 150 g/ha, PHI 14 days)

The results from the combined data set of NEU and SEU field trials on lettuces assessed at point (h) can be consider for extrapolation to spinaches and similar leaves, herbs and edible flowers as the GAPs are the same. The deficiency identified (lack of one NEU residue trials on open leaf) is acceptable. The MRL of 0.3 mg/kg[18] is proposed for spinaches and similar leaves and herbs and edible flowers.

k) Chicory roots (FR GAP: 2 × 75 g/ha, PHI 14 days)

Eight GAP-compliant residue trials on chicory roots conducted in northern France were provided. Chicory roots are minor crops and are essentially cultivated in the northern part of France (European Commission, 2016). Therefore, the data are sufficient to derive a MRL of 0.3 mg/kg in chicory roots for the NEU, including France.

l) Witloofs/Belgian endives

FR GAP: pre-harvest, spraying, 2 × 75 g/ha, harvest at growth stages of mono- and dicotyledonous plants (BBCH) 49 + post-harvest, dip/drench application before storage, 1 × 18.8 g/hL, PHI 21 days

Eight GAP-compliant residue trials conducted in France were submitted. A part of the harvested chicory roots from the field trials assessed at point (k) was dipped with a fluxapyroxad solution just

[18] The EMS-UK proposed the MRL of 4 mg/kg based on the single dataset of SEU trials on lettuces.

before storage and forcing for witloof leaves production. Based on the available data, a MRL of 3 mg/kg is derived.

FR GAP: pre-harvest, 2 × 75 g/ha, harvest at BBCH 49 + post-harvest, spray application before forcing, 1 × 1.13 g/m^2, PHI 21 days

Eight GAP-compliant (25% tolerance rule) residue trials conducted in France were submitted. A part of the harvested chicory roots from the field trials assessed at point (k) was stored for 8 days at about 0°C. Prior to move to the climatic chambers, the roots were treated with a spray application at a rate equivalent to 1.13 g/m^2 (15 mL product/m^2) before forcing for witloof leaves production. Based on the available data a MRL of 6 mg/kg is derived.

EU GAP: Post-harvest dip/drench application before storage, 1 × 18.8 g/hL + spray application before forcing, 1 × 1.13 m^2/ha, PHI 21 days

Four GAP-compliant residue trials combining one dipping application prior to root storage following by one spraying application 8 days apart were provided. Witloofs/Belgian endives are minor crop in the EU and the available data support a MRL of 5 mg/kg.

Based on the most critical residue situation observed from the residue trials submitted, EFSA proposed the MRL of 6 mg/kg. Post-harvest residue data performed with the post-harvest drenching application method were not provided. Therefore, evidence that equivalent or lower residues are expected after this alternative treatment is required.

m) Globe artichokes (NEU/SEU GAP: 2 × 45 g/ha, PHI 7 days)

GAP-compliant residue trials conducted in each northern (4 trials) and southern (4 trials) European region were provided. The results were combined (U-test, 5%) and the MRL of 0.3 mg/kg[19] proposed for globe artichokes.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3. When a higher value was measured at a longer PHI than the PHI of the GAP, this value was selected for the calculation. When more than one use was assessed, EFSA proposed the MRL from the most critical residue situation and highlighted it in bold in Table 3.

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 17 months (carrots) 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.

According to the EMSs, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proven to be fit for the purpose (Netherlands, 2016; United Kingdom, 2017).

EFSA concludes that the submitted residue trials are sufficient to derive MRL proposals for all the crops under assessment, except for citrus fruits other than oranges and grapefruits.

[19] The EMS-UK proposed the MRL of 0.4 mg/kg based on the single dataset of four NEU trials.

Table 3: 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)
Oranges	BR	0.03; 0.04; 0.05; 0.05; 2 × 0.06; 0.07; 0.14; 0.14; 0.16; 0.16; 0.17 Pulp: 4 × < 0.01	MRL_{OECD} 0.31/0.40 $MRL_{Exporting\ Country}$ 0.2 **Extrapolation to grapefruits**	(0.4) 0.2	0.17	0.07
Lemons	BR	0.04; 0.06; 0.09; 0.13 Pulp: 2 × < 0.01	Data set insufficient to support extrapolation to citrus whole group	–	–	–
(Potatoes)	NEU	6 × < 0.01; 2 × 0.01	MRL_{OECD} 0.02/0.02 **Extrapolation to tropical root and tuber vegetables**	0.02	0.01	0.01
Carrots (1 × 150 mg/kg)	NEU	0.01; 0.02; 0.02; 2 × 0.03; 0.03; 2 × 0.08; 0.10; 0.13	Combined data sets (U-test, 5%) MRL_{OECD} 0.18/0.20 **Extrapolation to other root and tuber vegetables, except sugar beets; herbal infusions from roots, roots and rhizome spices**	0.2	0.13	0.03
	SEU	2 × 0.01; 0.02; 0.02; 0.03; 0.03; 0.05; 0.06				
Carrots (2 × 75 mg/kg)	NEU	3 × 0.03; 0.03; 0.04 0.04; 0.06; 0.10; 0.13; 0.18	Combined data sets (U-test, 5%) MRL_{OECD} 0.24/0.30 **Extrapolation to other root and tuber vegetables, except sugar beets; herbal infusions from roots, roots and rhizome spices**	**0.3**	**0.18**	**0.04**
	SEU	< 0.01; 0.02; 0.03; 0.03; 0.04; 0.04; 0.05; 0.08				
Leeks	NEU	< 0.01; 0.02; 0.06; 0.09; 0.10; 0.12; 0.17; 0.22	Combined data sets (U-test, 5%) MRL_{OECD} 0.56/0.60 **Extrapolation to spring onions**	0.6	0.42	0.13
	SEU	0.07; 0.08; 0.14; 0.18; 0.19; 0.23; 0.26; 0.42				
Broccoli	NEU	2 × < 0.01; 0.01; 0.08	Data on broccoli and cauliflowers combined MRL_{OECD} 0.12/0.15 **Extrapolation to flowering brassica**	**0.15**	**0.08**	**0.01**
Cauliflowers		2 × < 0.01; 0.01; 0.02				
Broccoli	SEU	< 0.01; 0.01; 0.03; 0.05	Data on broccoli and cauliflowers combined MRL_{OECD} 0.07/0.07 **Extrapolation to flowering brassica**	0.07	0.05	0.01
Cauliflowers		4 × < 0.01				
Brussels sprouts	NEU	0.02; 0.04; 0.06; 0.14	MRL_{OECD} 0.29/0.30	0.3	0.14	0.05

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)
Head cabbage	NEU	5 × < 0.01; 0.01; 0.012; 0.27	MRL_{OECD} 0.41/0.40	**0.4**	**0.27**	**0.01**
	SEU	6 × < 0.01; 0.02; 0.03	MRL_{OECD} 0.04/0.04	0.04	0.03	0.01
Lettuces (2 × 90 g/ha)	Indoor	2 × < 0.01; 0.07; 0.23; 0.26; 0.58; 1.30; 1.80	Open leaf lettuces. All trials underdosed (75 g/ha) but within 25% of intended rate MRL_{OECD} 3.20/4.00 **Extrapolation to lettuces and salad plants**	**4**	**1.80**	**0.25**
Lettuces (1 × 150 g/ha)	NEU	0.01; (0.01); 0.03; 0.05; 0.06; 0.18; 0.87; 1.44	Open leaf lettuces, except one (in brackets). Combined data set (U-test, 5%) MRL_{OECD}(NEU/SEU): 3.01/3.00 MRL_{OECD} (NEU): 2.47/3.00 MRL_{OECD} (SEU): 3.58/4.00 **Extrapolation to lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers**	3	1.80	0.06
	SEU	2 × < 0.01; 0.05; 0.07; 0.16; 0.76; 1.58; 1.80				
Lamb's lettuces (2 × 90 g/ha)	Indoor	0.72; 0.79	Data set insufficient to support MRL proposal based on the trials reported on this crop However an extrapolation from open leaf lettuces to the lettuces and salad plants, which includes lamb's lettuces, is acceptable	–	–	–
Lamb's lettuces (1 × 150 g/ha)	NEU	0.65; 0.88; 1.15		–	–	–
Chicory roots	NEU (FR)	0.05; 3 × 0.06; 0.08; 0.10; 0.11; 0.21	All trials conducted in France (FR) MRL_{OECD} 0.30/0.30	0.3	0.21	0.07
Witloofs/Belgian endives (Po, dipping + spraying)	Indoor	1.40; 1.50; 2.40; 2.50	Post-harvest (Po) use MRL_{OECD} 4.27/5.00 (mean + 4 SD)	5	2.5	**1.95**
Witloofs/Belgian endives (pre + Po, dipping)	NEU (FR) + Indoor	0.60; 0.63; 0.64; 0.70; 0.82; 0.99; 1.35; 1.60	All trials conducted in France MRL_{OECD} 2.41/3.00 (mean + 4 SD)	3	1.6	0.76
Witloofs/ Belgian endives (pre + Po, spraying)	NEU (FR) + Indoor	0.32; 0.50; 0.62; 0.74; 0.79; 0.95; 1.80; 3.70	All trials conducted in France MRL_{OECD} 5.62/6.00 (mean + 4 SD)	**6**	**3.70**	0.77

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)
Globe artichokes	NEU	3 × 0.06; 0.19	Combined data sets (U-test, 5%) MRL_{OECD} 0.29/0.30	0.3	0.19	0.07
	SEU	2 × 0.07; 0.09; 0.14				

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code if non-EU (MX: Mexico; BR: Brazil).
(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). Underlined values: higher level measured at a longer PHI then the PHI of the intended GAP.
(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 raw agricultural commodities (RAC) is applicable (EFSA, 2012).

For citrus, the distribution of residues between peel and pulp was investigated in oranges (4 trials) and lemons (2 trials). Residues in the edible portion were always below the LOQ of 0.01 mg/kg (data from trials with median to highest residues in whole fruits). For processing studies, orange trees were treated in the field according to the notified Brazilian GAP but at an exaggerated application rate of 250 g/ha (5N). Orange fruits were then processed into juice, dried pulp and oil. Fluxapyroxad showed to concentrate only in oil. Residues of the metabolites were below the LOQ in all samples, except for M700F008 (0.03 mg/kg) in one oil sample (Netherlands, 2016).

Specific studies to assess the magnitude of fluxapyroxad residues during the processing of the other products under consideration were not provided and are not required. Commodities are mainly eaten raw (i.e. lettuces), residue levels in RAC were below the trigger value of 0.1 mg/kg (i.e. flowering brassica, tropical root and tubers) or the total theoretical maximum daily intake (TMDI) for each individual crop is not expected to exceed 10% of the acceptable daily intake (ADI) (European Commission, 1997d).

The processing factors derived from data submitted are summarised in Table 4.

Table 4: Overview of the available processing studies

Crop (RAC)/edible part or Crop (RAC)/ processed product	Number of studies	Processing factor (PF)		Conversion factor (CF_P) for RA[(a)]
		Individual values	Median PF	
Orange, pulp	4	–	–[(b)]	1
Lemon, pulp	2	–	–[(b)]	1
Orange, dry pulp	4	< 0.04; 0.08; 0.11; 0.12	0.10	1
Orange, juice	4	< 0.03; < 0.04; < 0.05; < 0.06	< 0.05	1
Orange, oil	4	14; 22; 32; 58	27	1

RAC: raw agricultural commodities; PF: processing factor; CF: conversion factor; RA: risk assessment.
(a): When the residue definition for risk assessment differs from the residue definition for monitoring.
(b): Since residues in citrus pulp were < LOQ, PFs were not calculated.

EFSA recommends the inclusion of the derived processing factors of 0.05 and 27 for orange juice and oil, respectively, in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

Several crops for which the EU use is under assessment can be grown in rotation with other plants. Therefore, the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. Fluxapyroxad is a high persistent compound ($DT_{90field}$ > 1,000 days) and tends to accumulate in soil treated for several consecutive years (EFSA, 2012).

3.1.2.1. Nature of residues

The metabolism of fluxapyroxad in rotational crops was assessed on the framework of the peer review (United Kingdom, 2011a; EFSA, 2012). The overview of the confined rotational stud design is presented in Table 5.

Table 5: Overview of the available confined rotational crop studies

Crop group	Crops	Application[(a)]	PBI (DAT)
Leafy crops	Spinach	Bare soil at 250 g/ha	30, 120/149, 365
Roots/tuber crops	Radish		
Cereals	Wheat		

PBI: plant-back interval; DAT: days after treatment.
(a): Fluxapyroxad was radio-labelled in both the aniline and the pyrazole moieties.

At all three plant-back intervals (PBI), 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. 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) and leafy crops (cauliflowers, broccoli and lettuces) were assessed in the framework of the peer review (United Kingdom, 2011a; EFSA, 2012). The trials were conducted with bare soil previously treated at a rate of 250 g/ha (1.1N the intended highest dose rate for the crops under consideration) and showed that no significant residue levels of metabolites M700F002, M700F008 and M700F048 were recovered in the edible parts of the rotated crops at all PBIs (< 0.01–0.02 mg/kg).

Significant levels of fluxapyroxad residues were quantified in carrot roots (0.08 mg/kg) and in immature lettuces and cauliflower leaves (0.03 and 0.06 mg/kg, respectively). Based on these findings, EFSA proposed a default MRL of 0.1 mg/kg for the root and tuber vegetables crop group (including sugar beet and potatoes) and for the crop 'leaves and sprouts of brassica spp.'[20] (EFSA, 2012). This default MRL value for rotational was implemented for potatoes in the EU legislation upon EFSA proposal (EFSA, 2015).

Considering the results of these studies, which were conducted at the annual seasonal application rate of 250 g/ha only, and the expected accumulation of the active substance in soil following several years of applications, the possibility of residues of fluxapyroxad to be present in rotational crops cannot be excluded. Member States granting an authorisation should take the necessary risk mitigation measures in order to minimise residues in rotational crops.

Additionally, EFSA would propose to risk managers, as an alternative to the lower MRL of 0.02 mg/kg derived from the residue trials conducted on potato as primary crop and extrapolated to the group of tropical root and tuber vegetables (see Table 3), the default MRL of 0.1 mg/kg. The default MRL proposed for fluxapyroxad based on rotational crop data should however be reconsidered once a guidance document on MRL setting based on rotational crops is available.

3.2. Nature and magnitude of residues in livestock

Several crops under consideration and their by-products may be used as livestock feed items. Therefore the potential transfer of residues in products of animal origin was investigated.

3.2.1. Dietary burden of livestock

The median and maximum dietary burden values for livestock were calculated in accordance with the OECD guidance document (OECD, 2009, 2013) and the animal dietary burden calculator developed by EFSA. To conduct the calculations, EFSA used the STMR/HR of the feed items and/or their by-products retrieved from a previous opinion (EFSA, 2011), from the JMPR reports (FAO, 2012, 2015) for the CXLs implemented in the EU legislation and derived for the crops under assessment in the framework of these MRL applications. For kale, the existing MRL was used as no input value was available to refine the calculation. When specific processing factors (PFs) were not available, the default PF was used to estimate the residue levels in the feed by-products. This calculation should be considered as indicative since it included MRL and default PFs. Furthermore, data for corn/popcorn stover, rice straw, sorghum stover, turnip/swede tops (leaves)[21] were not available. A more comprehensive dietary burden calculation will be conducted under the MRL review according to Article 12 of Regulation (EU) No 396/2005, when further information on the authorised uses of fluxapyroxad will be available to EFSA.

The input values for the dietary burden calculation are summarised in Table 6. Default processing factors have been added to the comment box of this table within brackets.

[20] Corresponding to the code '0251080 baby leaf crops (including Brassica species)' according to Commission Regulation (EU) No 725/2014.

[21] Since the intended use on turnips and swedes was supported by extrapolation from data on carrots, residue trials investigating the magnitude of residues in these new feed items were not performed (United Kingdom, 2017).

Table 6: Input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Barley/oat, straw	4.33	STMR (EFSA, 2011)	10.11	HR (EFSA, 2011)
Beet (mangel), fodder	0.04	STMR (EFSA, 2011)	0.07	HR (EFSA, 2011)
Beet, sugar tops	2.57	STMR (EFSA, 2011)	4.17	HR (EFSA, 2011)
Cabbage, head leaves	0.01	STMR	0.27	HR
Kale leaves, forage	0.07	MRL	0.07	MRL
Rye/wheat, straw	2.13	STMR (EFSA, 2011)	8.32	HR (EFSA, 2011)
Carrot culls	0.04	STMR	0.18	HR
Cassava/tapioca	0.01	STMR	0.01	HR
Potatoes	0.02	STMR (EFSA, 2015)	0.07	HR (EFSA, 2015)
Swedes/turnips	0.04	STMR (carrots)	0.18	HR (carrots)
Barley/oat, grain	0.54	STMR (EFSA, 2011)		
Wheat/rye, grain	0.12	STMR (EFSA, 2011)		
Bean/lupins, dry	0.04	STMR (EFSA, 2011)		
Peas (dry)	0.04	STMR (FAO, 2012)		
Maize grain	0.01	STMR (EFSA, 2011)		
Cotton seeds	0.07	STMR (FAO, 2015)		
Sorghum grain	0.20	STMR (FAO, 2015)		
Soybean seeds	0.01	STMR (EFSA, 2011)		
Apple, wet pomace	1.38 (0.3 × 4.6)	STMR (FAO, 2012)-P (EFSA, 2011)		
Beet, sugar dry pulp	0.07 (0.04 × 1.74)	STMR-P[(a)] (EFSA, 2011)		
Beet, sugar ensiled pulp	0.12 (0.04 × 3)	STMR (EFSA, 2011)-P (3)		
Beet, sugar molasses	0.03 (0.04 × 0.80)	STMR-P[(a)] (EFSA, 2011)		
Brewer's grain dry pulp	1.78 (0.54 × 3.3)	STMR (2011)-P (3.3)		
Citrus, dry pulp	0.007 (0.07 × 0.1)	STMR × PF		
Coconut meal	0.02 (0.01 × 1.5)	STMR (FAO, 2015)-P (1.5)		
Corn, field milled by-products	0.01 (0.01 × 1)	STMR (EFSA, 2011)-P (1)		
Corn, field hominy meal	0.06 (0.01 × 6)	STMR (EFSA, 2011)-P (6)		
Corn, field gluten feed	0.03 (0.01 × 2.5)	STMR (EFSA, 2011)-P (2.5)		
Corn, field gluten, meal	0.01 (0.01 × 1)	STMR (EFSA, 2011)-P (1)		
Cotton meal	0.004 (0.07 × 0.06)	STMR-P[(a)] (FAO, 2015)		
Distiller's grain	0.40 (0.12 × 3.3)	STMR (EFSA, 2011)-P (3.3)		
Linseed meal	0.04 (0.09 × 0.44)	STMR-P (EFSA, 2011)		
Lupin seed meal	0.04 (0.04 × 1.1)	STMR (EFSA, 2011)-P (1.1)		
Peanut meal	0.001 (0.01 × 0.12)	STMR-P[(a)] (EFSA, 2011)		
Potato, process waste	0.10 (0.02 × 5.00)	STMR-P (EFSA, 2011)		
Potato, dried pulp	0.16 (0.02 × 8.00)	STMR-P (EFSA, 2011)		
Rape/canola seed meal	0.05 (0.12 × 0.44)	STMR-P[(a)] (EFSA, 2011)		
Rice, bran/pollard	9.40 (0.94 × 10)	STMR (FAO, 2015)-P (10)		
Safflower seed meal	0.18 (0.09 × 2)	STMR (EFSA, 2011)-P (2)		
Soybean meal	0.013 (0.01 × 1.3)	STMR-P (EFSA, 2011)		
Soybean hulls	0.13 (0.01 × 13)	STMR (EFSA, 2011)-P (13)		
Sugarcane molasses	8.32 (0.26 × 32)	STMR (EFSA, 2016a)-P (32)		
Sunflower seed	0.011 (0.09 × 0.12)	STMR (EFSA, 2011)-P (FAO, 2012)		
Wheat gluten meal	0.22 (0.12 × 1.8)	STMR (EFSA, 2011)-P (1.8)		
Wheat milled by-products	0.84 (0.12 × 7)	STMR (EFSA, 2011)-P (7)		

STMR: supervised trials median residue; STMR-P: STMR for processed commodities; HR: highest residue.
(a): Indicative processing factor as based only on two trials.

The estimated animal dietary intakes taking into account the feed commodities listed in Table 6 and including the crops under consideration in these MRL applications are summarised in Table 7. The maximum animal intake estimates calculated by JMPR are reported in this table in the column 'Previous assessment' (FAO, 2012, 2015). The existing MRLs in products of animal origin were derived based on these figures (EFSA, 2013, 2016b).

Table 7: Results of the dietary burden calculation

Animal	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	> 0.1 mg/kg DM	Maximum burden (mg/kg DM)	Highest contributing commodity[a]	Previous assessment[b] (Max. burden)
Dairy cattle	0.220	0.310	Yes	8.07	Beet, root tops	40.9 (AU)
Beef cattle	0.091	0.135	Yes	5.64	Beet, root tops	45.2 (AU)
Ram/Eve	0.204	0.338	Yes	10.10	Barley straw	–
Lamb	0.260	0.430	Yes	10.13	Barley straw	–
Pig breeding	0.061	0.088	Yes	3.82	Beet, root tops	
Pig finishing	0.024	0.038	Yes	1.26	Swede roots	
Poultry broiler	0.107	0.117	Yes	1.65	Rice bran/pollard	1.37 (AU)
Poultry layer	0.112	0.144	Yes	2.11	Rice bran/pollard	8.53 (EU)
Turkey	0.039	0.049	Yes	0.68	Brewer's grain	–

DM: dry matter; bw: body weight.
(a): Considering the maximum dietary animal burden.
(b): The regions where the highest dietary burden was calculated are reported in brackets (AU: Australia, EU: Europe).

Based on the revised dietary burden calculations, EFSA concludes that the existing MRLs on commodities of animal origin cover the additional uses under consideration in these MRL applications and their modification is not required.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population[22] (EFSA, 2007).

To calculate the chronic exposure, EFSA used median residue values (STMR) derived from the residue trials conducted for the crops under consideration in these MRL applications and reported in Table 3, the STMR values reported in previous EFSA reasoned opinions (EFSA, 2011, 2015, 2016a) and STMR values derived by JMPR for the CXLs implemented in the EU legislation (FAO, 2012, 2015). In a conservative exposure scenario and in the absence of clear guidance, residues in root and tuber vegetables (including sugar beets), herbal infusions from roots, root and rhizome spices and baby leaf crops potentially arising after crop rotation were taken into account by summing to the primary residues the default MRL proposed during the peer review (EFSA, 2012). For the remaining commodities of plant and animal origin, the existing MRLs as established in Regulation (EU) 2017/626[23] were used as input values. To reflect the different residue definitions for monitoring and risk assessment for products of animal origin, the STMRs were multiplied by conversion factors (CF) for enforcement to risk assessment (EFSA, 2011).

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 highest residue level (HR) as observed in supervised field trials (Table 3). The approach used in the chronic risk assessment was applied to sum the residues potentially occurring from rotational sources. A variability factor accounting

[22] 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 Member States surveys are used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

[23] Commission Regulation (EU) 2017/626 of 31 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. OJ L 96, 7.4.2017, p. 1–43.

for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

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

Table 8: 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 for plants: Fluxapyroxad **Risk assessment residue definition for products of animal origin:** Fluxapyroxad (BAS 700F) and metabolite M700F008 expressed as parent equivalent				
Grapefruits	0.01	STMR-pulp (oranges)	0.01	HR-pulp
Tropical root and tuber vegetables	0.11	STMR (potatoes) + default MRL[(a)]	0.11	HR (potatoes) + default MRL[(a)]
Other root & tuber vegetables, except sugar beet, Herbal infusions from roots, Roots and rhizome spices	0.14	STMR (carrots) + default MRL[(a)]	0.28	HR (carrots) + default MRL[(a)]
Spring onions, leeks	0.13	STMR (leeks)	0.42	HR (leeks)
Flowering brassica, except broccoli	0.01	STMR (cauliflowers, broccoli)	0.08	HR (cauliflowers, broccoli)
Brussels sprouts	0.05	STMR	0.14	HR
Head cabbages	0.01	STMR	0.27	HR
Lettuces and salad plants, except baby leaf crops (including brassica species)	0.25	STMR (indoor, lettuces)	1.80	HR (indoor, lettuces)
Baby leaf crops (including brassica species	0.35	STMR (lettuces) + default MRL[(a)]	1.90	HR (lettuces) + default MRL[(a)]
Spinaches and similar leaves, Herbs and edible flowers	0.06	STMR (outdoor, lettuces)	1.80	HR (outdoor, lettuces)
Witloofs	1.95	STMR	3.70	HR
Globe artichokes	0.07	STMR	0.19	HR
Chicory roots	0.07	STMR	0.21	HR
Oranges	0.01	STMR-pulp (FAO, 2015)	Acute risk assessment undertaken only with regard to the crops under consideration	
Tree nuts	0.01	STMR (FAO, 2015)		
Pome fruits	0.30	STMR (FAO, 2012)		
Apricots	0.44	STMR (EFSA, 2011)		
Cherries	0.76	STMR (FAO, 2015)		
Peaches	0.47	STMR (FAO, 2015)		
Plums	0.44	STMR (EFSA, 2011)		
Grapes	0.47	STMR (FAO, 2015)		
Strawberries	0.82	STMR (EFSA, 2016a)		
Blueberries	2.39	STMR (EFSA, 2016a)		
Banana	0.06	STMR-pulp (FAO, 2015)		
Mangoes	0.18	STMR (EFSA, 2016a)		
Potatoes	0.12	STMR (EFSA, 2015) + default MRL[(a)]		
Solanaceae	0.07	STMR (FAO, 2012)		
Cucurbits edible peel	0.05	STMR (EFSA, 2016a)		
Cucurbits inedible peel	0.05	STMR (EFSA, 2016a)		
Sweet corns	0.01	STMR (EFSA, 2011)		
Broccoli	0.28	STMR (EFSA, 2016a)		
Chinese cabbages	1.7	STMR (FAO, 2015)		
Lettuces	0.51	STMR (FAO, 2015)		
Beans and peas, with pods	0.65	STMR (FAO, 2012)		

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Beans and peas, without pods	0.03	STMR (FAO, 2012)		
Celery, rhubarb, fennel, cardoon	1.68	STMR (EFSA, 2016a)		
Peas, lentils (dry)	0.04	STMR (FAO, 2012)		
Beans, lupins (dry)	0.04	STMR (EFSA, 2011)		
Linseed, poppy seed, sesame seed, mustard seed, pumpkin seed, safflower, borage, gold of pleasure, hempseed, castor bean, other oilseed	0.09	STMR (EFSA, 2011)		
Peanuts	0.01	STMR (EFSA, 2011)		
Sunflower seeds	0.06	STMR (EFSA, 2011)		
Rapeseeds	0.12	STMR (EFSA, 2011)		
Soya beans	0.01	STMR (EFSA, 2011)		
Cotton seeds	0.07	STMR (FAO, 2015)		
Barley, oats	0.54	STMR (EFSA, 2011)		
Maize	0.01	STMR (EFSA, 2011)		
Rice	0.94	STMR (FAO, 2015)		
Sorghum	0.20	STMR (FAO, 2015)		
Rye, wheat	0.12	STMR (EFSA, 2011)		
Sugar beets (roots)	0.14	STMR (EFSA, 2011) + default MRL[(a)]		
Sugar cane	0.26	STMR (EFSA, 2016a)		
Muscle from mammalians	0.05	STMR (meat) × CF[(b)]		
Fat tissue from mammalians	0.07	STMR (0.047) × CF (1.5)		
Liver from mammalians	0.32	STMR (0.081) × CF (3.9)		
Kidney from mammalians	0.05	STMR (0.024) × CF (2)		
Edible offal from mammalians	0.32	STMR (0.081) × CF (3.9)		
Other tissues from mammalians	0.20	MRL (0.1) × CF (2)		
Muscle from poultry	0.04	STMR (meat) × CF[(b)]		
Fat tissue from poultry	0.04	STMR (0.021) × CF (2)		
Liver from poultry	0.04	STMR (0.021) × CF (2)		
Kidney from poultry	0.04	MRL (0.02) × CF (2)		
Edible offal from poultry	0.04	MRL (0.01) × CF (2)		
Milk	0.01	STMR (0.004) × CF (2)		
Birds eggs	0.01	STMR (0.006) × CF (2)		
Other plant and animal commodities	MRL	MRLs in Regulation (EU) No 2017/626		

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; CF: conversion factor.

(a): For the dietary exposure of root and tuber vegetables (including sugar beets and potatoes), herbal infusions from roots, root and rhizome spices and baby leaf crops and in absence of an agreed methodology, EFSA used the sum of residues from application to the commodity as a primary crop (see Table 3) and the default MRL of 0.1 mg/kg proposed by the peer review to cover worst case scenario of residues potentially arising from rotational sources.

(b): Fluxapyroxad was designated as fat-soluble by the peer review (EFSA, 2012). Consumption figures in the EFSA PRIMo are expressed as meat. STMR values (mammalian muscle < 0.02 mg/kg × CF 2 and fat 0.05 mg/kg × CF 1.5; poultry muscle < 0.02 mg/kg × CF 2 and fat 0.02 mg/kg × CF 2) were calculated considering 80%/90% muscle and 20%/10% fat content for mammalian/poultry meat, respectively (FAO, 2009).

The estimated exposure was then compared with the toxicological reference values derived for fluxapyroxad (Table 1). The results of the intake calculation using the EFSA PRIMo is a key supporting document and is made publicly available as a background document to this reasoned opinion.

A long-term consumer intake concerns was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be 38% of the ADI (German child diet). Among the crops under consideration, witloofs/Belgian endives were the major contributors to the total consumer exposure accounting for a maximum of 1.8% of the ADI (Dutch child diet).

An acute consumer risk was not identified in relation to the MRL proposals for all the crops under consideration. The highest acute consumer exposure was calculated to be 69% of the acute reference dose (ARfD) for witloofs/Belgian endives (Dutch child diet).

It is also noted that the metabolite M700F002 was estimated to leach to groundwater at significant levels (above the trigger limit of 0.75 μg/L) according to environmental fate and behaviour models assessed under the peer review (EFSA, 2012). Nevertheless, the peer review concluded that the additional exposure of the consumers when groundwater is used as drinking water was not significantly contributing to the overall consumer exposure (< 1% of the ADI allocated to M700F002).

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				
0110010	Grapefruits	0.01*	0.2	Import tolerance (BR GAP) supported by trials on oranges and unlikely to pose consumer health risk. Using OECD calculator the MRL of 0.4 mg/kg is derived. The MRL of 0.2 mg/kg set in country of origin is proposed by extrapolation for grapefruits. A change of the existing MRL is not required for oranges
0110020	Oranges	0.3	No change	
0212000	Tropical root and tuber vegetables, except potatoes	0.01*	0.02 or 0.1	NEU use supported by extrapolation from data on potatoes. Alternatively, risk managers may consider the default MRL of 0.1 mg/kg for rotational crops proposed in the conclusion of the peer review. Unlikely to pose consumer health risk
0213000	Other root and tuber vegetables except sugar beets and radishes	0.1	0.3	NEU and SEU uses supported by extrapolation from data on carrots. MRL based on the most critical combined NEU/SEU data set of split applications. Unlikely to pose consumer health risk
0213080	Radishes	0.2	0.3	
0220040	Spring onions/green onions and Welsh onions	0.1	0.6	NEU and SEU uses supported by extrapolation from data on leeks. Unlikely to pose consumer health risk
0241010	Broccoli	0.2	No change	NEU and SEU uses supported by data on cauliflowers and broccoli. A change of the existing MRL is not required for broccoli. Unlikely to pose consumer health risk
0241020	Cauliflowers	0.07	0.15	
0241990	Others flowering brassica	0.07	0.15	
0242010	Brussels sprouts	0.07	0.3	NEU use supported. Unlikely to pose consumer health risk
0242020	Head cabbages	0.07	0.4	NEU and SEU uses supported. Unlikely to pose consumer health risk
0251000	Lettuces and salad plants, except lettuces	0.03	4	Indoor, NEU and SEU uses supported. MRL derived by extrapolation from the most critical indoor use on lettuces. A change of the existing MRL is not
0251020	Lettuces	4	No change	

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
				required for lettuces. Unlikely to pose consumer health risk
0252000	Spinaches and similar leaves	0.03	3	NEU and SEU uses supported by extrapolation from a combined data set of field trials on lettuces. Unlikely to pose consumer health risk
0255000	Witloofs/Belgian endives	0.03	6	Pre-harvest spraying and post-harvest dipping or spraying and post-harvest (dipping + spraying) uses supported. Unlikely to pose consumer health risk
0256000	Herbs and edible flowers	0.03	3	NEU and SEU uses supported by extrapolation from a combined data set on field trials on lettuces. Unlikely to pose consumer health risk
0270050	Globe artichokes	0.01*	0.3	NEU and SEU uses supported. Unlikely to pose consumer health risk
0270060	Leeks	0.01*	0.6	NEU and SEU uses supported. Unlikely to pose consumer health risk
0633000	Herbal infusions from roots	0.01*	0.3	NEU and SEU uses supported by extrapolation from data on carrots. Unlikely to pose consumer health risk
0840000	Root and rhizome spices	0.01*	0.3	NEU and SEU uses supported by extrapolation from data on carrots. Unlikely to pose consumer health risk
0900030	Chicory roots	0.01	0.3	NEU use supported. Unlikely to pose consumer health risk

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; BR GAP: Brazil good agricultural practices; OECD: Organisation for Economic Co-operation and Development.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report

DAT	days after treatment
DM	dry matter
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
HR	highest residue
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
SANCO	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)

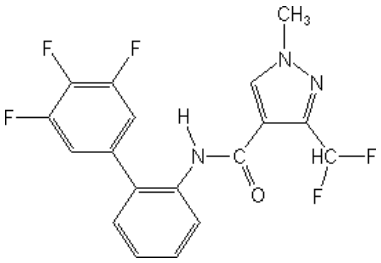
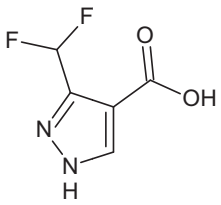
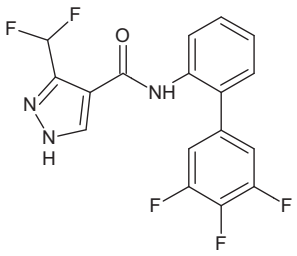
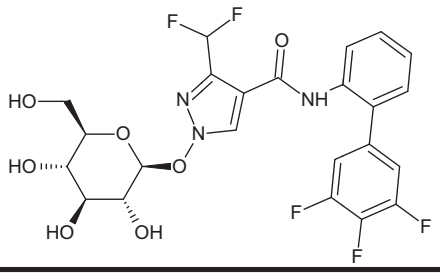
Crop	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number min–max	Interval between application	g/hL min–max	Water L/ha min-max	g/ha min–max		
Citrus fruits	MX	F	Fungal diseases	SC	167 g/L	Spraying		2	20 days	9–17	460–560	67	14	EMS-NL
	BR	F		SC	167 g/L	Spraying		1–3	7–30 days	1–3	2,000	50	14	EMS-NL
Tropical root and tuber vegetables	NEU	F	Fungal diseases	SC	75 g/L	Spraying	BBCH 38-89	4	7 days	14–37	150–400	56	3	EMS-UK
Other root and tuber vegetables except sugar beets, Herbal infusions from roots, Root rhizome spices	NEU	F	Fungal diseases	SC	75 g/L	Spraying	BBCH 12-49	1–2	7 days	7.5–37.5	200–1,000	75	7	EMS-UK
	SEU	F		SC	75 g/L	Spraying	BBCH 12-49	1–2	7 days	7.5–37.5	200–1,000	75	7	
	NEU	F		SC	75 g/L	Spraying	BBCH 12-49	1	–	15–75	200–1,000	150	7	
	SEU	F		SC	75 g/L	Spraying	BBCH 12-49	1	–	15–75	200–1,000	150	7	
Spring onions	NEU	F	Fungal diseases	SC	75 g/L	Spraying	BBCH 13-49	1–2	7 days	12.5–37.5	200–600	75	14	EMS-UK
	SEU	F		SC	75 g/L	Spraying	BBCH 20-49	1–2	7 days	7.5–37.5	200–1,000	75	14	
Flowering brassica	NEU	F	Fungal diseases	SC	75 g/L	Spraying	BBCH 41-49	1–3	7	9.38–37.5	200–800	75	14	EMS-UK
	SEU	F		SC	75 g/L	Spraying	BBCH 41-49	1–3	7	7.5–37.5	200–1,000	75	14	
Brussels sprouts	NEU	F	Fungal diseases	SC	75 g/L	Spraying	BBCH 41-49	1–3	7	9.38–37.5	200–800	75	14	EMS-UK
Head cabbages	NEU	F	Fungal diseases	SC	75 g/L	Spraying	BBCH 41-49	1–3	7	9.38–37.5	200–800	75	14	EMS-UK
	SEU	F		SC	75 g/L	Spraying	BBCH 41-91	1–3	7	7.5–37.5	200–1,000	75	14	
Lettuces and salad plants	EU	I	*Sclerotinia sclerotiorum, Sclerotinia minor, Rhizoctonia solani*	SC	75 g/L	Spraying	BBCH 12-49	1–2	7	9–45	200–1,000	90	14	EMS-UK

Crop	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number min–max	Interval between application	g/hL min–max	Water L/ha min-max	g/ha min–max		
Lettuces and salad plants Spinaches and similar leaves; Herbs and edible flowers	NEU	F	Fungal diseases	SC	75 g/L	Spraying	BBCH 12-49	1		15–75	200–1,000	150	14	EMS-UK
	SEU	F		SC	75 g/L	Spraying	BBCH 12-49	1		15–75	200–1,000	150	14	
Chicory roots	NEU (FR)	F	Rust *(Puccinia cichorii), Alternaria* spp.	SC	75 g/L	Spraying	BBCH 13-49	1–2	7 days	7.5–37.5	200–1,000	75	14	EMS-UK
Witloofs/ Belgian endives	NEU (FR)	F	Rust *(Puccinia cichorii), Alternaria* spp.	SC	75 g/L	1. Spraying	1. BBCH 13-49	1–2	7 days	7.5–37.5	200–1,000	75	21	EMS-UK 2. Before storage of roots
	EU	I				2. Dipping/ drenching	2. Post-harvest	1	–	–	–	18.8 g/hL (30–40 L/tonnes)		
	NEU (FR)	F		SC	75 g/L	1. Spraying	1. BBCH 13-49	1–2	7 days	7.5–37.5	200–1,000	75	21	EMS-UK 2. Before forcing[e]
	EU	I				2. Spraying	2. Post-harvest	1	–	–	5 L/m^2	1.13 g/m^2		
	EU	I		SC	75 g/L	1. Dipping/ drenching	Post-harvest	1 + 1		–		1. 18.8 g/hL (30–40 L/tonnes)	21	EMS-UK 1. Before storage of roots 2. Before forcing[e]
						2. Spraying						2. 1.13 g/m^2		
Globe artichokes	NEU (FR)	F	Powdery mildew *(Leveillula taurica, Golovinomyces cichoracearum (=Erysiphe c.), Alternaria* spp.	SC	75 g/L	Spraying	BBCH 51-57	1–2	7 days	3–11.3	400–1,500	45	7	EMS-UK Latest BBCH for year of harvest
	SEU	F		SC	75 g/L	Spraying	BBCH 51-57	1–2	7 days	3–11.3	400–1,500	45	7	

Crop	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number min–max	Interval between application	g/hL min–max	Water L/ha min-max	g/ha min–max		
Leeks	NEU		Purple blotch (*Alternaria* porri), Rust (Puccinia allii)	SC	75 g/L	Spraying	BBCH 13-49	1–2	7 days	12.5–37.5	200–600	75	14	EMS-UK
	SEU			SC	75 g/L	Spraying	BBCH 20-49	1–2	7 days	7.5–37.5	200–1,000	75	14	

NEU: northern European Union; SEU: southern European Union; MS: Member State; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
(e): Before forcing: shortly after preparation for forcing. Application rate reported in application form is 15 mL product/m^2, equivalent to 1.125 g a.s./m^2.

Appendix B – Used compound codes

Code/Trivial name	Chemical name	Structural formula
Fluxapyroxad	3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide MW: 381.31	
M700F002	3-(difluoromethyl)-1*H*-pyrazole-4-carboxylic acid	
M700F008	3-(difluoromethyl)-*N*-(3′,4′,5′-trifluorobiphenyl-2-yl)-1*H*-pyrazole-4-carboxamide	
M700F048	3-(difluoromethyl)-1-(*b*-D-glucopyranosyloxy)-*N*-(3′,4′,5′-trifluorobiphenyl-2-yl)-1*H*-pyrazole-4-carboxamide	

MW, molecular weight.