REASONED OPINION

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# Modification of the existing maximum residue levels for fluopyram in various crops

European Food Safety Authority (EFSA)

## Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member States (EMS) Hungary and Greece received applications from Bayer CropScience AG to modify the existing maximum residue levels (MRLs) for the active substance fluopyram in apricots, sweet peppers, sweet corn, spinaches, witloof, herbs and edible flowers, peas (with pods), lentils, other legume vegetables, sesame seeds, sunflower seeds, rapeseeds, pumpkin seeds, safflower seeds, borage seeds, hemp seeds, castor beans, barley, buckwheat, oat and sugar beet roots. In order to accommodate the intended European uses, both EMS proposed to raise existing EU MRLs for all requested crops, except for sweet corn and sugar beet roots. According to EFSA, the data are sufficient to derive MRL proposals for all requested crops, except for sugar beet. For sweet corn EFSA proposes to decrease the MRL value to the LOQ of 0.01 mg/kg since residues above the LOQ were not observed in the primary and rotation crop studies. Based on the risk assessment results, EFSA concludes that the proposed use of fluopyram on the crops under consideration for which new MRL proposals were supported will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.



**Keywords:** fluopyram, 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) Hungary and Greece received applications from Bayer CropScience AG to modify the existing maximum residue levels (MRLs) for the active substance fluopyram in a wide range of crops. The EMS Hungary and the EMS Greece 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 7 July and 9 November 2015, respectively. For reasons of efficiency EFSA assessed all applications within a single reasoned opinion.

EFSA bases its assessment on the updated evaluation reports submitted by the EMS Hungary and Greece, the draft assessment report prepared under Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance fluopyram, the JMPR evaluation reports as well as the conclusions from previous EFSA reasoned opinions on fluopyram.

The toxicological profile of fluopyram was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.012 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.5 mg/kg bw.

The metabolism of fluopyram in primary crops was investigated in the fruit (grape, pepper), root (potato) and pulses/oilseeds (bean) crop groups and the residue definition was proposed as 'fluopyram' for enforcement and as 'sum of fluopyram and fluopyram-benzamide (M25) expressed as fluopyram' for risk assessment. For the uses supported in this MRL application, EFSA concludes that the metabolism of fluopyram in primary crops is sufficiently addressed and that the derived residue definitions are applicable. Adequate analytical enforcement methods are available to monitor the residues of fluopyram in the plant matrices under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg.

EFSA concludes that the submitted residue trials were sufficient to derive MRL proposals for the majority of the crops under consideration. In contrast, an MRL is not proposed for sugar beet root as it is not supported by a sufficient number of trials. For sweet corn, EFSA proposes to decrease the existing MRL from 0.1 mg/kg to the LOQ of 0.01 mg/kg, as fluopyram residues were below the LOQ in the trials conducted on maize (as primary crop) and in cereal grains, in the rotational field crop studies.

New studies on the nature and magnitude of fluopyram residues in processed commodities were not submitted and are not requested as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI for each individual crop commodity.

The metabolism of fluopyram in rotational crops was assessed in the framework of the peer review and it was concluded that the residue definitions set on primary crops are applicable to rotational crops. Fluopyram is a highly persistent compound and based on rotational field trials, default MRLs of 0.1 and 0.2 mg/kg have been proposed in the conclusion of the peer review, to cover the residues in crops sown in rotation to crops treated with fluopyram. New studies have not been submitted and as suggested by the applicant, EFSA proposes to extrapolate to the group 'spinaches and similar leaves' the default MRL of 0.2 mg/kg that was set on spinaches in a previous assessment.

As oilseed, sunflower, oat and barley and their by-products are fed to livestock, transfer of residues in commodities of animal origin was assessed. Considering the OECD feedstuff table, the calculated dietary burdens are significantly lower than the animal intakes that were considered for the setting of the Codex limits (CXL) transposed in the EU legislation. Therefore, the uses assessed under the current MRL applications do not request a change of the MRL set for animal products.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term consumer exposure calculated in the latest EFSA reasoned opinion was updated with median residue levels (STMR) derived for the crops under consideration and with the STMRs related to the CXLs that have in a meanwhile been implemented in the EU legislation. For the remaining crops, the existing MRLs as listed under Regulation (EU) 2016/567 were used as input values. It is highlighted that these MRLs take into account the default MRL values set to cover fluopyram residues in rotational crops. 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 maximum calculated chronic intake accounted for 58% of the ADI (DE child). The contribution of residues in the crops under consideration to the total consumer exposure was low, being the highest for rapeseed (2% of the ADI).

An acute consumer risk was not identified in relation to the MRL proposals for the crops under consideration. The highest acute consumer exposure was calculated to be 18% of the ARfD for peppers and was below 10% of the ARfD for other crops under consideration.

EFSA concludes that the intended uses of fluopyram on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a concern for public health. 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:** Fluopyram | | | | |
| 0140010 | Apricots | 1.0 | 1.5 | SEU |
| 0231020 | Sweet/bell peppers | 0.8 | 3.0 (2.0/0.8) | Indoor and SEU (alternatively 2.0 or 0.8 if value of 1.4 mg/kg disregarded) |
| 0234000 | Sweet corn | 0.1(+) | 0.01* | Decrease to 0.01* mg/kg recommended as residues in primary and rotational crops all below the LOQ of 0.01 mg/kg |
| 0252000 | Spinaches/similar leaves: | – | 0.2 | Extrapolation to the whole group from field rotational crop trials on lettuce, spinach and mustard greens |
| | Spinach | 0.2 | – | |
| | Purslane, beet leaves | 0.1(+) | – | |
| 0255000 | Witloof/Belgian endive | 0.15 | 0.3 | NEU (field) + post-harvest applications |
| 0256000 | Herbs/edible flowers | 0.1(+) | 8 | NEU based on trials on parsley, sage, chervil and savory |
| 0260030 | Peas (with pods) | 0.4 | 1.5 | NEU and SEU |
| 0260050 | Lentils | 0.1(+) | 0.2 | NEU and SEU |
| 0260990 | Other legume vegetables | 0.1(+) | 0.9 | NEU and SEU. Extrapolation from trials on pea and bean (with pods) conducted with two applications at 200 g/ha |
| 0401050 | Sunflower seeds | 0.1(+) | 0.3 | NEU and SEU |
| 0401060 | Rapeseeds/canola seeds | 1.0 | 1.0 | NEU and SEU (2 x 125 g/ha; PHI 28 days) |
| 0401040 | Sesame seeds | 0.1(+) | 0.3 | NEU and SEU. Extrapolation from trials on rapeseed conducted in compliance with the proposed GAP (2 x 125 g/ha, up to BBCH 73, ca. 56-day PHI) |
| 0401100 | Pumpkin seeds | 0.1(+) | 0.3 | |
| 0401110 | Safflower seeds | 0.1(+) | 0.3 | |
| 0401120 | Borage seeds | 0.1(+) | 0.3 | |
| 0401140 | Hemp seeds | 0.1(+) | 0.3 | |
| 0401150 | Castor beans | 0.1(+) | 0.3 | |
| 0500010 | Barley | 0.1(+) | 0.2 | SEU |
| 0500020 | Buckwheat/pseudo-cereals | 0.1(+) | 0.2 | SEU. Extrapolation from barley |
| 0500050 | Oat | 0.1(+) | 0.2 | SEU. Extrapolation from barley |
| 0900010 | Sugar beet roots | 0.1(+) | No proposal | Insufficient number of residue trials |

MRL: maximum residue level; LOQ: limit of quantification; NEU: northern Europe; SEU: southern Europe; BBCH: growth stages of mono- and dicotyledonous plants; PHI: pre-harvest interval.

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

(+): The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the European Commission will take into account the information referred to in the first sentence, if it is submitted by 19 October 2015, or, if that information is not submitted by that date, the lack of it (Commission Regulation (EU) No 1004/2013.

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## Background

Regulation (EC) No 396/2005[1] establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at the 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 Council 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.

**Hungary**, hereafter referred to as the evaluating Member State Hungary (EMS Hungary) received an application from the company Bayer CropScience AG[4] to modify the existing MRLs for the active substance fluopyram in sunflower seed, oilseed rape, sweet corn, barley and oats.

**Greece**, hereafter referred to as the evaluating Member State Greece (EMS Greece) received two applications from Bayer CropScience AG[4] to modify the existing MRLs for the active substance fluopyram in peppers and in apricots, spinach and similar leaves, witloof, herbs and edible flowers, peas with pods, lentils, other legumes, sesame seeds, pumpkin seeds, safflower seeds, borage seeds, hemp seeds, castor beans, buckwheat and sugar beet.

All applications were notified to the European Commission and the European Food Safety Authority (EFSA) and were subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation reports were submitted to the European Commission and to EFSA on 7 July and 9 November 2015, respectively. Updated evaluation reports addressing various data requirements set by EFSA were submitted in November 2015 by Hungary and in February 2016 by Greece, combining together the two initial evaluation reports. The applications were included in the EFSA Register of Questions with the following reference numbers and subjects:

EFSA-Q-2015-00710: *Fluopyram – Setting new MRLs in pepper*
EFSA-Q-2015-00711: *Fluopyram – Modification of existing MRLs in various crops*
EFSA-Q-2015-00415: *Fluopyram – Setting new MRLs in sweet corn, sunflower seed, rapeseed, barley and oats*

The MRLs proposed by the applicant and by the EMS Hungary and Greece are compiled in Table 1.

**Table 1:** Overview of the existing MRLs and the proposals of the EMS

| Commodity code[(a)] | Crop | Existing EU MRL | MRL proposal | |
|---|---|---|---|---|
| | | | Applicant | EMS |
| 0140010 | Apricots | 0.7 | 1.5 | 1.5 |
| 0231020 | Sweet peppers/bell peppers | 0.8 | 2 | 2 |
| 0234000 | Sweet corn | 0.1(+) | 0.01 | 0.01 |
| 0252000 | Spinaches and similar leaves: | – | 0.2 | 0.2 |
| | Spinach | 0.2 | | |
| | Purslane, chards | 0.1(+) | | |
| 0255000 | Witloofs/Belgian endive | 0.15 | 0.3 | 0.3 |
| 0256000 | Herbs and edible flowers | 0.1(+) | 8 | 7 |
| 0260030 | Peas (with pods) | 0.4 | 1.5 | 1.5 |
| 0260050 | Lentils | 0.1(+) | 0.15 | 0.15 |
| 0260990 | Other legume vegetables | 0.1(+) | 1.5 | 1 |
| 0401040 | Sesame seeds | 0.1(+) | 0.3 | 0.3 |
| 0401050 | Sunflower seeds | 0.1(+) | 0.3 | 0.3 |

[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] Bayer CropScience AG, Alfred-Nobel-Str. 50, D-40789, Monheim am Rhein, Germany (for applications EFSA-Q-2015-00415 and EFSA-Q-00711) and Rue Jean-Marie Leclair 16, 69266, Lyon, France (for EFSA-Q-2015-00710).

| Commodity code[(a)] | Crop | Existing EU MRL | MRL proposal | |
|---|---|---|---|---|
| | | | Applicant | EMS |
| 0401060 | Rapeseeds/canola seeds | 1 | 1 | 1 |
| 0401100 | Pumpkin seeds | 0.1(+) | 0.3 | 0.3 |
| 0401110 | Safflower seeds | 0.1(+) | 0.3 | 0.3 |
| 0401120 | Borage seeds | 0.1(+) | 0.3 | 0.3 |
| 0401140 | Hemp seeds | 0.1(+) | 0.3 | 0.3 |
| 0401150 | Castor beans | 0.1(+) | 0.3 | 0.3 |
| 0500010 | Barley | 0.1(+) | 0.2 | 0.2 |
| 0500020 | Buckwheat and other pseudo-cereals | 0.1(+) | 0.2 | 0.2 |
| 0500050 | Oat | 0.1(+) | 0.2 | 0.2 |
| 0900010 | Sugar beet roots | 0.1(+) | 0.1 | No proposal |

EU: European Union; MRL: maximum residue level; EMS: evaluating Member State.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(+): The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the European Commission will take into account the information referred to in the first sentence, if it is submitted by 19 October 2015, or, if that information is not submitted by that date, the lack of it (Commission Regulation (EU) No 1004/2013[5].

EFSA proceeded with the assessment of applications and evaluation reports as required by Article 10 of the Regulation. For reasons of efficiency all applications were assessed within a single reasoned opinion.

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 active substance and its use pattern

Fluopyram is the ISO common name for N-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}-α,α,α-trifluoro-o-toluamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix B.

Fluopyram 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 540/2011 for use as a fungicide.

The representative uses evaluated in the peer review were foliar applications on grape, tomato and strawberry. The draft assessment report (DAR) has been peer reviewed by EFSA (EFSA, 2013).

The EU MRLs for fluopyram are established in Annex IIIA of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued several reasoned opinions on the modification of MRLs, including the default MRL proposals for rotational crops as derived by the peer review (EFSA, 2013). The review of fluopyram MRLs according to Article 12 of Regulation (EC) No 396/2005 has not been finalised yet. An overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005 is summarised in Table 2.

[5] Commission Regulation (EU) No 1004/2013 of 15 October 2013 amending Annexes II and III of Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 8-hydroxyquinoline, cyproconazole, cyprodinil, fluopyram, nicotine, pendimethalin, penthiopyrad and trifloxystrobin in or on certain products. OJ L 279, 13.10.2013, p. 10–56.

**Table 2:** 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 270/2012 | Various crops |
| Peer review (EFSA, 2013) | (EU) No 1004/2013 | Default MRL of 0.1 mg/kg for root/tuber and leafy rotational crops according to EFSA peer review |
| Implementation of CXL | (EU) No 491/2014 | CAC 2013 |
| Art. 10 (EFSA, 2014) | (EU) 2015/1101 | Various crops |
| Implementation of CXL | (EU) 2016/567 | Apricots, broccoli, brussels sprouts, rapeseed |

CXL: Codex maximum residue limit (Codex MRL).
(a): Art. 10: Assessment of MRL application according to Articles 6–10 of Regulation (EC) No 396/2005.

Codex Alimentarius has established maximum residue limits (CXL) for a wide range of commodities, including some crops under consideration: sugar beet root, rapeseed and apricots.

The details of the intended GAPs for fluopyram in NEU and SEU are given in Appendix A.

## Assessment

EFSA bases its assessment on the updated evaluation reports submitted by the EMS Greece (Greece, 2016) and the EMS Hungary (Hungary, 2015), the DAR (and its final addendum) prepared under Directive 91/414/EEC (Germany, 2011, 2012), the conclusion on the peer review of the pesticide risk assessment of the active substance fluopyram (EFSA, 2013), the JMPR Evaluation report (FAO, 2013, 2015) as well as the conclusions from previous EFSA opinions on fluopyram (EFSA, 2011, 2014). 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[6] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2015; OECD, 2011, 2013).

## 1. Method of analysis

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

Analytical methods for the determination of fluopyram residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (EFSA, 2013). An analytical method using GC-MS detection was concluded to be sufficiently validated for the determination of fluopyram residues in high acid (orange), high oil (oilseed rape), high water (lettuce), dry/protein (pea) and dry/starch (wheat) commodities at the validated LOQ of 0.01 mg/kg.

As the crops under consideration in this application refer to high water, high oil, dry/starch and dry/protein content commodities, EFSA concludes that sufficiently validated analytical methods are available to control fluopyram residues in the crops under consideration.

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

Analytical methods for the determination of fluopyram residues in food of animal origin according to the enforcement residue definition 'sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram' were evaluated during the peer review under Directive 91/414/EEC (EFSA, 2013). An analytical method using LC-MS/MS detection has been sufficiently validated for the determination of each compound in milk, egg, meat, liver, fat and kidney at the LOQ of 0.01 mg/kg.

EFSA concludes that sufficiently validated analytical methods are available for the control of fluopyram residues in food of animal origin.

## 2. Mammalian toxicology

The toxicological profile of the active substance fluopyram was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2013). The data were sufficient to derive toxicological reference values compiled in Table 3.

[6] 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 3:** Overview of the toxicological reference values

| | Source | Year | Value | Study | Safety factor |
|---|---|---|---|---|---|
| **Fluopyram** | | | | | |
| ADI | EFSA | 2013 | 0.012 mg/kg bw per day | 2 year, rat | 100 |
| ARfD | EFSA | 2013 | 0.5 mg/kg bw | Acute neurotoxicity, rat | 100 |

ADI: acceptable daily intake; ARfD: acute reference dose; EFSA: European Food Safety Authority; 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 fluopyram in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC (Germany, 2011; EFSA, 2013) in the fruit, root, pulses/oilseeds crop groups. An overview of the available metabolism studies is presented in Table 4.

**Table 4:** Summary of available metabolism studies in plants

| Crop group | Crops | Application | Sampling[(a)] (day, DAT) | Comments |
|---|---|---|---|---|
| Fruit | Grape | Foliar (1 × 100 + 2 × 200 g/ha) | 18–19 $DAT_3$ | |
| | Pepper | Drip irrigation (5 and 20 mg/plant) | 33–97 DAT | |
| Root | Potato | Foliar (3 × 167 g/ha) | 51 DAT | |
| Pulses/oilseeds | Bean | Foliar (2 × 250 g/ha) | 4–29 DAT | |

(a): DATx, days after treatment x.

Based on these studies, the plant residue definitions were concluded as 'fluopyram' for monitoring and as 'sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram' for risk assessment. These definitions are identical to the residue definitions proposed by the JMPR and to the residue definition for enforcement set in Regulation (EC) No 396/2005.

#### 3.1.1.2. Magnitude of residues

All samples from the submitted residue trials were analysed for fluopyram and its metabolite fluopyram-benzamide (M25) achieving an LOQ of 0.01 mg/kg per analyte.

*Apricots (NEU/SEU GAP: 2 × 250 g/ha, PHI 3 days)*

Four NEU residue trials on apricots and four trials on peaches, performed in Germany, France and Austria during the growing seasons of 2008, 2010, 2012 and 2013, were submitted. Peach trials were disregarded by EFSA from the MRL calculation, as it was conducted with a total of three applications instead of two. For the SEU, eight GAP-compliant trials on peaches and four GAP-compliant trials on apricots were submitted, performed in France, Spain and Italy in 2006, 2010 and 2012.

As the residue levels observed in the different data sets were not significantly different (*H*-test, 5%), NEU and SEU data sets on peach and apricot were merged together to derive an MRL proposal of 1.5 mg/kg on apricots.

Fluopyram-benzamide levels were one order of magnitude lower than fluopyram levels, with residues at or close to LOQ of 0.01 mg/kg and a maximum of 0.07 mg/kg observed on peach 28 days after the last application.

*Peppers (SEU outdoor/EU indoor GAP: 2 × 200 g/ha, PHI 3 days)*

Eight SEU residue trials on peppers performed in France, Spain, Italy, Portugal and Greece in 2013 were submitted with residues of fluopyram in the range of 0.11–0.39 mg/kg, resulting in a MRL proposal of 0.8 mg/kg.

To support indoor uses, eight trials conducted in Germany, the Netherlands, Belgium, France, Italy and Greece were submitted. Four additional trials, performed with three applications at 150 g/ha were

submitted, but disregarded by EFSA as GAP incompliant. Residues of fluopyram were in the range of 0.023–0.41 mg/kg, with one extreme high value of 1.40 mg/kg, resulting in an MRL proposal of 3 mg/kg. Based on the same data set, the EMS proposed an MRL of 2 mg/kg considering the EU MRL calculation approach and a $R_{max}$ value of 1.8 (European Commission, 1997g).

No information was provided to explain such an abnormal high value. If not included in the calculation and considering residues of fluopyram in the range of 0.023–0.41 mg/kg, the MRL proposal is 0.8 mg/kg, similar to the value derived from the SEU trials.

EFSA proposes to the risk managers to decide whether the value of 1.40 mg/kg should be disregarded from the calculations and which of the different proposals (0.8, 2.0 or 3.0 mg/kg) should finally be considered for the setting of an MRL for pepper.

In all samples except one and at all PHI intervals, fluopyram-benzamide residues were below the LOQ of 0.01 mg/kg.

*Sweet corn (NEU/SEU GAP: 2 × 125 g/ha; PHI 10–14 days)*

The applicant submitted eight NEU and eight SEU GAP-compliant trials, performed in various EU countries over the growing seasons of 2011 and 2012. All samples (ear without husk) were analysed for residues at two different PHI intervals of 14–31 and 23–49 days. Residues of fluopyram and its benzamide metabolite were all below the LOQ, resulting in an MRL proposal of 0.01 mg/kg.

The existing EU MRL is currently set at a value of 0.1 mg/kg, considering the default MRL of 0.1 mg/kg proposed to cover fluopyram residues in rotational crops (EFSA, 2013). As fluopyram residues were all below the LOQ of 0.01 mg/kg following the use of the active substance on sweet corn (as primary crop), and as residues in cereal grains were all below the LOQ of 0.01 mg/kg in the field rotational crop studies (see Table 7), EFSA proposes to decrease the default MRL value for sweet corn from 0.1 mg/kg to the LOQ of 0.01 mg/kg.

*Witloof/Belgian endive*

NEU GAP: Two field applications at 200 g/ha before harvest of the roots, followed by:

Either 1) Root dipping (66.5 g/hL) prior to storage + collar spraying (33 g/hL) prior to forcing
Or 2) Root spraying (25.0 g/hL) prior to storage + collar spraying (33 g/hL) prior to forcing

Four residue trials on witloof performed in Germany, Belgium, France and the Netherlands in 2011 and representing both types of treatments were submitted. The use involving the treatment of the roots by dipping prior to storage resulted in a more critical residue situation, leading to an MRL proposal of 0.3 mg/kg.

Except for two samples, fluopyram-benzamide residues were observed above the LOQ, in the range of 0.015–0.077 mg/kg.

*Herbs and edible flowers (NEU outdoor GAP: 1 × 200 g/ha, PHI 7 days)*

The applicant submitted a total of 11 residue trials conducted in Germany in 2012 and 2013 on various herbs: parsley (4), sage (3), chervil (2) and savory (2). The EMS and applicant proposed to extrapolate these data to the whole group 'herbs and edible flowers'. Although sage and savory are not foreseen for extrapolation purposes in the EU guidance document (European Commission, 2015) but since herbs are very minor crops, EFSA agrees with this proposal and an MRL of 8 mg/kg is derived from these data set and extrapolated to the group 'herbs and edible flowers'.

The EMS derived an MRL proposal of 7 mg/kg, as seven values at the LOQ referring to the benzamide metabolite were wrongly included in the MRL calculation.

Except for one sample (0.024 mg/kg), fluopyram-benzamide residues were all below the LOQ.

*Peas (with pods) (NEU/SEU GAP: 2 × 250 g/ha, PHI 7 days)*

Eight NEU trials on pea and six NEU trials on bean were submitted, all under-dosed as conducted with two applications at 200 g/ha. For SEU, nine trials on pea and eight trials on bean almost all conducted at 200 g/ha were provided. As most of the trials were under-dosed, the proportionality approach was applied by EFSA and values were scaled to the nominal application rate of 250 g/ha. One NEU trial on bean with residue below the LOQ was disregarded from the MRL calculation. Since not significantly different (*U*-test, 5%) NEU and SEU data sets on pea and bean were merged together to derive an MRL proposal of 1.5 mg/kg. It is noted that the EMS proposed the same value, not applying the proportionality approach.

Fluopyram-benzamide residues were in the range of 0.014–0.078 mg/kg.

*Lentils (NEU/SEU GAP: 2 × 200 g/ha, PHI 7 days)*

In support of the use on lentils, six NEU and eight SEU residue trials on pea (without pods), performed in Germany, France, Belgium, United Kingdom and in Spain, Italy and Greece in 2012 and 2013 were submitted. As residue levels were significantly higher in the SEU data set (*U*-test, 5%), an MRL proposal of 0.2 mg/kg was derived from the SEU trials and extrapolated to lentils.

Fluopyram-benzamide residue levels were mostly below the LOQ of 0.01 mg/kg except in some samples where residues were measured up to 0.022 mg/kg.

*Other legume vegetables (code 0260990) (NEU/SEU GAP: 2 × 200 g/ha, PHI 7 days)*

The applicant proposed to extrapolate to 'Other legume vegetables' the MRL of 1.5 mg/kg proposed on pea and bean (with pods) and derived from trials conducted with two applications at 250 g/ha.

However, as the GAPs for the crops covered by the group 'Other legume vegetables' (beans, fava beans, broad beans, vetches and flageolets, see Appendix A) were defined with a total of two application at 200 g/ha, EFSA proposes for the group 'Other legume vegetables' an MRL of 0.9 mg/kg derived from the NEU and SEU trials conducted on pea and bean at the dose rate of 200 g/ha.

*Sunflower (NEU/SEU GAP: 2 × 125 g/ha, PHI 28 days)*

Eight NEU and ten SEU GAP-compliant residue trials on sunflower, performed in Germany, Belgium, France and Hungary in 2010, 2011 and 2012 and in Greece, Spain, France, Portugal and Italy in 2010, 2011 and 2012 were submitted.

Residues in NEU trials ranged from < 0.01 to 0.069 mg/kg, leading to an MRL proposal of 0.15 mg/kg. In the SEU trials, residues were in the range of < 0.01 to 0.011 mg/kg, with an extreme value of 0.17 mg/kg, resulting in an MRL proposal of 0.3 mg/kg. Based on these data, an MRL of 0.3 mg/kg is proposed to cover the NEU and SEU uses of fluopyram on sunflower.

Fluopyram-benzamide residues were all below the LOQ of 0.01 mg/kg, except in one seed sample (0.015 mg/kg).

*Pumpkin seeds, sesame seeds, safflower seeds, borage, hemp seeds, castor beans (NEU/SEU GAP: 2 × 125 g/ha, BBCH 14-73, PHI 56 days)*

The EMS Greece proposes to extrapolate to minor oilseeds (pumpkin seed, sesame seed, safflower seed, borage, castor beans and hemp seed) the MRL of 0.3 mg/kg derived from trials on rapeseed conducted according to the same GAP (2 × 125 g/ha, up to BBCH 73) and already assessed in a previous MRL application (EFSA, 2011). EFSA agrees with this extrapolation.

*Oilseed rape (NEU/SEU GAP: 2 × 125 g/ha, PHI 28 days)*

Eight NEU and eight SEU GAP-compliant trials on oilseed rape, performed in Belgium, the United Kingdom, the Netherlands, Germany and France in 2010 and 2011 and in Spain, France and Italy in 2010 and 2011 were submitted. In one trial, the sample was analysed at a later PHI of 48 days, but this value was within a range of remaining values and thus not disregarded by EFSA from the MRL calculation. Since not significantly different (*U*-test, 5%), NEU and SEU data sets were merged together to derive an MRL proposal of 1 mg/kg.

It is noted that this MRL proposal is equal to the CXL value of 1 mg/kg that has been recently implemented in the EU legislation by Regulation (EU) 2016/567[7].

Fluopyram-benzamide was measured in all seed samples in the range of 0.02–0.18 mg/kg.

*Barley, oats (NEU GAP: 1 × 125 g/ha at BBCH 30-61)*
*(SEU GAP 1 × 78 g/ha at BBCH 30-61)*

Eight NEU residue trials on barley performed in Germany, France, the Netherlands, Belgium and the United Kingdom in 2012 according to the NEU GAP with an application at 125 g/ha at BBCH 61 were submitted. Fluopyram residues in the range of 0.014–0.033 mg/kg result in an MRL proposal of 0.07 mg/kg.

Eight SEU residue trials performed in France, Spain, Italy, Portugal and Greece in 2012 according to the SEU GAP with an application at 78 g/ha at BBCH 61 were submitted. Although driven by less

[7] Commission Regulation (EU) 2016/567 of 6 April 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 cyflumetofen, cyprodinil, dimethomorph, dithiocarbamates, fenamidone, fluopyram, flutolanil, imazamox, metrafenone, myclobutanil, propiconazole, sedaxane and spirodiclofen in certain products.

critical GAPs (78 g/ha while 125 g/ha in NEU), higher residue levels in grain up to 0.11 mg/kg result in an MRL proposal of 0.2 mg/kg.

An MRL of 0.2 mg/kg is therefore proposed to cover the uses of fluopyram on barley in NEU and SEU, extrapolated to oats.

Fluopyram-benzamide residues were almost all below the LOQ of 0.01 mg/kg in grain, except in two samples at levels close to the LOQ (0.011 and 0.013 mg/kg). In straw, this metabolite was present in most of the samples in the range of 0.013–0.061 mg/kg.

*Buckwheat (NEU/SEU GAP: 1 × 78 g/ha at BBCH 30-61)*

The EMS Greece proposes to extrapolate available residue data on barley to buckwheat. Such an extrapolation is not foreseen in the EU guidance document (European Commission, 2015). However as buckwheat is reported in the group cereals in Annex I of Regulation (EC) No 396/2016, EFSA agrees with the EMS proposal and the MRL of 0.2 mg/kg derived from the residue trials on barley is extrapolated to buckwheat.

*Sugar beet (NEU/SEU GAP: 2 × 150 g/ha; PHI 7 days)*

Five NEU trials only were provided in support of the proposed uses. As according to EU guidance document (European Commission, 2015) sugar beet is a major crop, at least eight residue trials shall be submitted per zone and therefore, the current residue data set is insufficient to propose an MRL value.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 5.

The stability of fluopyram and its benzamide metabolite in plant matrices under storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2013) and additional studies were assessed in the previous EFSA reasoned opinion (EFSA, 2014). Based on the available data, it was concluded that residues of fluopyram and its metabolite M25 are stable for at least 3 years in high water (lettuce, cabbage), high starch (wheat), high protein (dry pea), high oil (rapeseeds) and high acid matrices (orange), when stored frozen at $\leq -18°C$. As the trial samples were stored for less than 3 years under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

Additionally, in the framework of the current application, the applicant submitted a short-term storage stability study, reflecting the sample shipment process where samples are kept at $+1°C$ for 8 h, followed by 7-day storage at $-7°C$ (Hungary, 2015). The results indicate that significant degradation of fluopyram residues does not occur in samples of tomato, grape, wheat grain, potato, dry peas and rapeseed when subject to the above-mentioned storage conditions.

According to the EMS Hungary and Greece, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proved to be fit for purpose (Hungary, 2015; Greece, 2016).

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

- 1.5 mg/kg: Apricots (NEU and SEU)
- 3.0 mg/kg: Peppers (indoor SEU), alternatively 2.0 or 0.8 mg/kg
- 0.3 mg/kg: Witloof/Belgian endives (NEU + root application at harvest and collar application)
- 0.01* mg/kg: Sweet corn
- 8 mg/kg: Herbs/edible flowers (NEU), based on trials on parsley, sage, chervil and savory
- 1.5 mg/kg: Peas (with pods) in SEU
- 0.2 mg/kg: Lentils (NEU and SEU), extrapolation from trials on pea without pods
- 0.2 mg/kg: Sunflower seed (NEU and SEU)
- 1 mg/kg: Oilseed rape (NEU and SEU). Note: Existing EU MRL 1 mg/kg resulting from the implementation of the CXL value in the EU legislation
- 0.3 mg/kg: Pumpkin, sesame, safflower, borage, hemp, castor bean (NEU and SEU), extrapolation from trials on rapeseeds conducted according to the proposed GAP
- 0.2 mg/kg: Barley (NEU and SEU), extrapolated to oats and buckwheat.

In contrast, the intended use on sugar beet is not adequately supported by a sufficient number of residue trials and therefore an MRL is not proposed for this crop.

**Table 5:** Overview of the available residue trials data

| Crop (GAPs) | Region Indoor[a] | Residue levels in the residue trials[b] (mg/kg) Mo: fluopyram RA: sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram | Recommendations/comments[c] | MRL proposal (mg/kg) | HR[d] (mg/kg) | STMR[e] (mg/kg) |
|---|---|---|---|---|---|---|
| **Apricots, peaches** (2 × 250 g/ha, PHI 3 days) | NEU | Mo: 0.16; 0.20; 0.38; 0.46<br>RA: 0.17; 0.21; 0.39; 0.47 | Underlined values: trials on apricots<br>NEU/SEU data sets on apricot and SEU data set on peach not significantly different (*H*-test, 5%). MRL, STMR and HR derived from the merged data sets | 1.50 | (0.95)<br>0.97 | (0.35)<br>0.36 |
| | SEU | Mo: 0.20; 0.26; 2 × 0.28; 0.31; 0.33; 0.36;0.43; 0.58; 0.63; 0.73; 0.97<br>RA: 0.21; 0.27; 2 × 0.29; 0.32; 0.37; 0.37; 0.44; 0.59; 0.64; 0.74; 0.95 | | | | |
| **Peppers** (2 × 200 g/ha, PHI 3 days) | Indoor | Mo: 0.11; 0.14; 0.19; 0.19; 0.22; 0.33; 0.34; 0.39<br>RA: 0.12; 0.15; 0.20; 0.20; 0.23; 0.34; 0.35; 0.40 | Underlined values: higher residues at longer PHI<br>$MRL_{OECD}$: 0.72/0.80 | 0.8 | (0.39)<br>0.40 | (0.21)<br>0.22 |
| | SEU | Mo: 0.023; 0.04; 0.085; 0.18; 0.20; 0.29; 0.41; 1.40<br>RA: 0.033; 0.05; 0.095; 0.19; 0.21; 0.30; 0.42; 1.41 | Underlined values: higher residues at a longer PHI<br>$MRL_{OECD}$: 2.14/3.0 | 3.0 | 1.41<br>(1.40) | 0.20<br>(0.19) |
| **Sweet corn** (2 × 125 g/ha, PHI 10–20 days) | NEU | Mo: 8 × < 0.01<br>RA: 8 × < 0.02 | Existing EU MRL 0.1 mg/kg derived from rotational crops studies | 0.01 | (0.01)<br>0.02 | (0.01)<br>0.02 |
| | SEU | Mo: 8 × < 0.01<br>RA: 8 × < 0.02 | | | | |
| **Witloof/Belgian endive** | NEU | **GAP1:** Root dipping at storage + collar spaying at forcing<br>Mo: 0.038; 0.070; 0.12; 0.12<br>RA: 0.058; 0.147; 0.13; 0.14<br>**GAP2:** Root spraying at storage + collar sparing at forcing<br>Mo: 0.032; 0.036; 0.062; 0.063<br>RA: 0.060; 0.052; 0.072; 0.078 | GAP1: $MRL_{OECD}$: 0.26/0.30<br>GAP2: $MRL_{OECD}$: 0.14/0.15<br>MRL for witloof derived from the GAP1 involving the treatment of the root by dipping prior to storage | 0.3 | (0.12)<br>0.15 | (0.10)<br>0.14 |
| **Herbs** (1 × 200 g/ha, PHI 7 days) | NEU | Mo: 0.26; 0.30; 0.41; 0.74; 1.12; 1.18; 1.18; 1.24; 1.54; 1.98; 5.93<br>RA: 0.27; 0.31; 0.42; 0.75; 1.13; 1.19; 1.21; 1.25; 1.54; 1.99; 5.94 | Underlined values: trial on sage, chervil and savory<br>$MRL_{OECD}$: 7.8/8.0<br>**Extrapolation to herbs and edible flowers** | 8.0 | (5.93)<br>5.94 | (1.18)<br>1.19 |

| Crop (GAPs) | Region Indoor[a] | Residue levels in the residue trials[b] (mg/kg) Mo: fluopyram RA: sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram | Recommendations/comments[c] | MRL proposal (mg/kg) | HR[d] (mg/kg) | STMR[e] (mg/kg) |
|---|---|---|---|---|---|---|
| **Peas, beans** (with pods) (2 × 250 g/ha, PHI 7 days) | NEU | Mo: 0.03; 0.04; 0.05; 0.05; 0.06; 0.06; 0.10; 0.13; 0.14; 0.18; 0.19; 0.53<br>RA: 0.04; 0.05; 0.06; 0.08; 0.10; 0.08; 0.11; 0.14; 0.15; 0.19; 0.20; 0.54 (scaled data) | Underlined values: trials on beans<br>As all NEU trials and most of the SEU trials under-dosed (200 g/ha), values were scaled to the nominal rate of 250 g/ha<br>NEU and SEU data sets on pea/bean not significantly different (*U*-test, 5%) and merged together for MRL calculation<br>$MRL_{OECD}$: 1.1/1.5 | 1.5 | (0.90) 0.91 | (0.13) 0.15 |
| | SEU | Mo: 2 × 0.01; 0.05; 0.07; 0.09; 0.11; 0.13; 0.19; 0.21; 0.26; 0.30; 0.31; 0.40; 0.41; 0.59; 0.76; 0.90<br>RA: 2 × 0.03; 0.06; 0.08; 0.11; 0.12; 0.15; 0.21; 0.23; 0.34; 0.32; 0.33; 0.41; 0.43; 0.62; 0.79; 0.91 (scaled data) | | | | |
| **Peas** (without pods) (2 × 200 g/ha, PHI 7 days) | NEU | Mo: 3 × < 0.01; 0.012; 0.024; 0.028<br>RA: 3 × < 0.02; 0.022; 0.034; 0.038 | Underlined values: higher residues at longer PHIs. Data sets significantly different (*U*-test, 5%). MRL derived from the SEU trials<br>NEU $MRL_{OECD}$: 0.05/0.05<br>SEU $MRL_{OECD}$: 0.17/0.20<br>**Extrapolation to lentils** | – | (0.03) 0.04 | (0.01) 0.02 |
| | SEU | Mo: 0.012; 0.017; 0.02; 0.027; 0.055; 0.057; 0.085; 0.092<br>RA: 0.022; 0.027; 0.03; 0.037; 0.066; 0.070; 0.095; 0.110 | | 0.2 | (0.09) 0.11 | (0.04) 0.05 |
| **Peas, beans** (with pods) (2 × 200 g/ha, PHI 7 days) | NEU | Mo: < 0.01; 0.02; 0.03; 0.04; 0.04; 0.05; 0.05; 0.08; 0.10; 0.11; 0.14; 0.15; 0.42<br>RA: < 0.02; 0.03; 0.04; 0.05; 0.06; 0.08; 0.06; 0.09; 0.11; 0.12; 0.15; 0.16; 0.43 | Underlined values: trials on beans<br>NEU and SEU data sets on peas and beans not significantly different (*U*-test, 5%) and merged together for MRL calculation<br>$MRL_{OECD}$: 0.84/0.9<br>**Extrapolation to 'Other legume vegetables'** | 0.9 | (0.61) 0.63 | (0.10) 0.11 |
| | SEU | Mo: 0.01; 0.01; 0.04; 0.05; 0.08; 0.09; 0.10; 0.15; 0.17; 0.21; 0.25; 0.32; 0.33; 0.50; 0.53; 0.61<br>RA: 0.02; 0.02; 0.05; 0.06; 0.09; 0.10; 0.12; 0.17; 0.19; 0.25; 0.26; 0.33; 0.34; 0.52; 0.54; 0.63 | | | | |
| **Sunflower** (2 × 125 g/ha, PHI 28 days) | NEU | Mo: 5 × < 0.01; 0.01; 0.011; 0.17<br>RA: 5 × < 0.02; 0.02; 0.020; 0.18 | MRL proposal derived from the NEU data set<br>NEU $MRL_{OECD}$: 0.26/0.30<br>SEU $MRL_{OECD}$: 0.11/0.15 | 0.3 | (0.17) 0.18 | (0.01) 0.02 |
| | SEU | Mo: < 0.01; 0.014; 0.017; 0.019; 0.021; 0.032; 2 × 0.04; 0.062; 0.069<br>RA: < 0.02; 0.024;0.027; 0.029; 0.031; 0.042; 2 × 0.05; 0.072; 0.079 | | – | (0.07) 0.08 | (0.03) 0.04 |
| **Rapeseed** (2 × 125 g/ha, PHI 28 days) | SEU | Mo: 0.14; 0.25; 0.270; 0.33; 0.38; 0.38; 0.46; 0.46<br>RA: 0.19; 0.27; 0.316; 0.42; 0.44; 0.51; 0.54; 0.62 | NEU and SEU data sets not significantly different (*U*-test, 5%) and merged together to derive an MRL proposal<br>$MRL_{OECD}$: 1.01/1.0 | 1 | (0.61) 0.65 | (0.34) 0.40 |
| | NEU | Mo: 0.10; 0.260; 0.270; 0.29; 0.34; 0.35; 0.47; 0.61<br>RA: 0.13; 0.298; 0.329; 0.34; 0.38; 0.42; 0.51; 0.65 | | | | |

| Crop (GAPs) | Region Indoor[a] | Residue levels in the residue trials[b] (mg/kg) Mo: fluopyram RA: sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram | Recommendations/comments[c] | MRL proposal (mg/kg) | HR[d] (mg/kg) | STMR[e] (mg/kg) |
|---|---|---|---|---|---|---|
| **Rapeseed** (2 × 125 g/ha, BBCH 73) | NEU | Mo: 0.06; 0.07; 0.10; 0.14<br>RA: 0.07; 0.08; 0.11; 0.21 | Last application close to BBCH 73 (mostly 50–69 days before harvest). NEU and SEU data sets similar (*U*-test, 5%) and merged to derive the MRL value<br>**Extrapolation to minor oilseeds** | 0.3 | (0.19)<br>0.22 | (0.10)<br>0.12 |
| | SEU | Mo: 0.02, 0.04, 0.08, 0.09, 0.10, 2 × 0.11, 0.19<br>RA: 0.03; 0.05; 0.09; 0.12; 0.14; 2 × 0.13; 0.22 | | | | |
| **Barley** (1 × 125 g/ha; BBCH 61) | NEU | **Grain**<br>Mo: 0.014; 0.016; 2 × 0.018; 0.025; 0.026; 0.027; 0.033<br>RA: 0.024; 0.026; 2 × 0.028; 0.035; 0.036; 0.037; 0.046 | Although driven by less critical GAPs (78 g/ha), the MRL of 0.3 mg/kg for barley is derived from the SEU trials<br>NEU $MRL_{OECD}$: 0.07/0.07<br>SEU $MRL_{OECD}$: 0.28/0.30<br>**Extrapolation of the MRL of 0.2 mg/kg to oats and buckwheat** | 0.07 | (0.03)<br>0.05 | (0.02)<br>0.03 |
| | | **Straw**<br>Mo: 0.03; 0.06; 0.07; 0.08; 0.11; 0.13; 0.14; 0.14<br>RA: 0.04; 0.07; 0.08; 0.09; 0.14; 0.17; 0.15; 0.16 | | – | (0.14)<br>straw<br>0.16 | (0.10)<br>straw<br>0.12 |
| **Barley** (1 × 78 g/ha; BBCH 61) | SEU | **Grain**<br>Mo: 2 × < 0.01; 0.012; 0.017; 0.028; 0.034; 0.079; 0.11<br>RA: 2 × < 0.02; 0.022; 0.027; 0.038; 0.044; 0.090; 0.12 | | **0.2** | (0.11)<br>0.12 | (0.02)<br>0.03 |
| | | **Straw**<br>Mo: 0.03; 2 × 0.10; 0.18; 0.40; 0.77; 0.81; 1.10<br>RA: 0.04; 2 × 0.12; 0.20; 0.42; 0.80; 0.85; 1.16 | | | (1.10)<br>straw<br>1.16 | (0.29)<br>straw<br>0.31 |
| **Sugar beet** (2 × 150 g/ha, PHI 7 days) | NEU | Mo: < 0.01; 0.012; <u>0.018</u>; 0.03; 0.044<br>RA: < 0.02; 0.022; <u>0.028</u>; 0.04; 0.054 | <u>Underlined values</u>: higher residues at a longer PHI. Insufficient number of residue trials to derive an MRL proposal | No proposal | – | – |
| | SEU | No residue trials submitted | | | | |

(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 (2 × < 0.01, 0.01, 6 × 0.02, 0.04, 0.08, 2 × 0.10, 0.15, 0.17),
Mo: residue level according to the monitoring residue definition (fluopyram).
RA: residue level according to the residue definition for risk assessment (sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram).
(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 (in brackets; $HR_{Mo}$; according to enforcement residue definition).
(e): STMR: median residue level according to residue definition for risk assessment (in brackets; STMR: according to enforcement residue definition).

All trial samples were analysed for fluopyram and its metabolite fluopyram-benzamide (M25), included in the residue definition for risk assessment and therefore, conversion factors for risk assessment (CF) could be derived at the different pre-harvest intervals (PHI).

However, as metabolite M25 was almost never detected above the LOQ in pepper (four samples with residue at 0.01 mg/kg out of 136 analysed for), in herbs (2/22), in sunflower (1/48) and in cereal grain (2/16), CF values were not proposed for these crops as the calculations result in default CF value close to 1.

Metabolite M25 was detected in higher proportions in the other crops but always at levels one order of magnitude lower than fluopyram, resulting in CF values close to 1.1 with a maximum of 1.4 and 1.7 in legume vegetables at 14 or 21-day PHI (see Table 6). These highest CF values mainly result from the decrease in the parent fluopyram levels than an increase in M25 residue levels which remain at values close to the LOQ, in the range of 0.01–0.03 mg/kg.

**Table 6:** Median conversion factors calculated at the different PHIs[(a)]

| PHI[(b)] (days) | No. of samples | | PHI (days) | | | | | | CF proposed in previous assessment | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Total | M25 > LOQ | 0 | 7 | 14 | 21 | 28 | 60 | | |
| Apricots | 103 | 22 | 1.0 | **1.0** | 1.1 | 1.1 | 1.1 | | **1.1** | (EFSA, 2014) |
| Witloof | 8 | 8 | | | | **1.3** | | | – | |
| Legumes (with pods) | 128 | 48 | 1.0 | **1.1** | 1.3 | 1.7 | | | **1.2** | (EFSA, 2014) |
| Legumes (without pods) | 61 | 25 | | **1.3** | 1.4 | 1.3 | | | **1.5** | (EFSA, 2014) |
| Oilseed rape | 16 | 16 | | | | | **1.2** | | **1.2** | (EFSA, 2014) |
| Cereal straw | 16 | 11 | | | | | | **1.1** | – | |

PHI: pre-harvest interval; LOQ: limit of quantification.
(a): CF calculated at the supported PHI are underlined.
(b): Samples collected just after the last application.

Based on these data, EFSA proposes to confirm the CF values set in a previous assessment (EFSA, 2014) at 1.1 on stone fruits, 1.2 on legume vegetables (with pods) and oilseed rape and at 1.5 on legume vegetables (without pods). CF values of 1.1 and 1.3 are proposed for cereal straw and witloof.

#### 3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of fluopyram residues was investigated in the framework of the peer review (EFSA, 2013). Fluopyram and fluopyram-benzamide (metabolite M25) were found to be stable under standard hydrolysis conditions and it was therefore concluded that the residue definitions proposed from primary crops are also applicable to processed commodities (EFSA, 2013).

New studies to address the effect of processing on magnitude of fluopyram residues were not submitted in the framework of the current assessment. However, numerous processing studies were submitted in previous assessment (EFSA, 2013) and processing factors (PF) were proposed for apple, grape, strawberry, banana, tomato, melon and rapeseed processed fractions.

### 3.1.2. Rotational crops

The metabolism of fluopyram in rotational crops was assessed in the framework of the peer review (EFSA, 2013). The metabolism in rotational crops was shown to be similar to primary crop metabolism and it was therefore concluded that the residue definition set on primary crops is also applicable to rotational crops (EFSA, 2013).

Fluopyram is a highly persistent compound ($DT_{50}$ > 300 days, $DT_{90}$ > 1,000 days) and significant residues are expected to be present in rotational crops. Therefore, a default MRL of 0.1 mg/kg was recommended by the peer review for root and leafy crops and of 0.01 mg/kg for cereals, oilseed grown in rotation with crops treated with fluopyram. These proposals were derived from the EU field studies conducted at the exaggerated dose rate of 500 g/ha, as this dose level was considered to be more representative of the predicted plateau concentration (0.08 mg/kg soil, 20 cm depth) reached in soil after 10 years of consecutive applications (EFSA, 2013). In addition, a default MRL of 0.2 mg/kg was proposed for spinach grown in rotation to crops treated with fluopyram (EFSA, 2014). The

available rotational crop field studies, already considered in previous assessments (EFSA, 2013, 2014), are compiled in Table 7.

**Table 7:** Overview of the available rotational crop field studies

| **PBI (day)** | | | **28–36 (14 USA)** | **90–154** | **216–320** | **Reference** |
|---|---|---|---|---|---|---|
| **EU application (1 × 500 g/ha)** | | | **On bare soil** | **On primary crop (lettuce)** | | |
| **US application (2 × 250 g/ha)** | | | **On bare soil** | – | **On bare soil** | |
| Root and tuber crops | Potato | NEU | 0.02; 0.02 | | | EFSA (2014) |
| | | SEU | 0.02; 0.02 | | | |
| | Carrot and turnip root | NEU | < 0.01; 0.01 | < 0.01 | < 0.01; 0.02 | EFSA (2013) |
| | | SEU | 0.02; 0.05 | 0.03 | 0.02 | |
| | | USA | | | 3 × < 0.01 | |
| Leafy crops | Lettuce | NEU | 0.01; 0.02 | 0.01 | | EFSA (2013) |
| | | SEU | < 0.03; 0.03 | < 0.01 | < 0.01; 0.01 | |
| | Spinach | NEU | 0.03; 0.03 | | | EFSA (2014) |
| | | SEU | 0.02; 0.09 | | | |
| | Mustard green | USA | | | 0.01; 0.01, 0.04 | EFSA (2013) |
| Cereals | Wheat grain | NEU | < 0.01; < 0.01 | < 0.01; < 0.01 | < 0.01 | EFSA (2013) |
| | | SEU | < 0.01; 0.01 | < 0.01; < 0.01 | | |
| | | USA | | | 3 × < 0.01 | |
| | Wheat straw | NEU | 0.07; 0.28 | 0.09; 0.17 | 0.06 | EFSA (2013) |
| | | SEU | 0.05; 0.15 | < 0.01; 0.19 | | |
| | | USA | | | 0.01; 0.03; 0.12 | |
| Oilseeds | Cotton seed | USA | 11 × < 0.01 | | | EFSA (2013) |

PBI: plant back interval; NEU: northern Europe; SEU: southern Europe.

New rotational field studies were not submitted in the framework of the current application. The applicant requested to extrapolate to the group 'Spinach and similar leaves', the default MRL of 0.2 mg/kg recommended by EFSA in a previous assessment (EFSA, 2014), taking into account the rotational field trials conducted with an application of the active substance at 500 g/ha on bare soil and a plant back interval (PBI) of 30 days, with residues up to 0.09 mg/kg in spinach leaves.

EFSA agrees with this proposal. However, as there are 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, EFSA would recommend reconsidering these MRL proposals once such documents are available.

## 3.2. Nature and magnitude of residues in livestock

Barley, oats, sunflower and their by-products can be used as a livestock feed and therefore the nature and magnitude of fluopyram residues in livestock has to be further addressed in the framework of this application (European Commission, 1996; OECD, 2013).

### 3.2.1. Dietary burden of livestock

The dietary burdens for livestock were calculated in the previous EFSA reasoned opinion (EFSA, 2011) considering the approach and feedstuff table reported in the EU guidance 7031/VI/95 (European Commission, 1997g).

EFSA updated the animal burden calculations, taking into account the feedstuff table reported in the OECD guidance No 64-Series on Pesticides No 32 (OECD, 2009) and the animal model calculator developed by EFSA. Median (STMR) and highest (HR) residue levels derived for feed commodities in previous assessment (EFSA, 2011, 2013, 2014) and the values derived from new trials on barley, oats, sunflower seed and oilseed rape (see Table 5) were used as input values. It is highlighted that some feed commodities considered by EFSA in 2011 (wheat bran, sugar beet root) are no longer reported in the OECD feedstuff table and therefore disregarded from the animal intake calculation and some other ones were modified (e.g. citrus-dried pomace instead of citrus-wet pomace). The OECD livestock diets

include more feed and by-product commodities for which residue data are not available. The input values considered in the dietary burden calculation are summarised in Table 8 and the calculated livestock dietary intakes are given in Table 9.

**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 |
| **Risk assessment residue definition**: Sum fluopyram, fluopyram-benzamide (M25), expressed as fluopyram | | | | |
| Cabbage, apple pomace, wheat, sorghum and maize grain, wheat straw, pulses, potato, turnip, peanut and soybean meal | STMR | (EFSA, 2011) | HR or STMR | (EFSA, 2011) |
| Citrus-dried pulp | 0.34 | $STMR_{Mo} \times PF \times CF^{(a)}$ | 0.34 | $STMR_{Mo} \times PF \times CF^{(a)}$ |
| Barley, oat grain | 0.03 | STMR (Table 5) | 0.03 | STMR (Table 5) |
| Barley, oat straw | 0.31 | STMR (Table 5) | 1.16 | HR (Table 5) |
| Sunflower meal | 0.03 | $STMR_{Mo}$ (Table 5) $\times$ PF $\times$ $CF^{(b)}$ | 0.03 | $STMR_{Mo}$ (Table 5) $\times$ PF $\times$ $CF^{(b)}$ |
| Rapeseed meal | 0.32 | | 0.32 | |

STMR: supervised trials median residue; PF: processing factor; CF: conversion factor for enforcement to risk assessment residue definition.
(a): $STMR_{Mo}$ citrus (0.33 mg/kg), PF (0.93) and CF (1.1) derived for dry pomace in a previous assessment (EFSA, 2011).
(b): PF (0.73) and CF (1.29) derived for rapeseed meal in a previous assessment (EFSA, 2011).

**Table 9:** Results of the dietary burden calculation

| Animal | Median burden (mg/kg bw) | Maximum burden (mg/kg bw) | Maximum burden (mg/kg DM) | Highest contributor[a] | Previous assessment (max. burden DM) | |
|---|---|---|---|---|---|---|
| | | | | | (EFSA, 2011) | (FAO, 2013) |
| Dairy cattle | 0.020 | 0.037 | 0.95 | Cabbage leaves | 1.59 | 11.2 |
| Beef cattle | 0.013 | 0.023 | 0.95 | Cabbage leaves | 1.61 | 11.2 |
| Ram/ewe | 0.014 | 0.033 | 0.98 | Barley straw | Based on bovine intakes | – |
| Lamb | 0.018 | 0.042 | 0.98 | Barley straw | | – |
| Pig (breeding) | 0.012 | 0.017 | 0.74 | Cabbage leaves | 1.0 | 11.2 |
| Pig (finishing) | 0.013 | 0.013 | 0.43 | Sorghum grain | | 11.2 |
| Broiler | 0.026 | 0.026 | 0.37 | Sorghum grain | 0.65 | 1.97 |
| Laying hen | 0.035 | 0.042 | 0.62 | Cabbage leaves | | 1.97 |
| Turkey | 0.026 | 0.026 | 0.36 | Sorghum grain | | – |

bw: body weight; DM: dry matter.
(a): Considering the maximum dietary animal burden.

The results indicate that using the OECD feedstuff table and the input values reported in Table 8, the estimated intakes are significantly lower than the intakes considered for the setting of CXLs (FAO, 2013) that were transposed in EU legislation by Regulation (EU) No 491/2014. These intakes are indeed lower or similar to the intakes previously estimated by EFSA using the EU methodology (EFSA, 2011). Thus, it can be concluded that the crop commodities under consideration in this MRL application do not result in an increase in the animal burden that would request changes in the current MRLs set for animal in the 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 subgroups of the EU population[8] (EFSA, 2007).

The chronic consumer exposure calculated in the latest EFSA reasoned opinion (EFSA, 2014) was updated with the median residue values (STMR) derived from the residue trials reported in Table 5 and the STMRs related to the CXLs that have been implemented in EU legislation (FAO, 2015). For the remaining food commodities, the existing MRLs reported in Regulation (EU) 2016/567 were used as input values. It is highlighted that these MRLs take into account the default values of 0.1 and 0.2 mg/kg proposed to cover fluopyram residues in rotational crops.

The acute exposure assessment was performed only with regard to the commodities under consideration assuming that these items contained residues at the highest level (HR) as observed in supervised trials (Table 5). A variability factor accounting 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 10.

**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:** Sum fluopyram, fluopyram-benzamide (M25), expressed as fluopyram | | | | |
| Apricots | 0.36 | STMR (Table 5) | 0.97 | HR (Table 5) |
| Peppers | 0.22 | STMR (Table 5) | 1.41 | HR (Table 5) |
| Spinach and similar leaves | 0.2 | MRL rotational crop | 0.2 | MRL rotational crop |
| Witloof/Belgian endive | 0.14 | STMR (Table 5) | 0.15 | HR (Table 5) |
| Herbs/edible flowers | 1.19 | STMR (Table 5) | 5.94 | HR (Table 5) |
| Peas (with pods) | 0.15 | STMR (Table 5) | 0.91 | HR (Table 5) |
| Lentils | 0.05 | STMR (Table 5) | 0.11 | HR (Table 5) |
| Sunflower seed | 0.02 | STMR (Table 5) | 0.18 | HR (Table 5) |
| Rape seed | 0.40 | STMR (Table 5) | 0.65 | HR (Table 5) |
| Minor oilseeds | 0.12 | STMR (Table 5) | 0.22 | HR (Table 5) |
| Barley, oats, buckwheat | 0.03 | STMR (Table 5) | 0.12 | HR (Table 5) |
| Broccoli | 0.05 | STMR (FAO, 2015) | Acute risk assessment undertaken only with regard to the crops under consideration | |
| Brussels sprouts | 0.06 | STMR (FAO, 2015) | | |
| Other plant commodities | STMR | Table 4-1 (EFSA 2014) | | |
| | MRL | Regulation (EU) 2016/567 | | |
| **Risk assessment residue definition (animal products):** Sum fluopyram and metabolites M02, M03, M25, expressed as fluopyram | | | | |
| Animal commodities | STMR<br>MRL | See table 4-1 of EFSA reasoned opinion (EFSA, 2014)<br>Regulation (EU) 2016/567 | | |

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

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest calculated chronic intake accounted for 58% of the ADI (DE child). The contribution of residues in the crops under consideration to the total consumer exposure accounted individually for a maximum of 2% and 1% of the ADI for rapeseed and apricot respectively and for less than 1% for the other crops.

An acute consumer risk was not identified in relation to the MRL proposals for the crops under consideration. The highest acute consumer exposures were calculated to be 18%, 6% and 1% of the

[8] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from Member State surveys plus one regional and four cluster diets from the WHO GEMS Food database; for the acute exposure, the most critical large portion consumption data from 19 national diets collected from Member State surveys are used.

ARfD for pepper, apricot and witloof respectively and less than 1% for the other crops under consideration.

EFSA concludes that the intended use of fluopyram on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference values and therefore is 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:** Fluopyram | | | | |
| 0140010 | Apricots | 1.0 | 1.5 | SEU |
| 0231020 | Sweet/bell peppers | 0.8 | 3.0 (2.0/0.8) | Indoor and SEU (Alternatively 2.0 or 0.8 if value of 1.4 mg/kg disregarded) |
| 0234000 | Sweet corn | 0.1(+) | 0.01* | Decrease to 0.01* mg/kg recommended since residues in primary and rotational crops all below the LOQ of 0.01 mg/kg |
| 0252000 | Spinaches/similar leaves: | – | 0.2 | Extrapolation to the whole group from field rotational crop trials on lettuce, spinach and mustard greens |
| | spinach | 0.2 | – | |
| | purslane, beet leaves | 0.1(+) | – | |
| 0255000 | Witloof/Belgian endive | 0.15 | 0.3 | NEU (field) + post-harvest applications |
| 0256000 | Herbs/edible flowers | 0.1(+) | 8 | NEU based on trials on parsley, sage, chervil and savory |
| 0260030 | Peas (with pods) | 0.4 | 1.5 | NEU and SEU |
| 0260050 | Lentils | 0.1(+) | 0.2 | NEU and SEU |
| 0260990 | Other legume vegetables | 0.1(+) | 0.9 | NEU and SEU. Extrapolation from trials on pea and bean (with pods) conducted with two applications at 200 g/ha |
| 0401050 | Sunflower seeds | 0.1(+) | 0.3 | NEU and SEU |
| 0401060 | Rapeseeds/canola seeds | 1.0 | 1.0 | NEU and SEU (2 × 125 g/ha; PHI 28 days) |
| 0401040 | Sesame seeds | 0.1(+) | 0.3 | NEU and SEU. Extrapolation form trials on rapeseed conducted in compliance with the proposed GAP (2 × 125 g/ha, up to BBCH 73, ca. 56-day PHI) |
| 0401100 | Pumpkin seeds | 0.1(+) | 0.3 | |
| 0401110 | Safflower seeds | 0.1(+) | 0.3 | |
| 0401120 | Borage seeds | 0.1(+) | 0.3 | |
| 0401140 | Hemp seeds | 0.1(+) | 0.3 | |
| 0401150 | Castor beans | 0.1(+) | 0.3 | |
| 0500010 | Barley | 0.1(+) | 0.2 | SEU |
| 0500020 | Buckwheat | 0.1(+) | 0.2 | SEU. Extrapolation from barley |
| 0500050 | Oat | 0.1(+) | 0.2 | SEU. Extrapolation from barley |
| 0900010 | Sugar beet roots | 0.1(+) | No proposal | Insufficient number of residue trials |

MRL: maximum residue level; LOQ: limit of quantification; NEU: northern Europe; SEU: southern Europe; BBCH: growth stages of mono- and dicotyledonous plants; PHI: pre-harvest interval.

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

(+): The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 October 2015, or, if that information is not submitted by that date, the lack of it (Commission Regulation (EU) No 1004/2013.

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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 |
| CAC | Codex Alimentarius Commission |
| CF | conversion factor for enforcement to risk assessment residue definition |
| CXL | Codex maximum residue limit (Codex MRL) |
| DAR | draft assessment report |

| | |
|---|---|
| DAT | days after treatment |
| DM | dry matter |
| $DT_{50}$ | period required for 50% dissipation (define method of estimation) |
| $DT_{90}$ | period required for 90% dissipation (define method of estimation) |
| EC | emulsifiable concentrate |
| EMS | evaluating Member State |
| FAO | Food and Agriculture Organization of the United Nations |
| GAP | good agricultural practice |
| GC | gas chromatography |
| HR | highest residue |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| JMPR | Joint FAO/WHO Meeting on Pesticide Residues |
| LOQ | limit of quantification |
| MRL | maximum residue level |
| MS | 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 |
| $R_{max}$ | statistical calculation of the MRL by using a parametric method |
| SE | suspo-emulsion |
| SC | suspension concentrate |
| SEU | southern Europe |
| SMILES | simplified molecular-input line-entry system |
| STMR | supervised trials median residue |
| TMDI | theoretical maximum daily intake |

## Appendix A – Good agricultural practice

| Crop and/or situation[a] | MS or NEU/SEU or country | F G or I[b] | Pest or group of pests controlled[c] | Formulation | | Application | | | | Application rate per treatment | | | PHI (days)[k] | Remarks[l] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Type[d],[e] | Conc. a.s.[h] | Method kind[f],[g] | BBCH Growth stage and season[i] | No. Min–max[j] | Interval Min–max | g/hL Min–max | Water L/ha Min–max | g/ha Min–max | | |
| Apricot | SEU/NEU | F | Fungi | SC | 200 | Foliar spray | 57–87 | 2 | 7 | 10–15 | 100–1,500 | 150 | 3 | 0.75 L/ha product |
| | | | | | | | | 3 | 14 | 6.67–10 | 1,000–1,500 | 100 | 3 | 0.5 L/ha product |
| | | | | | 500 | | 1) 61–69<br>2) 85–87 | 2 | 7 | 25–50 | 500–1,000 | 250 | 3 | |
| Pepper | SEU | F | Fungi | SC | 250 | Foliar spray | 51–89 | 1–2 | 7 | 20–40 | 500–1,000 | 200 | 3 | Formulation 0.8 L/ha<br>Max concentration 0.08% |
| | | G | Fungi | SC | 250 | Foliar spray | 14–89 | 1–2 | 7 | 22.6 | 500–1,500 (500 L/m height) | 200 g/ha or 113 g/m Crown height | 3 | Formulation 0.45 L/ha/m height, up to 2 m |
| Sweet corn | SEU/NEU | F | Fungi | SE | 125 | Foliar spray | 30–69 | 1–2 | 14 | 42–125 | 100–300 | 125 | 10 | 1 L/ha product |
| Witfloof (Belgian endive) | NEU | F | Fungi | SC | 250 | Foliar spray | 40–49 | 2 | 7 | 25–100 | 200–800 | 200 | n.r. | Combined application for root production:<br>• Two field applications, followed by<br>• Two post-harvest applications. |
| | | G | | | 500 | a) Root dipping before storage<br>b) Collar spraying before forcery | 49 at storage | a) 1<br>b) 1 | 21 | a) 66.5 g/hL<br>b) 40 g/hL | a) –<br>b) 1/1.5 L/m$^2$ | a) n.r.<br>b) 0.5 g/m$^2$ | 19 | |

| Crop and/or situation[a] | MS or NEU/SEU or country | F G or I[b] | Pest or group of pests controlled[c] | Formulation | | Application | | | | Application rate per treatment | | | PHI (days)[k] | Remarks[l] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Type[d],[e] | Conc. a.s.[h] | Method kind[f],[g] | BBCH Growth stage and season[i] | No. Min–max[j] | Interval Min–max | g/hL Min–max | Water L/ha Min–max | g/ha Min–max | | |
| | NEU | F | Fungi | SC | 250 | Foliar spray | 40–49 | 2 | 7 | 25–100 | 200–800 | 200 | n.r. | — First dipping/ spraying on roots at storage<br>— Second spray during forcing. *Maximum 4 applications on root* |
| | | G | | | 500 | a) Root spraying before storage<br>b) Collar spraying before forcery | 49 at storage | a) 1<br>b) 1 | 21 | a) 25 g/hL<br>b) 40 g/hL | a) 100 L/t roots<br>b) 1–1.5 L/m2 | a) 25 g/t<br>b) 0.5 g/m$^2$ | 19 | |
| Herbs, edible flowers | NEU | F | Fungi | SC | 200 | Spraying | 13–40 | 1 | – | – | – | 200 | 7 | |
| Peas with pods | SEU/NEU | F | Fungi | SC | 500 | Spraying | 55–89 | 2 | 7 | 2.5–12.5 | 200–1,000 | 250 | 7 | 0.5 L/ha product |
| | | F | Fungi | SC | 250 | Spraying | 55–89 | 2 | 7 | 20–66.7 | 300–1,000 | 200 | 7 | 0.8 L/ha product |
| Peas without pods | SEU/NEU | F | Fungi | SC | 500 | Spraying | 55–89 | 2 | 7 | 3–12.5 | 200–800 | 250 | 7 | 0.5 L/ha product |
| Peas and other legumes without pods | SEU/NEU | F | Fungi | SC | 250 | Spraying | 55–89 | 2 | 7 | 20–66.7 | 300–1,000 | 200 | 7 | 0.8 L/ha product |
| Other legumes without and with pods[m] | SEU/NEU | F | Fungi | SC | 250 | Spraying | 55–89 | 2 | 7 | 20–66.7 | 300–1,000 | 200 | 7 | 0.6–0.8 L/ha product |

| Crop and/or situation[a] | MS or NEU/SEU or country | F G or I[b] | Pest or group of pests controlled[c] | Formulation | | Application | | | | Application rate per treatment | | | PHI (days)[k] | Remarks[l] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Type[d],[e] | Conc. a.s.[h] | Method kind[f],[g] | BBCH Growth stage and season[i] | No. Min–max[j] | Interval Min–max | g/hL Min–max | Water L/ha Min–max | g/ha Min–max | | |
| Sunflower, rapeseed, pumpkin, sesame, safflower, borage seed | NEU/SEU | F | Fungi | SE | 250 | Spraying | 14–73 | 2 | 14 | 31.25–125 | 100–400 | 125 | 56 | 1 L/ha product |
| Oilseed rape | NEU/SEU | F | Fungi | SE | 125 | Foliar spray | At occurrence | 2 | 14 | 31–63 | 200–400 | 125 | 28 | 1.0 L/ha product |
| Sunflower | NEU/SEU | F | Fungi | SE | 250 | Spraying | 16–69 | 1–2 | 14 | 25–62.5 | 150–400 | 125 | 28 | 0.8–1 L/ha product |
| | NEU/SEU | F | Fungi | SE | 125 | Foliar spray | At occurrence | 1–2 | 14 | 31–83 | 150–400 | 125 | 28 | 1.0 L/ha product |
| Barley | NEU | F | Fungi | SE | 125 | Foliar spray | 30–61 | 1 | – | 42–125 | 100–300 | 125 | n.r. | 1.0 L/ha product |
| | SEU | F | | EC | 65 | Foliar spray | 30–61 | 1 | – | 20–78 | 100–400 | 78 | n.r. | 1.2 L/ha product |
| | NEU | F | Fungi | SE | 250 | Spraying | 30–61 | 1 | – | 31.25–125 | 100–400 | 125 | – | |
| Barley, Buckwheat and other pseudo cereals | NEU/SEU | F | Fungi | EC | 65 | Spraying | 30–61 | 1 | – | 19.5–78 | 100–400 | 78 | n.r. | 1.2 L/ha product |
| Oats | NEU | F | Fungi | SE | 125 | Foliar spray | 30–61 | 1 | – | 42–125 | 100–300 | 125 | n.r. | 1.0 L/ha product |
| | SEU | F | Fungi | EC | 65 | Foliar spray | 30–61 | 1 | – | 20–78 | 100–400 | 78 | n.r. | 1.2 L/ha product |

| Crop and/or situation[a] | MS or NEU/SEU or country | F G or I[b] | Pest or group of pests controlled[c] | Formulation | | Application | | | | Application rate per treatment | | | PHI (days)[k] | Remarks[l] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Type[d],[e] | Conc. a.s.[h] | Method kind[f],[g] | BBCH Growth stage and season[i] | No. Min–max[j] | Interval Min–max | g/hL Min–max | Water L/ha Min–max | g/ha Min–max | | |
| Sugar beet | NEU/SEU | F | Fungi | SE | 125 | Soil application | Bare soil | 1 | – | 62.5–125 | 200–400 | 250–500 | 14 | |
| | NEU/SEU | F | Fungi | SE | 250 | Foliar spray | 31–49 | 2 | 21–28 | 19–75 | 200–800 | 150 | 7 | |

MS: Member State; NEU: northern Europe; SEU: southern Europe; a.s.: active substance; BBCH: growth stages of mono- and dicotyledonous plants; SC: suspension concentrate; SE: suspo-emulsion; EC: emulsifiable concentrate; n.r.: not reported.

(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): For example, biting and sucking insects, soil-born insects, foliar fungi, weeds.

(d): For example, wettable powder (WP), water-soluble granule (WG).

(e): GCPF Codes – GIFAP Technical Monograph No 2, 1989.

(f): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.

(g): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants. Type of equipment used must be indicated.

(h): g/kg or μg/L.

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

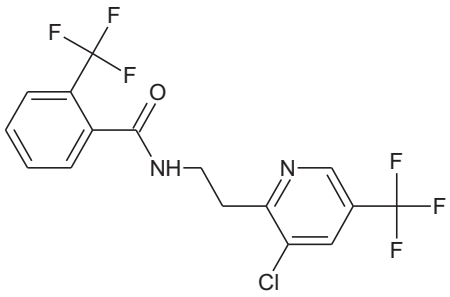
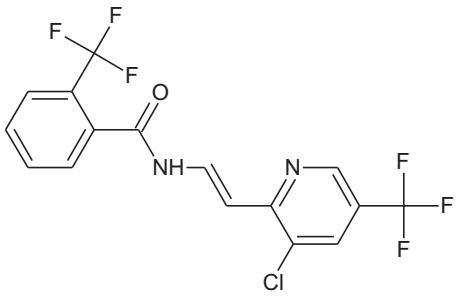
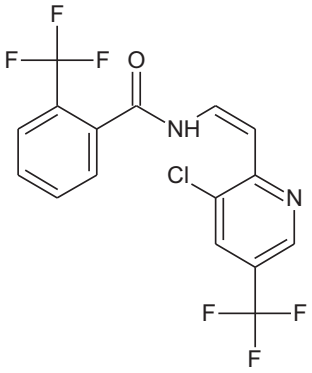
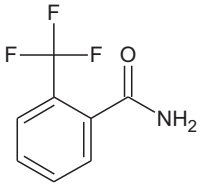
(j): The minimum and maximum number of application possible under practical conditions of use must be provided.

(k): PHI – minimum pre-harvest interval.

(l): Remarks may include: Extent of use/economic importance/restrictions.

(m): Other legumes without pods (lentil, flageolet, black eyed bean, faba bean, vetche) and other legumes with pods (black eyed bean, faba bean, vetche, broad bean).

## Appendix B – Used compound codes

| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|---|---|---|
| Fluopyram | *N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}-α,α,α-trifluoro-*o*-toluamide<br>FC(F)(F)c1ccccc1C(=O)NCCc2ncc(cc2Cl)C(F)(F)F |  |
| **M02**<br>fluopyram-E-olefine | *N*-{(*E*)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]vinyl}-2-(trifluoromethyl)benzamide<br>FC(F)(F)c1ccccc1C(=O)N\C=C\c2ncc(cc2Cl)C(F)(F)F |  |
| **M03**<br>fluopyram-Z-olefine | *N*-{(*Z*)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]vinyl}-2-(trifluoromethyl)benzamide<br>FC(F)(F)c1ccccc1C(=O)N\C=C/c2ncc(cc2Cl)C(F)(F)F |  |
| **M25**<br>fluopyram-benzamide | 2-(trifluoromethyl)benzamide<br>FC(F)(F)c1ccccc1C(N)=O |  |

SMILES: simplified molecular-input line-entry system.