Modification of the existing maximum residue level for etofenprox in plums

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant SIPCAM Italia S.p.A. submitted a request to the competent national authority in Italy to modify the existing maximum residue level (MRL) for the active substance etofenprox in plums. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for plums. Adequate analytical methods for enforcement are available to control the residues of etofenprox in plums 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 existing and intended uses of etofenprox according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, SIPCAM Italia S.p.A. submitted an application to the competent national authority in Italy (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance etofenprox in plums. The EMS 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 18 March 2020. To accommodate for the intended SEU use of etofenprox, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under the previous MRL assessment and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of etofenprox following foliar application was investigated in crops belonging to the groups of fruit crops, leafy crops, pulses/oilseeds. It was concluded that metabolism of etofenprox proceeds in a similar pathway in all crop groups investigated with parent etofenprox and its metabolite alpha-CO being relevant residues.

Studies investigating the effect of processing on the nature of etofenprox (hydrolysis studies) demonstrated that the active substance is stable.

As the proposed use of etofenprox is on permanent crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the residue definitions for plant products were proposed as etofenprox for enforcement and as sum of etofenprox and alpha-CO, expressed as etofenprox for risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application, the metabolism of etofenprox in primary crops and the possible degradation in processed products have been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on gas chromatography with mass spectroscopy (GC-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 or above 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive an MRL proposal of 0.2 mg/kg for plums.

Specific studies investigating the magnitude of etofenprox residues in processed commodities are in principle not required, since the total theoretical maximum daily intake (TMDI) for plums is below the trigger value of 10% of the acceptable daily intake (ADI). However, robust processing factors (PF) on peaches (puree, juice and jam) which can be extrapolated to plums have already been derived in the framework of the MRL review.

Residues of etofenprox in commodities of animal origin were not assessed since plums are normally not fed to livestock.

The toxicological profile of etofenprox 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 0.03 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 1 mg/kg bw. The metabolite included in the residue definition is not of higher toxicity than the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRiMo). For plums, the risk assessment values as derived from submitted residue trials were used as input values; for the remaining commodities, the risk assessment values were as derived in the previous EFSA assessment. Acute consumer exposure was assessed only from residues in plums. The crops for which no authorised uses were reported in the MRL review, and crops for which the MRLs were lowered to the LOQ because the assessed uses were not supported by data, were excluded from the exposure calculation.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRiMo. The total calculated intake accounted for a maximum of 37% of the ADI (NL, toddler diet). The contribution of residues in plums to the total exposure was low with 0.03% of the ADI (GEMS/Food G15).
The acute exposure calculation did not identify acute consumer intake concerns related to etofenprox residues from the intended use on plums (0.5% of the ARFD (IE child diet)).

EFSA concluded that the existing uses and the proposed use of etofenprox on plums 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 MRL as reported in the summary table below.

Full details of all end points 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 |
|----------------|-----------|------------------------|-------------------------|------------------------|
| 0140040 Plums | 0.01*     | 0.2                    | The submitted data are sufficient to derive an MRL proposal for the intended SEU use. Risk for consumers unlikely |

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

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for etofenprox in plums. The detailed description of the intended SEU use of etofenprox in plums, which is the basis for the current MRL application, is reported in Appendix A.

Etofenprox is the ISO common name for 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix A.

Etofenprox was evaluated in the framework of Directive 91/414/EEC with Italy designated as rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar spray applications on oilseed rape, head cabbage, grape, peach and apple. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2009). Etofenprox was approved for the use as insecticide on 1 January 2010. The approval of etofenprox has been extended by Commission Regulation (EU) No 2017/555.

The EU MRLs for etofenprox are established in Annex II of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2017) and the proposed modifications have been implemented in the MRL legislation. In addition, certain Codex maximum residue limits (CXLs) were implemented in the EU MRL legislation. No Codex MRL is in place for plums.

In accordance with Article 6 of Regulation (EC) No 396/2005, SIPCAM Italia S.p.A. submitted an application to the competent national authority in Italy (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance etofenprox in plums. The EMS 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 18 March 2020. To accommodate for the intended SEU use of etofenprox, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

EFSA based its assessment on the evaluation report submitted by the EMS (Italy, 2020), the draft assessment report (DAR) and its addendum (Italy, 2007, 2008) prepared under Council Directive 91/414/EEC, the Commission review report on etofenprox (European Commission, 2009), the conclusion on the peer review of the pesticide risk assessment of the active substance etofenprox (EFSA, 2009) and the conclusions of the review of the existing EU MRLs for etofenprox in the framework of Article 12 of Regulation (EU) No 396/2005 (EFSA, 2017).

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, 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 this MRL application including the end points of relevant studies assessed previously is presented in Appendix B.

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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 2009/77/EC of 1 July 2009 amending Council Directive 91/414/EEC to include chlorosulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron as active substances. OJ L 172, 2.7.2009, p. 23–33.
3. Commission Implementing Regulation (EU) 2017/555 of 24 March 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme). OJ L 80, 25.3.2017, p. 1–6.
4. 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.
5. Commission Regulation (EU) No 293/2013 of 20 March 2013 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 emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, phosmet, pyraclostrobin, spinosad and spiriotetramat in or on certain products. OJ L 96, 5.4.2013, p. 1–30.
6. Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
7. 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.
The evaluation report submitted by the EMS (Italy, 2020) 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.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of etofenprox in primary crops belonging to the groups of fruit crops, leafy crops, pulses/oilseeds has been investigated in the framework of the MRL review and EU pesticides peer review (EFSA, 2009, 2017).

Etofenprox was the major compound in all studies and represented the main radioactive fraction (62–88% total radioactive residue (TRR)). The metabolite alpha-CO was the only metabolite occurring at more than 1% of the TRR in plant metabolism studies (1–7% TRR). It was concluded that in all crop groups investigated the metabolism of etofenprox proceeds in a similar pathway.

For the intended use under consideration, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

As the proposed use of etofenprox is on permanent crop, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of etofenprox was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2009, 2017).

These studies showed that etofenprox and metabolite alpha-CO are hydrolytically stable under standard processing conditions.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of etofenprox residues and residues of alpha-CO were assessed during the EU pesticides peer review and the MRL review (EFSA, 2009, 2017). The overview is provided in Appendix B.1.1.1.

EFSA concludes that sufficiently validated methods are available for the determination of residues of etofenprox and alpha-CO in plums at or above the LOQ of 0.01 mg/kg.

1.1.5. Storage stability of residues in plants

The storage stability of etofenprox and alpha-CO in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2009). The overview is provided in Appendix B.1.1.2.

Etofenprox and the metabolite alpha-CO were demonstrated to be stable for a period of 24 months at −20°C in commodities with high water, high acid and high oil content. It is therefore concluded that in plums, etofenprox residues are stable for at least 24 months when stored at −18°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the peer review and the MRL review:

- residue definition for enforcement: etofenprox
- residue definition for risk assessment: sum of etofenprox and alpha-CO, expressed as etofenprox

The same residue definitions are applicable to rotational crops and processed products.

The peer review experts noted that the chemical structure of metabolite alpha-CO is related to the parent etofenprox; no higher toxicity was evidenced from the data available in comparison to the
parent compound, and therefore in the framework of the EU pesticides peer review, it was concluded that, if necessary, the reference values of etofenprox could be used also for the metabolite alpha-CO (EFSA, 2009, 2017).

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

Taking account of the proposed use assessed in this application, EFSA concluded that these residue definitions are appropriate and no further information is required.

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 residue trials performed in plums. The samples were analysed for the parent compound and the metabolite included in the residue definition for risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Italy, 2020).

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

In support of the intended outdoor SEU GAP on plums, eight independent residue trials were performed on plums in various countries of Southern Europe. Five of these residue trials were performed during the 2017 growing season whereby two of them were performed within a distance of less than 7 km, and therefore, the highest residue value among these trials was considered. In addition, four decline trials were performed during the 2018 growing season. All trials were performed according to the intended SEU GAP.

EFSA concludes that the available trials are sufficient to derive an MRL proposal of 0.2 mg/kg on plums in support of the intended SEU GAP of etofenprox.

1.2.2. Magnitude of residues in rotational crops

As the proposed use of etofenprox is on permanent crop, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Specific studies investigating the magnitude of etofenprox residues in processed commodities are in principle not required, since the total theoretical maximum daily intake (TMDI) for plums is below the trigger value of 10% of the ADI.

New studies on plums were not submitted in the framework of the current application. However, in the framework of the MRL review, the effect of processing on the magnitude of etofenprox residues was investigated in peaches and robust processing factors (PF) for peaches (puree, juice and jam) were derived. Considering morphological similarities between peaches and plums and a similar use pattern, the results can be extrapolated to plums.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for plums in support of the intended SEU use of etofenprox. In Section 3, EFSA assessed whether residues on these crops resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant for this assessment because plums are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2019). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (EFSA, 2018).

The toxicological reference values for etofenprox used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (EFSA, 2009). The metabolite
included in the risk assessment residue definition was considered to be not more toxic than the parent compound (EFSA, 2009).

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking account of the existing uses at EU level and the acceptable CXLs (EFSA, 2017). This exposure was now updated with the supervised trials median residue (STMR) values as derived from the residue trials on plums (see Appendix B.1.2.1). For the remaining commodities, the STMR values as derived in the previous EFSA assessments were used as input values (EFSA, 2017). The crops for which no authorised uses were reported in the MRL review, and crops for which the MRLs were lowered to the LOQ because the assessed uses were not supported by data, were excluded from the exposure calculation. The complete list of input values is presented in Appendix D.1.

The acute consumer exposure was performed only for residues in plums. The calculation was based on the highest residue as derived according to the risk assessment residue definition from the submitted residue trials.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for a maximum of 37% of the ADI (NL, toddler diet). The contribution of residues in plums to the total exposure was low with 0.03% of the ADI (GEMS/Food G15).

The acute exposure calculation did not identify acute consumer intake concerns related to etofenprox residues from the intended use on plums (0.5% of the ARfD (IE child)).

EFSA concluded that the long-term and short-term intake of residues of etofenprox resulting from the existing uses and the intended use on plums is unlikely to present a risk to consumer health.

Further details on the exposure calculations and a screenshot of the Report sheet of the PRIMo are presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for plums in support of the intended SEU use of etofenprox.

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

The MRL recommendations are summarised in Appendix B.4.

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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
CAS Chemical Abstract Service
CF conversion factor for enforcement to risk assessment residue definition
CIRCA (EU) Communication & Information Resource Centre Administrator
CS capsule suspension
CV coefficient of variation (relative standard deviation)
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DM dry matter
DP dustable powder
DS powder for dry seed treatment
EC emulsifiable concentrate
EDI estimated daily intake
EMS evaluating Member State
eq residue expressed as a.s. equivalent
EC Emulsifiable concentrate
FID flame ionisation detector
GAP Good Agricultural Practice
GC gas chromatography
GC-FID gas chromatography with flame ionisation detector
GC-MS gas chromatography with mass spectrometry
GC-MS/MS  gas chromatography with tandem mass spectrometry
HR  highest residue
IEDI  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  Member States
MS  mass spectrometry detector
MS/MS  tandem mass spectrometry detector
MW  molecular weight
NEU  northern Europe
OECD  Organisation for Economic Co-operation and Development
PBI  plant back interval
PF  processing factor
PHI  preharvest interval
PRIMo  (EFSA) Pesticide Residues Intake Model
RA  risk assessment
RD  residue definition
RMS  rapporteur Member State
SANCO  Directorate-General for Health and Consumers
SC  suspension concentrate
SEU  southern Europe
SL  soluble concentrate
SP  water-soluble powder
STMR  supervised trials median residue
TAR  total applied radioactivity
TMDI  theoretical maximum daily intake
TRR  total radioactive residue
UV  ultraviolet (detector)
WHO  World Health Organization
WP  wettable powder
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop          | NEU, SEU, MS or country | F | G | I (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|---------------|-------------------------|---|---|------|-----------------------------------|-------------|-------------|--------------------------------|----------------|---------|
| Plums         | SEU, IT                 | F |   |      | Cydia funebrana, Aphids, Anarsia lineatella, leafhopper, fruit tree tortrix, Thrips | EC          | Foliar treatment – broadcast spraying | 287.5 g/L | 10–87 | 2 | 8 | 1,000–1,500 | 215.60 g a.i./ha | 7 |         |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; a.i: active ingredient; EC: emulsifiable concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. 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 preharvest interval.
Appendix B – List of end points

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 |
|----------------------------------|-------------|---------|----------------|----------------|---------------|
| Fruit crops                      | Grapes      | Foliar, 1 × 300 g a.s./ha | 14, 28         |                | EFSA (2009)   |
|                                  |             | Foliar, 1 × 3,000 g a.s./ha | 14, 28         |                |               |
| Leafy crops                      | Lettuce     | Foliar, 1 × 180 g a.s./ha  | 8              |                |               |
|                                  |             | Foliar, 1 × 1,800 g a.s./ha | 8              |                |               |
| Pulses/oilseeds                 | Winter rape | Foliar, 1 × 120 g a.s./ha  | 56             |                |               |
|                                  |             | Foliar, 1 × 1,200 g a.s./ha | 56             |                |               |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                     | Carrots     | Bare soil, 311.8 g a.s./ha | 28         | EFSA (2009) |
| Leafy crops                          | Lettuce     | Bare soil, 311.8 g a.s./ha  | 28         |            |
| Cereal (small grain)                 | Barley      | Bare soil, 311.8 g a.s./ha  | 28         |            |

| Processed commodities (hydrolysis study) | Conditions                          | Investigated? | Comment/Source |
|------------------------------------------|-------------------------------------|---------------|----------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | Yes           | Available hydrolysis studies cover the stability of both etofenprox and alpha-CO (EFSA, 2009) |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Yes | |
|                                          | Other processed conditions | – | – |

Can a general residue definition be proposed for primary crops? Yes
Rotational crop and primary crop metabolism similar? Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities? Yes
Plant residue definition for monitoring (RD-Mo) Etofenprox
Plant residue definition for risk assessment (RD-RA) Sum of etofenprox and alpha-CO, expressed as etofenprox
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

High water, high acid and high oil commodities:
- GC–MS, LOQ: 0.01 mg/kg for etofenprox and for alpha-CO; ILV and confirmatory method available (EFSA, 2009)
- GC–MS/MS, LOQ: 0.01 mg/kg for etofenprox (EFSA, 2017)
- LC-MS/MS, LOQ: 0.01 mg/kg alpha-CO (EFSA, 2017)

DAT: days after treatment; PBI: plant-back interval; a.s.: active substance; GC–MS: gas chromatography with mass spectrometry; GC–MS/MS: gas chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category               | Commodity      | T (°C) | Stability (months) | Comment/Source                                                                 |
|-----------------------------------|------------------------|----------------|--------|-------------------|-------------------------------------------------------------------------------|
| High water content                | Head cabbage           | –20            | 24     |                   | Stability was investigated for etofenprox and alpha-CO (EFSA, 2009)         |
|                                   | Peach, apple           | –20            | 24     |                   |                                                                                |
| High oil content                  | Oil seed rape          | –20            | 24     |                   |                                                                                |
| High acid content                 | Grape                  | –20            | 24     |                   |                                                                                |
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\(^{(d)}\) |
|-----------|--------------------------|---------------------------------------------------------------|-----------------|-----------------------|-------------------|----------------------|---------|
| Plum      | SEU                      | **Mo:** < 0.01; 0.0151\(^{(e)}\); 0.0181; 0.0218; 0.0240; 0.0316; 0.0956; 0.1119<br>**RA:** < 0.02; 0.0251\(^{(e)}\); 0.0281; 0.0318; 0.034; 0.0416; 0.1056; 0.1309 | GAP compliant residue trials on plums | 0.2 | Mo: 0.11<br>RA: 0.13 | Mo: 0.02<br>RA: 0.03 | 1.44 |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.

(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 refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment 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.

(e): Higher residue at a longer PHI of 28 days.
B.1.2.2. Residues in rotational crops

| Confined rotational crop study (quantitative aspect) | Based on the available information, it can be concluded that no significant residues of etofenprox and alpha-CO are expected in rotational crops (EFSA, 2017) |
| Field rotational crop study | Not available and not required |

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

**ARfD**

| Highest IESTI, according to EFSA PRIMo | Plums: 0.5% of ARfD (IE, child) |
| Assumptions made for the calculations | The calculation is based on the highest residue level according to the risk assessment residue definition as estimated in plums from the submitted residue trials. Other commodities were not considered in the calculation. The calculations were performed with PRIMo revision 3.1 |

**ADI**

| Highest IEDI, according to EFSA PRIMo | 37% ADI (NL, toddler diet) Contribution of crop assessed: Plum: 0.03% of ADI (GEMS/Food G15) |
| Assumptions made for the calculations | The calculation is based on the median residue level according to the risk assessment residue definition as estimated in plums from the submitted residue trials. For the remaining commodities, the STMR values as derived in the previous EFSA assessments were used as input values. The crops for which no authorised uses were reported in the MRL review, and crops for which the MRLs were lowered to the LOQ because the assessed uses were not supported by data, were excluded from the exposure calculation. The calculations were performed with PRIMo revision 3.1 |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; LOQ: limit of quantification.
### B.4. Recommended MRLs

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|-----------|------------------------|-------------------------|-----------------------|
| 0140040        | Plums     | 0.01*                  | 0.2                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU use. Risk for consumers unlikely |

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

**Enforcement residue definition:** Etofenprox\(^{(F)}\)
Appendix C – Pesticide Residue Intake Model (PRIMo)

**LOQs (mg/kg)** range from: 0.01 to: 0.05

**ADI (mg/kg bw per day):** 0.03

**ARfD (mg/kg bw):** 1

Source of ADI: EFSA

Source of ARfD: EFSA

EFSA PRIMo revision 3.1; 2019/03/19

Year of evaluation: 2009

No of diets exceeding the ADI: ---

### Calculated exposure (% of ADI)

| Commodity/group of commodities | Exposure resulting from | 
|-------------------------------|------------------------|
|                               |                        |

### Details – chronic risk assessment

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of etofenprox is unlikely to present a public health concern.

### Details – acute risk assessment/children

Details – acute risk assessment/adults

## Supplementary results – chronic risk assessment

The refined calculation mode (IEDI/TMDI) was used below the ADI.

### Details – chronic risk assessment

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

### Conclusions

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of etofenprox is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

| Commodity               | MRL/ADI (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity               | MRL/ADI (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------------------|-----------------|---------------------|----------------------|-------------------------|-----------------|---------------------|----------------------|
| Head cabbages           | 0.7/0.44        | 20                  | 2%                   | Spinaches               | 3/1.81          | 7.2                 | 2%                   |
| Kabu/Japanese           | 0.8/0.37        | 17                  | 2%                   | Bovine: Edible offals   | 2/1.91          | 6.3                 | 2%                   |
| Apricots                | 0.6/0.41        | 14                  | 1%                   | Broccoli                | 0.4/0.24        | 5.7                 | 1%                   |
| Cauliflowers            | 0.4/0.24        | 14                  | 1%                   | Cauliflowers            | 0.4/0.24        | 5.6                 | 1%                   |
| Bovine: Edible offals   | 2/1.91          | 14                  | 1%                   | Lemons                  | 1.5/0.58        | 5.2                 | 1%                   |
| Limes                   | 1.5/0.58        | 12                  | 1%                   | Apricots                | 0.6/0.41        | 4.5                 | 1%                   |
| Broccoli                | 0.4/0.24        | 10.0                | 1.0%                 | Limes                   | 1.5/0.58        | 4.1                 | 0.5%                 |
| Milk: Cattle            | 0.07/0.05       | 6.5                 | 0.6%                 | Cherries (sweet)        | 0.8/0.4         | 4.0                 | 0.5%                 |
| Plums                   | 0.2/0.13        | 5.5                 | 0.5%                 | Lamb's lettuce/com salads | 3/1.81         | 3.4                 | 0.5%                 |

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short-term intake of residues of etofenprox is unlikely to present a public health risk.

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

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of etofenprox is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                   | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Plums                            | 0.03                    | STMR                  | 0.13               | HR      |
| Grapefruits                      | 0.395                   | STMR (EFSA, 2017)     |                    |         |
| Oranges                          | 0.395                   | STMR (EFSA, 2017)     |                    |         |
| Lemons                           | 0.395                   | STMR (EFSA, 2017)     |                    |         |
| Limes                            | 0.395                   | STMR (EFSA, 2017)     |                    |         |
| Mandarins                        | 0.395                   | STMR (EFSA, 2017)     |                    |         |
| Chestnuts                        | 0.01*                   | STMR (EFSA, 2017)     |                    |         |
| Hazelnuts/cobnuts                | 0.01*                   | STMR (EFSA, 2017)     |                    |         |
| Pine nut kernels                 | 0.01*                   | STMR (EFSA, 2017)     |                    |         |
| Apples                           | 0.241                   | STMR (EFSA, 2017)     |                    |         |
| Pears                            | 0.241                   | STMR (EFSA, 2017)     |                    |         |
| Apricots                         | 0.2                     | STMR (EFSA, 2017)     |                    |         |
| Cherries (sweet)                 | 0.318                   | STMR (EFSA, 2017)     |                    |         |
| Peaches                          | 0.2                     | STMR (EFSA, 2017)     |                    |         |
| Table grapes                     | 0.88                    | STMR (EFSA, 2017)     |                    |         |
| Wine grapes                      | 0.88                    | STMR (EFSA, 2017)     |                    |         |
| Table olives                     | 0.01*                   | STMR (EFSA, 2017)     |                    |         |
| Kaki/Japanese persimmons         | 0.183                   | STMR (EFSA, 2017)     |                    |         |
| Kiwi fruits (green, red, yellow) | 0.196                   | STMR (EFSA, 2017)     |                    |         |
| Potatoes                         | 0.01                    | STMR (EFSA, 2017)     |                    |         |
| Garlic                           | 0.01                    | STMR (EFSA, 2017)     |                    |         |
| Onions                           | 0.01                    | STMR (EFSA, 2017)     |                    |         |
| Tomatoes                         | 0.24                    | STMR (EFSA, 2017)     |                    |         |
| Broccoli                         | 0.09                    | STMR (EFSA, 2017)     |                    |         |
| Cauliflowers                     | 0.09                    | STMR (EFSA, 2017)     |                    |         |
| Head cabbages                    | 0.096                   | STMR (EFSA, 2017)     |                    |         |
| Lamb’s lettuce/corn salads       | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Lettuces                         | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Escaroles/broad-leaved endives   | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Cress and other sprouts and shoots | 0.9               | STMR (EFSA, 2017)     |                    |         |
| Roman rocket/rucoila             | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Spinaches                        | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Chards/beet leaves               | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Chervil                          | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Chives                           | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Celery leaves                    | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Parsley                          | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Sage                             | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Rosemary                         | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Thyme                            | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Basil and edible flowers         | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Laurel/bay leaves                | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Tarragon                         | 0.9                     | STMR (EFSA, 2017)     |                    |         |
| Beans (with pods)                | 0.102                   | STMR (EFSA, 2017)     |                    |         |

The acute exposure assessment was performed only for the commodity under consideration.
### Commodity Risk Assessment

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-------------------------|-----------------------|
|                                 | **Input value** (mg/kg) | **Comment**           | **Input value** (mg/kg) | **Comment** |
| Beans (dry)                     | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Linseeds                        | 0.01                    | STMR (EFSA, 2017)     |                       |             |
| Sesame seeds                    | 0.01                    | STMR (EFSA, 2017)     |                       |             |
| Rapeseeds/canola seeds          | 0.011                   | STMR (EFSA, 2017)     |                       |             |
| Mustard seeds                   | 0.01                    | STMR (EFSA, 2017)     |                       |             |
| Borage seeds                    | 0.01                    | STMR (EFSA, 2017)     |                       |             |
| Gold of pleasure seeds          | 0.01                    | STMR (EFSA, 2017)     |                       |             |
| Hemp seeds                      | 0.01                    | STMR (EFSA, 2017)     |                       |             |
| Olives for oil production       | 0.01                    | STMR (EFSA, 2017)     |                       |             |
| Swine: Muscle/meat              | 0.13                    | STMR (EFSA, 2017)     |                       |             |
| Swine: Fat tissue               | 0.452                   | STMR (EFSA, 2017)     |                       |             |
| Swine: Liver                    | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Swine: Kidney                   | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Bovine: Muscle/meat             | 0.149                   | STMR (EFSA, 2017)     |                       |             |
| Bovine: Fat tissue              | 0.546                   | STMR (EFSA, 2017)     |                       |             |
| Bovine: Liver                   | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Bovine: Kidney                  | 0.051                   | STMR (EFSA, 2017)     |                       |             |
| Sheep: Muscle/meat              | 0.073                   | STMR (EFSA, 2017)     |                       |             |
| Sheep: Fat tissue               | 0.167                   | STMR (EFSA, 2017)     |                       |             |
| Sheep: Liver                    | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Sheep: Kidney                   | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Goat: Muscle/meat               | 0.073                   | STMR (EFSA, 2017)     |                       |             |
| Goat: Fat tissue                | 0.167                   | STMR (EFSA, 2017)     |                       |             |
| Goat: Liver                     | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Goat: Kidney                    | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Equine: Muscle/meat             | 0.149                   | STMR (EFSA, 2017)     |                       |             |
| Equine: Fat tissue              | 0.546                   | STMR (EFSA, 2017)     |                       |             |
| Equine: Liver                   | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Equine: Kidney                  | 0.051                   | STMR (EFSA, 2017)     |                       |             |
| Poultry: Muscle/meat            | 0.001                   | STMR (EFSA, 2017)     |                       |             |
| Poultry: Fat tissue             | 0.009                   | STMR (EFSA, 2017)     |                       |             |
| Poultry: Liver                  | 0.001                   | STMR (EFSA, 2017)     |                       |             |
| Other farm and terrestrial animals: muscle | 0.073 | STMR (EFSA, 2017) |                       |             |
| Other farm and terrestrial animals: fat tissue | 0.167 | STMR (EFSA, 2017) |                       |             |
| Other farm and terrestrial animals: liver | 0.05 | STMR (EFSA, 2017) |                       |             |
| Other farm and terrestrial animals: kidney | 0.05 | STMR (EFSA, 2017) |                       |             |
| Milk: Cattle                    | 0.052                   | STMR (EFSA, 2017)     |                       |             |
| Milk: Sheep                     | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Milk: Goat                      | 0.05                    | STMR (EFSA, 2017)     |                       |             |
| Milk: Horse                     | 0.052                   | STMR (EFSA, 2017)     |                       |             |
| Eggs: Chicken                   | 0.004                   | STMR (EFSA, 2017)     |                       |             |

STMR: supervised trials median residue; HR: highest residue; CXL: Codex maximum residue limit.
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-----------------------------------------------|---------------------------------|
| etofenprox                      | 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether  
CCOc1ccc(cc1)C(C)(C)COCc1cc(Oc2cccc2)ccc1  
YREQHYQNNWYQCJ-UHFFFAOYSA-N | ![Structural formula for etofenprox](image1.png) |
| alpha-CO                        | 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzoate  
CCOc1ccc(cc1)C(C)COC(=O)c1cc(Oc2cccc2)ccc1  
LXGQWWFUERYNCP-UHFFFAOYSA-N | ![Structural formula for alpha-CO](image2.png) |

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.  
<sup>(b)</sup> ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 Jul 2019).  
<sup>(c)</sup> ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 Jul 2019).