Modification of the existing maximum residue levels for fluoxastrobin in oilseeds

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Arysta LifeSciences SAS submitted a request to the competent national authority in the United Kingdom to modify the existing maximum residue levels (MRL) for the active substance fluoxastrobin in certain oilseeds. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the oilseeds for which a modification was requested. Adequate analytical methods for enforcement are available to control the residues of fluoxastrobin and its Z-isomer in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the new intended use of fluoxastrobin according to the reported agricultural practice is unlikely to present a risk to consumer health. The reliable end points, appropriate for use in regulatory risk assessment are presented.

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Keywords: fluoxastrobin, oilseeds, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Arysta LifeSciences SAS submitted an application to the competent national authority in the United Kingdom (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance fluoxastrobin in rapeseed, linseed, poppy seed, mustard seed and gold of pleasure seed. The United Kingdom drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 29 August 2017. To accommodate for the intended uses of fluoxastrobin, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 to 0.05 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL Regulation and taking into account the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of fluoxastrobin in primary crops was investigated in different crops, including oilseeds/pulses. Similar metabolic behaviour has been described and fluoxastrobin and its Z-isomer are the main identified compounds in primary crops.

In rotational crops, the same metabolic pattern as in primary crops has been observed. Studies investigating the effect of processing on the nature of fluoxastrobin (hydrolysis studies) demonstrated that the active substance is stable.

Therefore, pending the outcome of the currently ongoing process for the renewal of the approval, EFSA proposed to use the residue definitions for enforcement and risk assessment agreed previously, i.e. fluoxastrobin and its Z-isomer, express as fluoxastrobin.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive a MRL proposal of 0.05 mg/kg for rapeseeds. The extrapolation from rapeseeds to the other oilseeds (linseeds, poppy seeds, mustard seeds and gold of pleasure seeds) is acceptable.

Specific studies investigating the magnitude of fluoxastrobin residues in processed commodities are not required, as significant residues (> 0.1 mg/kg) are not expected in raw agricultural commodities (RAC).

Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

Considering the new methodology in the animal dietary burden (OECD, 2013), the livestock dietary burden has been calculated considering two scenarios. Scenario 1 is the transposition of the assessment performed during the MRL review in the new calculator based on the OECD No 73. While in Scenario 2, the new intended uses and the restrictions concerning the use of straw for feeding livestock were also considered; the expected animal intake was calculated resulting in a lower exposure in comparison with Scenario 1. Under these considerations, the modification of the MRLs of food product of animal origin is not necessary.

The toxicological profile of fluoxastrobin was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.015 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.3 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic calculated intake accounted for less than 6% of the ADI (Dutch, children) and the contribution of the residues in oilseeds to the total exposure accounting for a maximum of 0.04% of the ADI (WHO Cluster diet E).

No acute consumer risk was identified in relation to the MRL proposal for oilseeds, the highest calculated acute exposure being less than 1 % of the ARfD.

Overall, EFSA concluded that the proposed use of fluoxastrobin on the oilseeds for which new uses of fluoxastrobin are intended to be granted will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA proposes to amend the existing MRLs as reported in the summary table below.
Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|-----------|-------------------------|-------------------------|-----------------------|
| 0401060        | Rapeseeds/canola seeds | 0.01* | 0.05 | The submitted residue data on rapeseed are sufficient to derive a MRL proposal of 0.05 mg/kg for the NEU use. Risk for consumers unlikely |
| 0401010        | Linseeds   | 0.01* | 0.05 | The MRL proposal was derived by extrapolation from residue trials in rapeseeds. Risk for consumers unlikely |
| 0401030        | Poppy seeds |                     |                          |                       |
| 0401080        | Mustard seeds |                  |                          |                       |
| 0401130        | Gold of pleasure seeds |                 |                          |                       |

**Enforcement residue definition:** fluoxastrobin (sum of fluoxastrobin and its Z-isomer)\(^{(R)}(F)\)

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MRL: maximum residue level; NEU: northern Europe.

*: 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.

\(^{(R)}\): The residue definition differs for the animal products (except honey) (residue definition: Fluoxastrobin (sum of fluoxastrobin, its Z-isomer and its metabolite 6-(2-chlorophenoxo)-5-fluoro-4-pyrimidinol, expressed as fluoxastrobin).

\(^{(F)}\): Fat soluble.
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Assessment

The detailed description of the intended uses of fluoxastrobin in oilseeds, which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A. Fluoxastrobin is the ISO common name for \((E)-2-[6-(2\text{-chlorophenoxy})-5\text{-fluoropyrimidin}-4\text{-yloxy}]\) phenyl\((5,6\text{-dihydro}-1,4,2\text{-dioxazin}-3\text{-yl})\)methanone O-methylxime (IUPAC). The active substance used in the pesticide formulations also contains the Z-isomer at a much lower level (approximately 2%). Fluoxastrobin belongs to the group of strobilurin compounds which are used as fungicides. The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Fluoxastrobin was evaluated in the framework of Directive 91/414/EEC\(^1\) with the United Kingdom designated as rapporteur Member State (RMS); as representative uses a foliar spraying on wheat, rye and barley were assessed. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2005). Fluoxastrobin was approved for the use as fungicide on 1 August 2008. For the use conditions set out in Directive 2008/44/EC\(^2\), it was specified that Member States must pay particular attention to the levels of residues of the metabolites of fluoxastrobin, when straw from treated areas is used as animal feeding stuff. Conditions of use shall include restrictions for feeding to animals, where appropriate. Furthermore, the risk of accumulation in the soil surface was highlighted, if the substance is used in perennial crops or in succeeding crops in crop rotation. Conditions of use shall include appropriate risk mitigation measures. The process of renewal of the first approval is currently on-going.

The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2012) and the proposed modifications have been implemented in the MRL legislation (Annexes II of Regulation (EC) No 396/2005\(^3\)). Since for barley, oats and kidney and fat from bovine, from sheep and from goat some information was not available, the MRLs will be reviewed upon submission missing information that has to be submitted by 29 June 2018.

After completion of the MRL review, EFSA has issued one reasoned opinion on the modification of MRL for fluoxastrobin. The proposals from this reasoned opinion has been considered in a recent regulation\(^4\) for the European Union (EU) MRL legislation.

EFSA based its assessment on the evaluation report submitted by the EMS (United Kingdom, 2017), the draft assessment report (DAR) and its addenda (United Kingdom, 2003, 2007) prepared under Council Directive 91/414/EEC, the Commission review report on fluoxastrobin (European Commission, 2012), the conclusion on the peer review of the pesticide risk assessment of the active substance fluoxastrobin (EFSA, 2005), as well as the conclusions from previous EFSA opinions on fluoxastrobin (EFSA, 2012, 2015).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

A selected list of end points of the studies assessed by EFSA in the framework of the this MRL application, review, including the end points of relevant studies assessed previously, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation report submitted by the EMS (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 as background documents to this reasoned opinion.

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\(^1\) 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.

\(^2\) Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthialvalicarb, boscalid, carvone, fluoxastrobin, Paecilomyces lilacinus and prothioconazole as active substances. OJ L 94, 5.4.2008, p. 13–20.

\(^3\) Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

\(^4\) For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
1. **Residues in plants**

1.1. **Nature of residues and methods of analysis in plants**

1.1.1. **Nature of residues in primary crops**

In the framework of the peer review under Council Directive 91/414/EEC, a metabolism study in wheat was evaluated (one seed treatment, followed by two foliar applications). In cereal grain, parent fluoxastrobin and its Z-isomer were the main compounds accounting for up to 86% and 80% of the total radioactivity residue (TRR). Some metabolites found in plants were not observed in rat metabolism. However, due to their insignificant levels (< 0.01 mg/kg) they were considered being of no concern in grain. In wheat straw, some metabolites not identified in the rat metabolism (i.e. 2-chlorophenol (M82) and its glycoside (M84)) were present at significant levels (EFSA, 2005). Since the toxicity of these metabolites has not been fully addressed, the use conditions have to be restricted, excluding the use of straw from treated areas to be used for animal feed (European Commission, 2012).

Additional metabolism studies with fluoxastrobin were performed which will be peer reviewed in the framework of the AIR III process (renewal of the approval of fluoxastrobin). A new metabolism study in tomatoes (foliar spray) and two new metabolism studies in peanuts (foliar spray) and rapeseeds (seed treatment) are available. Detailed information on these studies has been provided in the Evaluation Report (United Kingdom, 2017). In peanut meat, the TRR amounted for 0.146 mg eq/kg and 0.055 mg eq/kg for the pyrimidine and methoxyiminotolyl radiolabel, respectively. Parent fluoxastrobin was not recovered. 

1.1.2. **Nature of residues in rotational crops**

Oilseed crops can be grown in rotation with other plants. Since the DT$_{90}$ of fluoxastrobin in soil is above the trigger value of 100 days (EFSA, 2012), the nature of residues in succeeding crops resulting from the use of fluoxastrobin on primary crops has been assessed in the framework of the peer review; parent fluoxastrobin and its Z-isomer were identified as the major residues in rotational crops (EFSA, 2005).

1.1.3. **Nature of residues in processed commodities**

Based on the available information on the nature of fluoxastrobin residues, EFSA concluded that the compound is hydrolytically stable under the representative processing conditions (EFSA, 2005).

1.1.4. **Methods of analysis in plants**

Analytical methods for the determination of fluoxastrobin and its Z-isomer in plant commodities were assessed in the framework of the peer review and the MRL review (EFSA, 2005, 2012). EFSA concluded that adequate analytical methods are available to monitor residues in high water content commodities and in dry/high starch content commodities with a limit of quantification (LOQ) of 0.01 mg/kg for fluoxastrobin and 0.002 mg/kg for its Z-isomer.

Information on the full validation of the analytical method for the determination of fluoxastrobin by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in oilseeds has been submitted under the current application. It has been demonstrated that fluoxastrobin residues can be enforced in...
high oil content commodities with a LOQ of 0.009 mg/kg for fluoxastrobin and 0.001 mg/kg for its Z-isomer (United Kingdom, 2017). Analytical methods are sufficiently validated to enforce the MRLs in the crop group to which oilseeds belong to.

1.1.5. Stability of residues in plants

Studies on the storage stability of fluoxastrobin were previously evaluated (EFSA, 2005, 2012). Residues of fluoxastrobin were found to be stable for 30 months at –20°C in high water content matrices (tomatoes, lettuce and potatoes) as well as in dry commodities (wheat) (EFSA, 2005). Storage stability information for high oil content matrices (oilseeds) has been submitted under the current MRL application (United Kingdom, 2017) and residues of fluoxastrobin and its Z-isomer were found to be stable for 12 months when stored at –20°C.

1.1.6. Proposed residue definitions

Metabolism studies in cereals were evaluated in previous assessments (EFSA, 2005, 2012); in the framework of the current application, new metabolism studies representative for pulses/oilseeds were assessed. The metabolism studies in pulses/oilseeds crops (rapeseed and peanuts) are valid, but for the following reasons they are considered not fully representative for the crops under assessment:

- Rapeseed metabolism study: the type of application (seed treatment) is not representative for the intended good agricultural practices (GAPs);
- Peanuts (foliar use): considering the different morphology of rapeseeds, linseeds, and other seeds, where the oilseeds are formed after blossom, compared with peanuts where the nuts are formed under the ground, peanuts are not considered the best plant model to investigate the metabolism for active substances that are not translocated from the treated leaves to the roots/nuts growing in the soil.

It is acknowledged that a metabolism study for a third crop group is available (i.e. in tomatoes). Considering the results of all available metabolism studies, EFSA is of the opinion that the previously derived residue definitions for plants are appropriate for the crops under assessment, i.e.

- Residue definition for risk assessment: sum of fluoxastrobin (E-isomer) and its Z-isomer.
- Residue definition for enforcement: sum of fluoxastrobin (E-isomer) and its Z-isomer.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical as the above mentioned and are applicable for primary crops, rotational crops and processed commodities.

It is noted that the residue definitions may be reconsidered in the framework of the renewal process of the active substance under Regulation (EC) No 1107/2009. It is also highlighted that in previous assessments metabolites were identified in parts of the crops that can be used for feed purpose. Since the toxicological properties of these metabolites are not yet fully addressed, the restrictions implemented in the approval conditions for fluoxastrobin are still applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted eight residue trials performed in rapeseed compliant with the intended GAPs. Samples were analysed for residues of fluoxastrobin and its Z-isomer separately (United Kingdom, 2017). Detailed information of the residue levels can be found in Table B.1.2.1. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (11 months).

In accordance with the provisions of the relevant EU guidance document (European Commission, 2017), the trials in rapeseeds can be used to derive MRL proposals by extrapolation for other minor oilseeds. This extrapolation has been considered to derive an MRL proposal for linseed, poppy seeds, mustard seeds and gold of pleasure seeds.
1.2.2. Magnitude of residues in rotational crops

Residues of fluoxastrobin and its Z-isomer above the trigger of 0.1 mg/kg are not expected in rotational crops (except in cereal straw), if the active substance is applied on primary crops up to the maximum dose rate of 680–850 g/ha (EFSA, 2005, 2012).

Since the intended application rate for oilseeds is limited to a maximum total application rate of 144 g/ha (1 application), it is unlikely that significant residues in rotational crops occur, provided that the active substance is applied according to the proposed GAPs.

1.2.3. Magnitude of residues in processed commodities

Specific studies to assess the magnitude of residues of fluoxastrobin and its Z-isomer during the processing of oilseeds are not necessary as the residue levels in RAC did not exceed the trigger value of 0.1 mg/kg (European Commission, 1997d).

1.2.4. Proposed MRLs

EFSA concluded that sufficient information was provided to calculate a MRL proposal of 0.05 mg/kg from the residue trials conducted in rapeseed in northern Europe (NEU). Moreover, the MRL proposal of 0.05 mg/kg can be extrapolated to linseeds, poppy seeds, mustard seeds and gold pleasure seeds as requested in the framework of the current MRL application.

2. Residues in livestock

As some of the crops under assessment in the current application can be used to feed livestock (linseeds, rapeseeds), it is necessary to assess whether the intended use triggers a modification of the existing MRLs for animal products. For this purpose, the previous dietary burden calculation (EFSA, 2012) has been updated by using the new dietary burden calculator according to the international agreed methodology (OECD, 2013); EFSA calculated two scenarios to estimate the impact of the new uses: in Scenario 1 the calculations were performed with the commodities assessed in the framework of the MRL review only; while in Scenario 2, the expected residues on oilseeds under assessment and their by-products were included as well; straw has been excluded in Scenario 2, taking into account that according to the restrictions of the approval conditions, straw should not be used for feed purposes. The input values used for this exposure calculation are presented in Appendix D.

Comparing the results of Scenario 1 with the results reported in the MRL review (EFSA, 2012), it becomes evident that the new calculation methodology (OECD, 2013), compared with the methodology used previously (European Commission, 1996), has a major impact on the overall result. The estimated exposure calculated according to the OECD methodology is higher for dairy cattle, swine and poultry, while for beef cattle the results are lower. For sheep, the expected dietary intake is even higher than for cattle. With the OECD methodology, the trigger values have been exceeded in all the diets, with barley/wheat straw and potato process waste being the main contributors. Overall, the calculations are considered to be overly conservative, considering that treated straw should not be used for feed purposes.

In Scenario 2 where treated straw was not considered, the exposure was significantly lower. Rape and linseed were only minor contributors to the total dietary burden. Thus, it is concluded that the new uses do not require a modification of the existing MRLs for animal origin commodities.

3. 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 (EFSA, 2007).

The estimated exposure was then compared with the toxicological reference values derived for fluoxastrobin during the peer-review process. Based on the results of mammalian toxicity studies conducted with different isomer ratios, the peer review concluded that it is unlikely that the Z-isomer is more toxic than the E-isomer of fluoxastrobin (EFSA, 2005). Hence, the acceptable daily intake (ADI) and

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5 The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).
the acute reference dose (ARfD) are applicable to the proposed risk assessment residue definition which includes both the E- and Z-isomers of fluoxastrobin (EFSA, 2012).

In the framework of the review of the existing MRLs for fluoxastrobin according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses of fluoxastrobin at EU level supported by data. Those food commodities for which no uses were reported in the framework of the Article 12 review were excluded from the exposure calculation assuming that there is no use on these crops (EFSA, 2012). EFSA updated the chronic risk assessment performed under the Article 12 review with the median residue value (STMR) derived from previous assessments (EFSA, 2015) and STMR from the residue trials conducted on rapeseeds and extrapolated to the oilseeds under assessment in the MRL application.

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food item as reported in the national food surveys and considering highest residue (HR) level observed in supervised field trials (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Appendix D.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic calculated intake accounted for less than 6% of the ADI (Dutch, children) and the contribution of the residues in oilseeds to the total exposure accounting for a maximum of 0.04% (rapeseeds, WHO Cluster diet E).

No acute consumer risk was identified in relation to the MRL proposal for oilseeds, the highest calculated acute exposure being less than 1% of the ARfD.

EFSA concludes that the proposed use of fluoxastrobin on oilseeds will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a health risk to consumers; however, the consumer assessment described should be considered on tentative basis in view of the submission of the missing information identified in the current and previous assessment.

4. Conclusion and Recommendations

Overall, EFSA concluded that the proposed use of fluoxastrobin in oilseeds will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

Therefore, the MRL recommendations are summarised in Appendix B.4.

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United Kingdom, 2017. Evaluation report on the setting of MRLs for fluoxastrobin in oilseeds. May 2017, 69 pp.

**Abbreviations**

- **a.s.**: active substance
- **ADI**: acceptable daily intake
- **AR**: applied radioactivity
- **ARfD**: acute reference dose
- **BBCH**: growth stages of mono- and dicotyledonous plants
- **bw**: body weight
- **CF**: conversion factor for enforcement to risk assessment residue definition
- **DAR**: draft assessment report
- **DAT**: days after treatment
- **DM**: dry matter
- **DT90**: period required for 90% dissipation (define method of estimation)
- **EMS**: evaluating Member State
- **eq**: residue expressed as a.s. equivalent
- **FAO**: Food and Agriculture Organization of the United Nations
- **GAP**: Good Agricultural Practice
- **HPLC-MS/MS**: high performance liquid chromatography with tandem mass spectrometry
- **HR**: highest residue
- **IEEDI**: international estimated daily intake
- **IESTI**: international estimated short-term intake
- **ILV**: independent laboratory validation
- **ISO**: International Organisation for Standardisation
- **IUPAC**: International Union of Pure and Applied Chemistry
- **LC**: liquid chromatography
- **LOQ**: limit of quantification
- **MRL**: maximum residue level
- **MS/MS**: tandem mass spectrometry detector
- **NEU**: northern Europe
- **OECD**: Organisation for Economic Co-operation and Development
- **PBI**: plant-back interval
- **PF**: processing factor
- **PHI**: pre-harvest interval
| Acronym | Description |
|---------|-------------|
| PRIMo   | (EFSA) Pesticide Residues Intake Model |
| QuEChERS | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA      | risk assessment |
| RAC     | raw agricultural commodity |
| RD      | residue definition |
| RMS     | rapporteur Member State |
| SANCO   | Directorate-General for Health and Consumers |
| SC      | suspension concentrate |
| SEU     | southern Europe |
| STMR    | supervised trials median residue |
| TRR     | total radioactive residue |
| WG      | water-dispersible granule |
| WHO     | World Health Organization |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F or G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|------------------------|----------------|-----------------------------------|-------------|-------------|-------------------------------|---------------|---------|
| Major crop: Oilseed rape | NEU | F | Fungus *Sclerotinia sclerotiorum* | SC 180 g/L | Foliar BBCH 61–70 | 1 | 36–72 | 200–400 | 144 g/ha | 56 | Other active substance tebuconazole (250 g/L) |

NEU: northern Europe; SEU: southern Europe; MS: Member State; a.s.: active substance; 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 formulation types and international coding system.

(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 pre-harvest interval.
Appendix B – List of end points

Note: In case new tox data are received in the framework of the application, the main findings can be reported at beginning of the LoEPs.

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/source |
|----------------------------------|-------------|---------|----------------|---------------|---------------|
| Cereals/grass                    | Wheat       | Seed treatment and foliar applications\(^{(a)}\) – G Rate: 0.0325\(^{(b)}\) + 1 - 2 x 0.3 | Forage: BBCH 23 Hay: BBCH 75 Grain/straw: BBCH 89 (DAT not reported) | U-\(^{14}\)C-chlorophenyl 2-\(^{14}\)C-pyrimidine and U-\(^{14}\)C-methoxyiminotolyl radiolabelled fluoxastrobin One seed treatment followed by two foliar applications (EFSA, 2005, 2012) |
| Fruit                            | Tomato      | Foliar spray, 3 x 144 g/ha | Tomatoes: 3 DAT | \(^{14}\)C-chlorophenyl and U-\(^{14}\)C-methoxyiminotolyl radiolabelled fluoxastrobin (United Kingdom, 2017) |
| Oilseed/Pulses                   | Peanuts     | Foliar spray, indoor 3 x 270 g/ha interval 14 days | Hay: 14 DAT Nutmeat: 14 DAT | \(^{14}\)C-pyrimidine and U-\(^{14}\)C-methoxyiminotolyl radiolabelled fluoxastrobin (United Kingdom, 2017) |
| Oilseed/Pulses                   | Rapeseed    | Seed treatment, 1 x 3.5 g/ha (5 kg seeds/ha) | Forage: 46 DAT Seeds: 160 DAT Straw: 160 DAT | Methoxyiminotolyl-ring-UL-\(^{14}\)C (United Kingdom, 2017) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                   | Turnip      | Soil treatment, G Rate: 0.68–0.85 kg a.s./ha | 30, 157-175, 301-328 | U-\(^{14}\)C-chlorophenyl, 2-\(^{14}\)C-pyrimidine and U-\(^{14}\)C-methoxyiminotolyl fluoxastrobin (EFSA, 2012) |
| Leafy crops                        | Swiss chard |                      |               |           |               |
| Cereal (small grain)               | Wheat       |                      |               |           |               |
### Processed commodities (hydrolysis study)

| Conditions                                    | Stable? | Comment/Source |
|------------------------------------------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)           | Yes     | EFSA (2012)    |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     | EFSA (2012)    |
| Sterilisation (20 min, 120°C, pH 6)           | Yes     | EFSA (2012)    |

DAT: days after treatment; PBI: plant-back interval.

(a): The use of fluoxastrobin as a seed treatment followed by two foliar applications is assumed to represent the worst case scenario with respect to the consumer risk assessment. Therefore the crop metabolism and residue data have been constructed to support this pattern of use.

(b): Assuming a seed treatment of 0.025 kg a.s./100 kg of seed (United Kingdom, 2003) with seed planted at a rate of 130 kg/ha.

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**Can a general residue definition be proposed for primary crops?**

| Rotational crop and primary crop metabolism similar? | Yes | EFSA (2005) |
|-----------------------------------------------------|-----|-------------|
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes | EFSA (2005) |
| Plant residue definition for monitoring (RD-Mo) | Sum of fluoxastrobin (E-isomer) and its Z-isomer |
| Plant residue definition for risk assessment (RD-RA) | Sum of fluoxastrobin (E-isomer) and its Z-isomer |
| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | Matrices with high water content and dry matrices: HPLC–MS/MS, LOQ 0.02 mg/kg (fluoxastrobin) and LOQ 0.002 (Z-isomer) (EFSA, 2005). No ILV available. Matrices with high water content: HPLC–MS/MS, LOQ 0.05 mg/kg (fluoxastrobin) and LOQ 0.005 (Z-isomer) ILV available (EFSA, 2012). Matrices with dry matrices: HPLC–MS/MS, LOQ 0.02 mg/kg (fluoxastrobin) and LOQ 0.002 (Z-isomer). ILV available (EFSA, 2012). Matrices with high water content and dry commodities: QuEChERS – HPLC–MS/MS, LOQ 0.01 mg/kg Matrices with high oil content: LC–MS/MS, LOQ 0.01 mg/kg (0.009 mg/kg for fluoxastrobin and LOQ 0.001 mg/kg for Z-isomer) (United Kingdom, 2017). |

HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; LC–MS/MS: liquid chromatography with tandem mass spectrometry.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category                     | Commodity          | T (°C) | Stability period | Compounds covered                      | Comment/source |
|-----------------------------------|------------------------------|--------------------|--------|------------------|----------------------------------------|---------------|
|                                    | High water content           | Tomatoes, Lettuce, Potatoes | –20 °C | 30 Months        | Fluoxastrobin (E-isomer) Z-isomer      | EFSA (2005)   |
|                                    | High oil content             | Rapeseed           | –20 °C | 12 Months        | Fluoxastrobin (E-isomer) Z-isomer      | United Kingdom (2017) |
|                                    | Dry/High starch              | Wheat grain, Wheat straw | –20 °C | 30 Months        | Fluoxastrobin (E-isomer) Z-isomer      | EFSA (2005)   |

### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|------------------|-----------------------------------------------------------------|-----------------|------------------------|--------------|----------------|-------|
| Rapeseeds | NEU              | 7 × < 0.01, 0.031                                                | Residue trials on rapeseeds compliant with GAP. Extrapolation to other minor crops in the oilseeds group possible; the extrapolation allows the use of the same MRL for linseeds, poppy seeds, mustards seeds and gold of pleasure seeds | 0.05        | 0.031          | 0.01            | 1     |

MRL: maximum residue level; GAP: good agricultural practice.

*: Indicates that the MRL is proposed at the limit of quantification.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?

|                | Residues of fluoxastrobin and its Z-isomer above the trigger of 0.1 mg/kg are not expected in rotational crops (except in straw), when the active substance is applied on primary crops up to the maximum dose rate of 680–850 g/ha |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Residues in rotational and succeeding crops expected based on field rotational crop study? | No                                                                                                                                                                                                 |

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Scenario 1- Expected residues intake in livestock from the authorised uses (EFSA, 2012) according to the OECD 73 (2013).

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|----------------------------|---------------------------------------------|---------------------------|---------------------------|------------------------|
|                            | Median Maximum | Median Maximum |                       |                         |                        |
| Cattle (all)               | 0.036 0.165 1.10 4.45 | Dairy cattle | Barley straw | Y                       |
| Cattle (dairy only)        | 0.036 0.165 0.94 4.29 | Dairy cattle | Barley straw | Y                       |
| Sheep (all)                | 0.050 0.331 1.51 8.08 | Lamb | Barley straw | Y                       |
| Sheep (ewe only)           | 0.050 0.269 1.51 8.08 | Ram/Ewe | Barley straw | Y                       |
| Swine (all)                | 0.009 0.011 0.37 0.47 | Swine (breeding) | Potato process waste | Y                       |
| Poultry (all)              | 0.013 0.055 0.19 0.80 | Poultry layer | Wheat straw | Y                       |
| Poultry (layer only)       | 0.013 0.055 0.19 0.80 | Poultry layer | Wheat straw | Y                       |
| Fish                       | N/A                                                         |                           |                           |                        |

Scenario 2- Expected residue intake in livestock considering the restriction not to feed livestock with cereals straw and the new uses intended uses in oilseeds.

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|----------------------------|---------------------------------------------|---------------------------|---------------------------|------------------------|
|                            | Median Maximum | Median Maximum |                       |                         |                        |
| Cattle (all)               | 0.021 0.023 0.70 0.76 | Dairy cattle | Potato process waste | Y                       |
| Cattle (dairy only)        | 0.021 0.023 0.53 0.59 | Dairy cattle | Potato process waste | Y                       |
| Sheep (all)                | 0.023 0.025 0.70 0.76 | Ram/Ewe | Potato process waste | Y                       |
| Sheep (ewe only)           | 0.023 0.025 0.70 0.76 | Ram/Ewe | Potato process waste | Y                       |
### Relevant groups (subgroups)

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|-----------------------------|---------------------------------------------|---------------------------|----------------------------|----------------------|
|                            | Median | Maximum | Median | Maximum |                      |                           |                           |
| Swine (all)                 | 0.009  | 0.011   | 0.37   | 0.47     | Swine (breeding)     | Potato process waste    | Y                          |
| Poultry (all)               | 0.009  | 0.010   | 0.12   | 0.14     | Poultry broiler      | Potato dried pulp       | Y                          |
| Poultry (layer only)        | 0.007  | 0.008   | 0.10   | 0.12     | Poultry layer        | Potato dried pulp       | Y                          |
| Fish                        | N/A    |         |        |          |                      |                            |                            |

bw: body weight; DM: dry matter.

(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden based on the calculations in ‘mg/kg bw per day’.

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

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

| Livestock (available studies) | Animal          | Dose (mg/kg bw per day) | Duration (days) | Comment/source                                          |
|-------------------------------|-----------------|-------------------------|-----------------|--------------------------------------------------------|
|                               | Laying hen      | 187–198 mg/kg in feed   | 3 days          | U-14C-chlorophenyl and U-14C-methoxyminotolyl labelled fluoxastrobin |
|                               | Lactating ruminants | 180–256 mg/kg in feed | 3 days          | U-14C-chlorophenyl and U-14C-methoxyminotolyl labelled fluoxastrobin Goat metabolism study |
|                               | Pig             |                         |                 |                                                        |
|                               | Fish            |                         |                 |                                                        |

Time needed to reach a plateau concentration in milk and eggs (days)

- Milk: 12 days (plateau of 0.03 mg/kg)
- Eggs: No information available

Metabolism in rat and ruminant similar

- Yes
- EFSA (2012)

Can a general residue definition be proposed for animals?

- Yes
- EFSA (2012)

Animal residue definition for monitoring (RD-Mo)

- Sum of fluoxastrobin (E-isomer), its Z-isomer and its phenoxyhydroxypyrimidine (M55) metabolite, express as fluoxastrobin

Animal residue definition for risk assessment (RD-RA)

- Sum of fluoxastrobin (E-isomer), its Z-isomer and its phenoxyhydroxypyrimidine (M55) metabolite, express as fluoxastrobin

Fat soluble residues

- No
- EFSA (2005)

Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)

- HPLC–MS/MS, fat, muscle, milk, LOQ 0.02 mg/kg
- HPLC–MS/MS, kidney, liver, LOQ 0.04 mg/kg

HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
B.3. Consumer risk assessment

ARfD: 0.3 mg/kg bw (EFSA, 2005)

Highest IESTI, according to EFSA PRIMo
- Rapeseed: < 1% of ARfD
- Linseed: < 1% of ARfD
- Poppy seed: < 1% of ARfD
- Mustard seed: < 1% of ARfD

Assumptions made for the calculations
The calculation is based on the highest residue levels expected in raw agricultural commodities under assessment in the current MRL application. Conversion factors for risk assessment are not necessary.

ADI: 0.015 mg/kg bw per day (EFSA, 2005)

Highest IEDI, according to EFSA PRIMo
- Rapeseed: < 1% of ADI
- Linseed: < 1% of ADI
- Poppy seed: < 1% of ADI
- Mustard seed: < 1% of ADI

Assumptions made for the calculations
The calculation is based on the median residue levels derived for raw agricultural commodities under assessment in the current MRL application, the median residue levels of the uses supported by data under the MRL review and for which no consumer concern was identified, the median residue levels of the previous intended use in shallots evaluated by EFSA and implemented in MRL regulation according to Reg. (EU) 2016/1016.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level.

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0401060 | Rapeseeds/canola seeds | 0.01* | 0.05 | The submitted residue data on rapeseed are sufficient to derive a MRL proposal of 0.05 mg/kg for the NEU use Risk for consumers unlikely |
| 0401010 | Linseeds | 0.01* | 0.05 | The MRL proposal was derived by extrapolation from residue trials in rapeseeds Risk for consumers unlikely |
| 0401030 | Poppy seeds | 0.01* | 0.05 |
| 0401080 | Mustard seeds | 0.01* | 0.05 |
| 0401130 | Gold of pleasure seeds | 0.01* | 0.05 |

MRL: maximum residue level; NEU: northern Europe.

*: 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.
(R) = The residue definition differs for the following combinations pesticide-code number:
Fluoxastrobin — code 1000000 except 1040000: 'Fluoxastrobin (sum of fluoxastrobin, its Z-isomer and its metabolite 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol, expressed as fluoxastrobin) (F) (F = fat soluble)'.

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Fluoxastrobin

Status of the active substance: Approved

Code no.

LOQ (mg/kg bw): 0.01

proposed LOQ:

ADI (mg/kg bw per day): 0.015

ARfD (mg/kg bw):

0.3

Source of ADI:

EC

Source of ARfD:

EC

Year of evaluation:

2007, 2012

No of diets exceeding ADI:

---

Highest calculated TMDI values in % of ADI

| Countries | Commodity/group of commodities | TMDI (range) in % of ADI |
|-----------|--------------------------------|--------------------------|
| NL child  | Milk and milk products: Cattle | 5.6 Wheat 0.4 Potatoes |
| FR infant | Milk and milk products: Cattle | 4.0 Milk and milk products: Cattle 0.1 Potatoes |
| DE child  | Milk and milk products: Cattle | 3.1 Milk and milk products: Cattle 0.5 Wheat |
| ES child  | Milk and milk products: Cattle | 3.1 Milk and milk products: Cattle 0.6 Wheat |
| SE general population 90th percentile | Milk and milk products: Cattle | 2.6 Milk and milk products: Cattle 0.4 Wheat |
| WHO Cluster diet B | Wheat | 2.4 Wheat 0.2 Potatoes |
| WHO Cluster diet D | Wheat | 2.2 Wheat 0.6 Milk and milk products: Cattle |
| WHO regional European diet | Milk and milk products: Cattle | 2.0 Milk and milk products: Cattle 0.4 Wheat |
| WHO Cluster diet E | Milk and milk products: Cattle | 2.0 Milk and milk products: Cattle 0.5 Wheat |
| NL general | Milk and milk products: Cattle | 1.8 Milk and milk products: Cattle 0.3 Wheat |
| DK child | Wheat | 1.8 Wheat 0.2 Potatoes |
| ES adult | Milk and milk products: Cattle | 1.6 Milk and milk products: Cattle 0.3 Wheat |
| IE adult | Milk and milk products: Cattle | 1.6 Milk and milk products: Cattle 0.3 Barley |
| LT adult | Milk and milk products: Cattle | 1.3 Milk and milk products: Cattle 0.2 Potatoes |
| FR toddler | Wheat | 1.2 Wheat 0.3 Potatoes |
| FR all population | Wheat | 1.1 Wheat 0.4 Milk and milk products: Cattle |
| IT kids/toddler | Wheat | 1.0 Wheat 0.1 Potatoes |
| IT General population | Wheat | 1.0 Wheat 0.4 Potatoes |
| UK Toddlers | Wheat | 0.9 Wheat 0.2 Potatoes |
| UK infant | Wheat | 0.9 UK Infant 0.2 Potatoes |
| DK adult | Wheat | 0.6 DK Adult 0.10 Potatoes |
| IT adult | Wheat | 0.6 IT Adult 0.10 Potatoes |
| UK vegetarian | Wheat | 0.5 UK Vegetarian 0.1 Wheat |
| UK Adult | Wheat | 0.4 UK Adult 0.1 Wheat |
| FI adult | Wheat | 0.4 FI adult 0.1 Wheat |
| PL general population | Wheat | 0.3 PL General population 0.2 Potatoes |

Highest contributor to MS diet (in % of ADI) | Commodity/group of commodities
--- | ---
0.6 Wheat | 0.4 Potatoes
0.3 Milk and milk products: Cattle | 0.1 Potatoes
0.5 Milk and milk products: Cattle | 0.2 Potatoes
0.6 Milk and milk products: Cattle | 0.2 Potatoes
0.4 Milk and milk products: Cattle | 0.2 Potatoes
0.6 Milk and milk products: Cattle | 0.3 Potatoes
0.5 Milk and milk products: Cattle | 0.3 Potatoes
0.5 Milk and milk products: Cattle | 0.3 Potatoes
0.4 Milk and milk products: Cattle | 0.2 Potatoes
0.4 Milk and milk products: Cattle | 0.1 Barley
0.3 Milk and milk products: Cattle | 0.3 Wheat
0.2 Milk and milk products: Cattle | 0.1 Barley
0.3 Milk and milk products: Cattle | 0.3 Wheat
0.2 Milk and milk products: Cattle | 0.2 Wheat
0.3 Milk and milk products: Cattle | 0.2 Wheat
0.3 Milk and milk products: Cattle | 0.2 Barley
0.2 Milk and milk products: Cattle | 0.1 Rye
0.2 Milk and milk products: Cattle | 0.2 Potatoes
0.3 Milk and milk products: Cattle | 0.1 Rye
0.3 Milk and milk products: Cattle | 0.2 Wheat
0.3 Milk and milk products: Cattle | 0.2 Barley
0.3 Milk and milk products: Cattle | 0.3 Wheat
0.2 Milk and milk products: Cattle | 0.2 Barley
0.2 Milk and milk products: Cattle | 0.1 Rye
0.2 Milk and milk products: Cattle | 0.2 Potatoes
0.1 Milk and milk products: Cattle | 0.1 Rye
0.1 Milk and milk products: Cattle | 0.0 Potatoes
0.0 Milk and milk products: Cattle | 0.0 Potatoes
0.1 Milk and milk products: Cattle | 0.01 Rye
0.0 Milk and milk products: Cattle | 0.01 Rye
0.0 Milk and milk products: Cattle | 0.01 Rye
0.1 Milk and milk products: Cattle | 0.01 Rye
0.1 Milk and milk products: Cattle | 0.01 Rye

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDIs), based on pTMRLs, were below the ADI.

A long-term intake of residues of Fluoxastrobin is unlikely to present a public health concern.
**Acute risk assessment/children – refined calculations**

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

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

| Commodity          | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI |
|--------------------|------------------------------|-----------------------|
| Rape seed          | 0.031/-                      | 0.012                 |
| Linseed            | 0.031/-                      | 0.011                 |
| Poppy seed         | 0.031/-                      | 0.010                 |
| Mustard seed       | 0.031/-                      | 0.002                 |
| Potato puree (flakes) | 0.05/-                      | 0.02                  |
| Wheat flour        | 0.02/-                       | 0.01                  |
| Fried potatoes     | 0.05/-                       | 0.001                 |

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

| Commodity          | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI |
|--------------------|------------------------------|-----------------------|
| Lettuce            | 0.031/-                      | 0.005                 |
| Poppy seed         | 0.031/-                      | 0.003                 |
| Mustard seed       | 0.031/-                      | 0.000                 |

**Conclusion:**

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

---

**Modification of existing MRLs for fluoxastrobin in oilseeds**

For Fluoxastrobin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

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

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

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

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

For unprocessed commodities:

| Commodity          | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI |
|--------------------|------------------------------|-----------------------|
| Rape seed          | 0.031/-                      | 0.012                 |
| Linseed            | 0.031/-                      | 0.011                 |
| Poppy seed         | 0.031/-                      | 0.010                 |
| Mustard seed       | 0.031/-                      | 0.002                 |

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

For processed commodities:

| Commodity          | pTMRL/threshold MRL (mg/kg) | pTMRL: provisional temporary MRL for unprocessed commodity |
|--------------------|------------------------------|----------------------------------------------------------|
| Potato puree (flakes) | 0.05/-                      |                                                          |
| Wheat flour        | 0.02/-                       |                                                          |
| Fried potatoes     | 0.05/-                       |                                                          |
### Appendix D – Input values for the exposure calculations

#### D.1. Livestock dietary burden calculations

| Feed commodity                        | Median dietary burden | Maximum dietary burden |
|---------------------------------------|-----------------------|------------------------|
|                                       | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Risk assessment residue: Sum of fluoxastrobin (E-isomer) and its Z-isomer |                       |                        |                       |                        |
| Barley, oat (grain)                   | 0.04                  | STMR (EFSA, 2012)     | 0.04                  | HR (EFSA, 2012)       |
| Wheat, rye (grain)                    | 0.02                  | STMR (EFSA, 2012)     | 0.02                  | HR (EFSA, 2012)       |
| Barley, oat (straw)(b)                | 1.25                  | STMR (EFSA, 2012)     | 11                    | HR (EFSA, 2012)       |
| Wheat, rye (straw)(b)                 | 0.76                  | STMR (EFSA, 2012)     | 6                     | HR (EFSA, 2012)       |
| Potato (culls)                        | 0.01                  | STMR (EFSA, 2012)     | 0.05                  | HR (EFSA, 2012)       |
| Potato (process waste)                | 0.20                  | STMR (EFSA, 2012) × 20(a) | 0.20                  | STMR (EFSA, 2012) × 20(a) |
| Potato (dried pulp)                   | 0.38                  | STMR (EFSA, 2012) × 38(a) | 0.38                  | STMR (EFSA, 2012) × 38(a) |
| Brewer's grain (dried)                | 0.13                  | STMR (EFSA, 2012) × 3.3(a) | 0.13                  | STMR (EFSA, 2012) × 3.3(a) |
| Rapeseed meal(c)                      | 0.02                  | STMR (EFSA, 2012) × 2(a) | 0.02                  | STMR (EFSA, 2012) × 2(a) |
| Distiller's grain                     | 0.07                  | STMR (EFSA, 2012) × 3.3(a) | 0.07                  | STMR (EFSA, 2012) × 3.3(a) |
| Linseed meal(c)                       | 0.02                  | STMR (EFSA, 2012) × 2(a) | 0.02                  | STMR (EFSA, 2012) × 2(a) |
| Wheat meal                            | 0.04                  | STMR (EFSA, 2012) × 1.8(a) | 0.04                  | STMR (EFSA, 2012) × 1.8(a) |
| Wheat milled by-pdts                  | 0.14                  | STMR (EFSA, 2012) × 7(a) | 0.14                  | STMR (EFSA, 2012) × 7(a) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): In the absence of processing factors supported by data, default processing factors of 20, 38, 3.3, 2, 3.3, 2, 1.8 and 7 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.
(b): Residues in straw from cereals were only considered in Scenario 1, considering that the restriction to not feed livestock with treated straw was not implemented at MS level and without considering the new intended uses.
(c): Residues in straw from cereals were not considered in Scenario 2, assuming that MS implemented the restriction to not feed livestock with treated straw. The new intended uses in oilseeds were considered for livestock dietary intake.

#### D.2. Consumer risk assessment

| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------|-------------------------|-----------------------|
| Rapeseeds, linseeds, poppy seeds, mustard seeds, gold of pleasure seeds | 0.01         | STMR (Table B.1.2.1) | 0.031                  | HR (Table B.1.2.1)     |
| Potatoes                                       | 0.01                    | STMR (EFSA, 2012)    |                       |                        |
| Onions                                         | 0.02                    | STMR (EFSA, 2012)    |                       |                        |
| Shallots                                       | 0.02                    | STMR (EFSA, 2015)    |                       |                        |
| Barley and oats grain                          | 0.04                    | STMR (EFSA, 2012)    |                       |                        |
| Rye and wheat grain                            | 0.02                    | STMR (EFSA, 2012)    |                       |                        |
| Meat(a) (swine, ruminants)                     | 0.02                    | STMR (EFSA, 2012)    |                       |                        |
| Fat (swine, ruminants)                        | 0.02                    | STMR (EFSA, 2012)    |                       |                        |
| Liver (swine, ruminants)                       | 0.04                    | STMR (EFSA, 2012)    |                       |                        |
| Kidney (swine, ruminants)                      | 0.04                    | STMR (EFSA, 2012)    |                       |                        |
| Milk (ruminants)                               | 0.02                    | STMR (EFSA, 2012)    |                       |                        |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
(a): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).
## Appendix E – Used compound codes

| Code/trivial name                     | Chemical name/SMILES notation<sup>(a)</sup>                                                                 | Structural formula<sup>(a)</sup>                                                                 |
|---------------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Fluoxastrobin                        | (E)-[2-[6-(2-chlorophenoxy)-5-fluoropyrimidin-4-yloxy]phenyl] (5,6-dihydro-1,4,2-dioxazin-3-yl) methanone O-methylxime | ![Fluoxastrobin_E_isomer](image1)                                                              |
| E-isomer                              | Clc1cccc1Oc1ncnc(Occ2cccc2c(=N\(\text{OC}\))/C(=2OCCON=2)c1F                                                     | UFED0ZBUAFNAEU-NLRVBDNBSA-N                                                                   |
| Fluoxastrobin                         | (Z)-[2-[6-(2-chlorophenoxy)-5-fluoropyrimidin-4-yloxy]phenyl] (5,6-dihydro-1,4,2-dioxazin-3-yl) methanone O-methylxime | ![Fluoxastrobin_Z_isomer](image2)                                                              |
| Z-isomer                              | Clc1cccc1Oc1ncnc(Occ2cccc2c(=N\(\text{OC}\))/C(=2OCCON=2)c1F                                                     | UFED0ZBUAFNAEU-ITYLOIPMSA-N                                                                   |
| M38 (HEC 5725-E/Z-amide)              | (E/Z)-2-(2-[6-(2-chlorophenoxy)-5-fluoropyrimidin-4-yloxy]phenyl)-2-(methoxyimino)acetamide                      | ![M38_amide](image3)                                                                            |
|                                       | NC(=O)c(=N\(\text{OC}\)/c1cccc1Oc1ncnc(Occ2cccc2Cl)c1F                                                        | DPNOYUY1QDKVL-XYGWBWBKA-N                                                                    |
| 2-chlorophenol (M82)                  | 2-chlorophenol                                                                                                  | ![2-chlorophenol](image4)                                                                       |
|                                       | Oc1cccc1Cl                                                                                                     | ISPYQTSUDJAMAB-UHFFAOYSA-N                                                                   |
| M84 / HEC 5725-2-chlorophenol-       | 2-chlorophenyl D-glucopyranoside                                                                                | ![M84_HEC_2-chlorophenol_glucoside](image5)                                                   |
| glucoside                              | Clc1cccc1Oc1Cc[H][CO][C@@H][O][C@@H](O)[C@@H](O)                                                                | XVRYBMZGZJIPY-OZRWWLHGSA-N                                                                    |

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