Setting of import tolerances for haloxyfop-P in linseed and rapeseed

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Australian Government Department of Agriculture and Water Resources submitted two requests to the competent national authority in Denmark to set import tolerances for the active substance haloxyfop-P in linseed and rapeseed. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for linseed and rapeseed. Adequate analytical methods for enforcement are available to control the residues of haloxyfop-P in plant matrices under consideration at the validated limit of quantification (LOQ) of 0.05 mg/kg. EFSA reiterates the recommendation from the Article 12 MRL review that an independent laboratory validation (ILV) should be provided. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of haloxyfop-P 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, the Australian Government Department of Agriculture and Water Resources submitted two applications to the competent national authority in Denmark (evaluating Member State (EMS)) to set import tolerances for the active haloxyfop-P in linseeds and rapeseeds. The EMS drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 17 July 2017. Denmark proposed to lower the existing maximum residue level (MRL) of haloxyfop-P in rapeseeds from 0.2 mg/kg to 0.1 mg/kg and to raise the existing MRL of haloxyfop-P in linseeds from the limit of quantification (LOQ) of 0.01 mg/kg to 0.1 mg/kg (extrapolation from rapeseeds).

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 26 June 2018, the EMS submitted revised evaluation reports (Denmark, 2017a,b), which replaced the previously submitted evaluation reports.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessment and the additional data provided by the EMS in the framework of these applications, the following conclusions are derived.

The metabolism of haloxyfop-P following foliar application was investigated in crops belonging to the groups of root crops, leafy crops, cereals, pulses/oilseeds.

Studies investigating the effect of processing on the residues of haloxyfop-P are not available and were requested in the framework of the Art. 12 MRL review. As residues in linseeds or rapeseeds are not expected above the LOQ of 0.05 mg/kg when haloxyfop-P is used according to the Good Agricultural Practices (GAPs) authorised in Australia, there is no need to investigate the effect of industrial and/or household processing on the nature of the residues for the crops under consideration. However, EFSA reiterates the recommendation derived in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 that the study is required to complete the risk assessment for uses of haloxyfop in other crops.

As the MRL application for haloxyfop-P refers to imported crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in the plant metabolism studies, the residue definitions for plant products were proposed as the sum of haloxyfop, its esters, salts and conjugates expressed as haloxyfop (sum of the R- and S-isomers at any ratio) for enforcement and risk assessment.

EFSA concluded that for the crops assessed in this application, metabolism of haloxyfop-P has been sufficiently addressed and that the previously derived residue definitions are applicable.

Analytical methods for enforcement are available to control the residues of haloxyfop, its salts, esters and conjugates in linseeds and rapeseeds at the LOQ of 0.05 mg/kg. Based on the available data, it can be reasonably assumed that the method is sufficiently validated in accordance with the enforcement residue definition. In a previous assessment, indications were given on a valid independent laboratory validation (ILV) (EFSA, 2016b). However, the ILV was not provided with this application and details of the results are not reported in detail.

The available residue trials are sufficient to derive MRL proposals of 0.05* mg/kg for linseeds and rapeseeds.

Residue trials investigating the effect of processing on the magnitude of residues resulting from the use of haloxyfop-P in rapeseeds meal, crude oil and refined oil were assessed and processing factors were derived. Considering that the studies investigating the nature of residues under the standard processing conditions are not available, these processing factors are not recommended for inclusion in Annex VI of Regulation (EC) No 396/2005.

As the crops under consideration and their by-products are used as feed products, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant species/animal species. However, the contribution of residues resulting from the use of haloxyfop-P in the crops assessed in these MRL applications to the total livestock exposure was insignificant, and therefore, a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

The toxicological profile of haloxyfop-P 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 0.00065 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.075 mg/kg bw.
The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The estimated long-term dietary intake accounted for up to 90.2% of the ADI for UK infant. Rapeseeds and linseeds contributed up to 4.6% and 1.1% of the ADI, respectively. The short-term exposure was up to 0.1% of the ARfD for both of the crops assessed.

EFSA concluded that the existing use of haloxyfop-P on linseeds and rapeseeds authorised in Australia 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 |
|---------|------------|-------------------------|-------------------------|------------------------|
| 401010  | Linseeds   | 0.01*                   | 0.05*                   | The submitted data are sufficient to derive an import tolerance (Australia GAP). Risk for consumers unlikely. It is noted that the MRL in the country of origin is 0.1 mg/kg |
| 401060  | Rapeseeds/canola seeds | 0.2(ft) | 0.05* | Further risk management considerations required |

Enforcement residue definition: the sum of haloxyfop, its ester, salts and conjugates expressed as haloxyfop (sum of the R- and S-isomers at any ratio)

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: 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.
(ft): The European Food Safety Authority identified some information on analytical methods, nature of residues in processed commodities, residue trials, storage conditions used in the residue trials, analytical methods used in the residue trials, analytical methods used in the storage stability studies and the northern Good Agricultural Practice as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or, if that information is not submitted by that date, the lack of it.
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Assessment

The applicant applied for setting an import tolerance for linseed and rapeseed; the detailed description of the existing uses of haloxyfop-P authorised in Australia in rapeseed and linseed, which are the basis for the current maximum residue level (MRL) applications, are reported in Appendix A.

Haloxyfop-P is the ISO common name for \((R)-2-([3\text{-}chloro-5-(\text{trifluoromethyl})-2\text{-}pyridyloxy}]\text{-}2\text{-}propionic\text{ acid})\) (IUPAC). The chemical structure of the active substance is reported in Appendix E.

Haloxyfop-P was evaluated in the framework of Directive 91/414/EEC\(^1\) with Denmark designated as rapporteur Member State (RMS); the representative uses assessed were post-emergence foliar applications on carrots, fodder legumes (beans, peas dry), rape seeds, soya beans and sugar beets. The draft assessment report (DAR) and its addenda have been peer reviewed by EFSA (2006, 2009, 2014b).

Haloxyfop-P was approved\(^2\) for the use as a herbicide only, on 1 January 2011. The conditions of the approval have been amended in 2015 following the assessment of the confirmatory data (EFSA, 2014b), limiting the application rate to 0.052 kg/ha to be applied only once every 3 years.\(^3\)

The EU MRLs for haloxyfop-P are established in Annexes 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, 2014a) and the proposed modifications have been implemented in the MRL legislation.\(^4\) Confirmatory data were requested for a number of commodities, where EFSA concluded that the existing authorised uses of haloxyfop-P were not fully supported by data as required by legislation.\(^5\) The data should have been submitted by an applicant having an interest in the MRL concerned by 19 November 2017. The assessment of these confirmatory data requested is still pending. After completion of the MRL review, EFSA has issued two reasoned opinions on the modification of MRLs for haloxyfop-P. The proposals from these reasoned opinions have been considered in recent regulations for EU MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, the Australian Government Department of Agriculture and Water Resources submitted two applications to the competent national authority in Denmark (evaluating Member State (EMS)) to set import tolerances for the active haloxyfop-P in linseed and rapeseed. The EMS drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 17 July 2017. The EMS proposed to lower the existing MRL of haloxyfop-P in rapeseed from 0.2 mg/kg to 0.1 mg/kg and to raise the existing MRL of haloxyfop-P in linseed from the limit of quantification of 0.01 mg/kg to 0.1 mg/kg (extrapolation from rapeseed). The Australian MRLs for linseed and rapeseed are set at the level of 0.1 mg/kg (residue definition: sum of haloxyfop (including haloxyfop-P), its esters and its conjugates expressed as haloxyfop).

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 26 June 2018, the EMS submitted revised evaluation reports (Denmark, 2017a,b), which replaced the previously submitted evaluation reports.

EFSA based its assessment on the evaluation reports submitted by the EMS (Denmark, 2017a,b), the DAR and its addenda prepared under Directive 91/414/EEC (Denmark, 2004), the addendum to the DAR on haloxyfop-P with respect to confirmatory data submitted after Annex I inclusion and its final addendum (Austria, 2013, 2014), the European Commission review report on haloxyfop-P (European Commission, 2015), the conclusions on the peer review of the pesticide risk assessment of the active substance haloxyfop-P (EFSA, 2006, 2009, 2014b) as well as the conclusions from previous EFSA opinions on haloxyfop-P including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (hereafter Article 12 MRL review) (EFSA, 2014a, 2016a,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 2010/86/EU of 2 December 2010 amending Council Directive 91/414/EEC to include haloxyfop-P as an active substance. OJ L 317, 3.12.2010, p. 36–38.

\(^3\) Commission Implementing Regulation (EU) No 2015/2233 of 2 December 2015 amending Implementing Regulation (EC) No 540/2011 as regards the conditions of approval of the active substance haloxyfop-P. OJ L 317, 3.12.2015, p. 26–28.

\(^4\) Commission Regulation (EU) No 2015/2075 of 18 November 2015 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 abamectin, desmedipham, dichlorprop-P, haloxyfop-P, oryzalin and phenthramid in or on certain products. OJ L 302, 19.11.2015, p. 15–50.

\(^5\) 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
For this application, the data requirements established in Regulation (EU) No 544/2011\textsuperscript{6} 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\textsuperscript{7}.

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, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation reports submitted by the EMS (Denmark, 2017a,b) 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 haloxyfop-P following foliar treatment was investigated in the framework of the peer review in primary crops belonging to the groups of leafy vegetables (lettuce), root and tuber vegetables (sugar beet) and in pulses and oilseeds (soya beans, cotton seeds) (EFSA, 2009). The metabolism in all the studied crops was found to be similar.

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

As the MRL application for haloxyfop-P refers to imported crops, investigations of residues in rotational crops are not required.

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

Studies investigating the effect of processing on the nature of residues of haloxyfop-P are not available and were requested in the framework of the Art. 12 MRL review, since residues in rapeseed were found to contribute for more than 10% of the ADI in the long-term exposure calculation (EFSA, 2014a).

Considering that according to the available residue trials (see Section 1.2.1) residues haloxyfop-P above the LOQ of 0.05 mg/kg are not expected in rapeseed and linseed, and considering the updated dietary exposure calculation (see Section 3), according to the applicable guidance documents there is no need to investigate the effect of industrial and/or household processing on the nature of the residues for the crops under consideration. However, considering the high toxicity of the active substance and the fact that other crops are significantly contributing to the overall dietary intake, studies investigating the nature of the residues studies in processed products are still required as highlighted in the previous MRL review (EFSA, 2014a), especially for major contributors to the chronic exposure, or major contributors to the livestock dietary burden.

1.1.4. **Methods of analysis in plants**

Analytical methods for enforcement are available to control the residues of haloxyfop, its esters, salts and conjugates in linseeds and rapeseeds at the LOQ of 0.05 mg/kg. Based on the available data, the EMS concluded that it can reasonably be assumed that the method is sufficiently validated in accordance with the enforcement residue definition (Denmark, 2017a,b).

It should be also highlighted that a fully validated analytical method, including a validation of the hydrolysis step, and its independent laboratory validation (ILV) was requested as confirmatory data in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014a). This information should have been provided by 19 November 2017.

\textsuperscript{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.

\textsuperscript{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.
Under a previous application the EMS submitted information on ILV method based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) for determination of haloxyfop-P and its conjugates at the LOQ of 0.01 mg/kg in linseed (flax grain). Based on this information, EFSA concluded that there are analytical methods available for the determination of haloxyfop-P residues in plant commodities (in accordance with the enforcement residue definition) (EFSA, 2016b).

1.1.5. Stability of residues in plants

The storage stability of haloxyfop and its esters, salts and conjugates in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2009). The storage stability data are acceptable. Accordingly, in linseed and rapeseed (high oil content matrices) residues are stable for a period of 17 months at –20°C.

1.1.6. Proposed residue definitions

Based on the metabolism studies, the residue definitions were proposed as ‘sum of haloxyfop, its esters, salts and conjugates expressed as haloxyfop (sum of the R- and S-isomers at any ratio)’ for both enforcement and risk assessment in the conclusion of the peer review and during the Article 12 MRL review (EFSA, 2009, 2014a).

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

EFSA concludes that based on the available information for the uses assessed in this application, the proposed residue definitions are still applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Overall more than 20 trials on rapeseeds were submitted in support of this application; however, only seven residue trials were considered independent. Three independent trials from France, two from Germany and two conducted in Australia were performed during the growing seasons 1986, 1988 and 1989. Despite only two trials were carried out in the country of origin, in view of the explanation provided by the applicant, EFSA considered the European trials acceptable, i.e. comparable with the Australian practices and climatic conditions.

Three residue trials were compliant with the GAP and the remaining four trials were overdosed. In the trials, residues were below the LOQ of 0.05 mg/kg, except in an overdosed trial, in which following downscaling calculated residues were also below 0.05 mg/kg. In the additional nine trials conducted in France deemed non-independent, residues were also below the LOQ of 0.05 mg/kg. The number of residue trials on rapeseeds is not fully compliant with the data requirements for a major crop worldwide and one additional GAP-compliant residue trial on rapeseeds is in principle required. However, considering that the residue levels in all the trials were below the LOQ of 0.05 mg/kg and that additional non-independent trials support the same conclusion, the number of residue trials on rapeseeds with an extrapolation to linseeds is considered as sufficient.

According to the assessment of the EMSs, the analytical methods used were sufficiently validated and fit for purpose and samples were taken and stored in compliance with the demonstrated storage conditions (Denmark, 2017a,b).

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Appendix B.1.2.1.

EFSA concludes that the submitted residue trials are sufficient to derive MRL proposals for the crops under assessment.

1.2.2. Magnitude of residues in rotational crops

As the MRL application refers to uses of haloxyfop-P are on imported crops, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

The magnitude of haloxyfop-P residues during processing was assessed in the framework of the peer review in several crops including rapeseeds (EFSA, 2009). Three residue trials investigating the
effect of processing on the magnitude of residues in rapeseed meal, crude oil and refined oil were assessed and processing factors were derived (see Annex B.1.2.3). Considering that the nature of residues under the standard processing conditions was not investigated, these processing factors are not recommended to be included in Annex VI of Regulation (EC) No 396/2005.

1.2.4. Proposed MRLs

The data were sufficient to derive a MRL proposal of 0.05* mg/kg for both rapeseeds and linseeds based on the Australian GAP. It is noted that the MRL in the country of origin for a comparable residue definition is higher (0.1 mg/kg) compared to the proposed MRL derived by EFSA.

In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

As rapeseeds and linseeds are used as feed products, a potential carry-over into food of animal origin was assessed. The median and maximum dietary burden for livestock was calculated under the Article 12 MRL review using the previously agreed European methodology (European Commission, 1996) considering livestock intake of all feed products containing residues resulting from all authorised uses of haloxyfop-P in Europe (EFSA, 2014a).

EFSA recalculated the livestock dietary burden according to OECD guidance (OECD, 2013) considering also the previous Article 10 MRL assessment on soybeans (EFSA, 2016a) and the supervised trials median residue (STMR) levels derived for linseeds and rapeseeds in the framework of this application, as well as the processing factors derived for rapeseed meal and sugar beet by-products derived in the framework of the peer review (Denmark, 2004) (see Appendix D.1). The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant species/animal species. However, the contribution of haloxyfop-P residues in the crops under consideration in this MRL application to the total livestock exposure was insignificant; the estimated animal intakes remained the same irrespective whether linseed and rapeseed were included in the calculations or not. Therefore, there is currently no need to reconsider the livestock exposure assessment as regards to linseeds and rapeseeds.

It is noted that the different dietary burden derived in the current calculation compared with the calculation performed in the framework of the MRL review was mainly related to the use of the new methodology (OECD, 2013). Consequently, the estimated animal intake is lower compared to the estimation carried out applying the previously agreed European methodology. The STMR values established in the Article 12 MRL review for animal products were used in the consumer risk assessment. Modification of the existing MRLs or risk assessment reference values for commodities of animal origin is not considered necessary based on the present assessment, as further considerations related to the dietary burden calculation as assessed under the MRL review is needed, which is not in the scope of the present assessment (see conclusions and recommendations below).

3. Consumer risk assessment

The toxicological profile of haloxyfop-P 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 0.00065 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.075 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (EFSA, 2007). The complete list of input values is presented in Appendix D.2.

The long-term exposure assessment was performed taking into account the STMR values derived for the commodities assessed in this application and for the remaining commodities taking into account the STMR values derived in the Art. 12 MRL review and the previous reasoned opinions (EFSA, 2014a, b, 2016a,b). The risk assessment was performed under the assumption that the risk assessment values derived in the framework of the MRL review are confirmed by the confirmatory data identified as missing (EFSA, 2014a). The risk assessment calculation did not take into account the fact that the use of haloxyfop-P was restricted to a maximum application rate of 52 g/ha every third year. Thus, the STMR values derived for carrots, onions, spring onions, beans (dry), peas (dry), sunflower seeds, sugar beets, parsley roots and leek are based on residue trials that reflect GAPs that are not in line with the restrictions in the application rates. Thus, the calculation of the chronic exposure is expected to overestimate the actual exposure for the revised GAPs.
The estimated long-term dietary intake accounted for up to 90.2% of the ADI for UK infant. Rapeseeds and linseeds contributed up to 4.6% and 1.1% of the ADI, respectively. EFSA concludes that the long-term intake of residues of haloxyfop-P resulting from the existing and the intended use on rapeseeds and linseeds is unlikely to present a risk to consumer health.

The short-term exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the median residue level as observed in supervised field trials (Appendix B.1.2.1).

The short-term exposure did not exceed the ARfD for either of the crops assessed in this application (see Appendix C). The highest international estimated short-term intake (IESTI) was up to 0.1% of the ARfD for rapeseeds and linseeds, respectively.

Based on these calculations, EFSA concludes that the Australian authorised use of haloxyfop-P on the crops assessed is unlikely to pose a risk for the consumers. However, the above assessment does not consider the possible impact of plant and animal metabolism on the isomer ratio of the active substance and further investigation on this matter would in principle be required. Since guidance is not yet available on the consideration of isomer ratios in the consumer risk assessment, EFSA recommends that this issue is reconsidered when such guidance is available.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for rapeseeds and linseeds. The current EU MRLs for rapeseed set in Regulation (EC) No 396/2005 is 0.2 mg/kg while for linseed the LOQ of 0.01 mg/kg is the applicable MRL.

Considering that for rapeseed certain data were identified as unavailable in the MRL review (EFSA, 2014a),8 the existing MRL will be reviewed in due time, taking into account the information submitted within the deadline, i.e. 19 November 2017. In case risk managers will decide to lower the existing MRL if the requested information was not submitted within the defined deadline, the setting of an import tolerance at the level of 0.05 mg/kg would be an alternative risk management option. If the existing EU MRL for rapeseed will be supported by the required information and the existing level of the EU MRL of 0.2 mg/kg is confirmed, the Australian use on rapeseed would be covered by the EU MRL.

Furthermore, EFSA recommends to revise the existing MRLs in the light of the restrictions of the approval implemented in 2015 and the availability of confirmatory data that had to be submitted by 19 November 2017 as defined in the MRL review (EFSA, 2014a).

Overall, EFSA concluded that the Australian authorised use of haloxyfop-P on rapeseeds and linseeds 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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8 Information was requested on analytical methods, nature of residues in processed commodities, residue trials, storage conditions used in the residue trials, analytical methods used in the residue trials, analytical methods used in the storage stability studies.
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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
- CF conversion factor for enforcement to risk assessment residue definition
- DAR draft assessment report
- DAT days after treatment
- DM dry matter
- EC emulsifiable concentrate
- EMS evaluating Member State

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Setting of import tolerances for haloxyp-P in linseed and rapeseed

FAO: Food and Agriculture Organization of the United Nations
GAP: Good Agricultural Practice
GC-ECD: gas chromatography with electron capture detector
GS: growth stage
HR: highest residue
IEDI: international estimated daily intake
IESTI: international estimated short-term intake
ILV: independent laboratory validation
InChIKey: International Chemical Identifier Key.
ISO: International Organisation for Standardisation
IUPAC: International Union of Pure and Applied Chemistry
LC: liquid chromatography
LOQ: limit of quantification
Mo: monitoring
MRL: maximum residue level
MS: Member States
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: preharvest interval
PRIMo: (EFSA) Pesticide Residues Intake Model
RA: risk assessment
RAC: raw agricultural commodity
RD: residue definition
RMS: rapporteur Member State
SANCO: Directorate-General for Health and Consumers
SEU: southern Europe
STMR: supervised trials median residue
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, G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-------------|------------------------------------|-------------|-------------|--------------------------------|--------------|---------|
| Canola (oilseed rape) and Linseed | Australia | F | Grass weeds (including annual ryegrass, barley grass, brome grass, volunteer cereals, wild oats) | EC 520 g/L | Broadcast ground or aerial spraying | Apply between 2 leaf and 8 leaf stage of crop growth. Do not apply after the 8-leaf stage of the crop, or after commencement of stem elongation, whichever comes soonest | 1 Not applicable | Ground: 50–150 Aerial: minimum 30 (recommended, not mandatory) | 19.5–52 g a.s./ha min–max | Harvest: not required when used as directed Grazing: 28 days | Product to be applied in a tank mix with a non-ionic wetter or a paraffinic oil/non-ionic surfactant adjuvant. Rates vary within the specified range depending on the target weed and the particular spray adjuvant used |

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; EC: emulsifiable 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

#### 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 | Sampling (DAT) | Comment/source |
|-----------------------------------|-------------|---------|-------------|----------------|---------------|
| Root crops                        | Sugar beet  | Foliar: | 113 g as/ha | 0, 28, 61      | 14C-pyridyl haloxyfop-P (methyl ester) (EFSA, 2009) |
| Leafy crops                       | Lettuce     | Foliar: | 1 × 106 g as/ha | 0, 14, 29 | 14C-pyridyl haloxyfop-P (methyl ester) (EFSA, 2009) |
| Pulses/ oilseeds                  | Soya bean   | Direct leaf application: 0.2 mg/leaf | 2, 4, 8 | 14C-pyridyl and/or 14C-phenyl haloxyfop-P (methyl ester) (EFSA, 2009) 14C-phenyl haloxyfop (n-butyl ester) (EFSA, 2009) 14C-phenyl haloxyfop (ethoxyethanol ester) (EFSA, 2009) |
|                                   |             | Foliar, 1 × 560 g/ha | Forage: 15 Beans, straw: 61-89 | 14C-pyridyl haloxyfop (butyl ester) (EFSA, 2009) |
| Cotton seed                       |             | Foliar, 1 × 560 g/ha | 78, 105 | 14C-pyridyl haloxyfop (butyl ester) (EFSA, 2009) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application | PBI (DAT) | Comment/source |
|--------------------------------------|-------------|---------|-------------|-----------|---------------|
| Root/tuber crops                     | Turnips, carrots | Bare soil, 560 g a.s./ha | 30 | 14C-phenyl haloxyfop (butyl ester) (EFSA, 2009) |
| Leafy crops                          | Lettuce     | Bare soil, 560 g a.s./ha | 30 | 14C-phenyl haloxyfop (butyl ester) (EFSA, 2009) |
| Cereal (small grain)                 | Wheat       | Bare soil, 560 g a.s./ha | 30 | 14C-phenyl haloxyfop (butyl ester) (EFSA, 2009) |
| Pulses and oilseeds                  | Soya bean   | Bare soil, 560 g a.s./ha | 30 | 14C-phenyl haloxyfop (butyl ester) (EFSA, 2009) |

#### Processed commodities (hydrolysis study)

| Conditions                             | Stable?       | Comment/source                                                                 |
|----------------------------------------|---------------|-------------------------------------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4)    | Not triggered | Not triggered as residues in linseeds or rapeseeds are < 0.05 mg/kg (LOQ) when haloxyfop-P is used according to the Australian authorised use |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered | |
| Sterilisation (20 min, 120°C, pH 6)    | Not triggered | |

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### Setting of import tolerances for haloxyfop-P in linseed and rapeseed

**B.1.1.2. Stability of residues in plants**

| Plant products (available studies) | Category     | Commodity                  | T (°C) | Stability period Value | Unit | Compounds covered                                             | Comment/source |
|-----------------------------------|--------------|----------------------------|--------|------------------------|------|--------------------------------------------------------------|----------------|
| High water content                | Cabbage, peas| –16                        | 16     | Months                 |      | Haloxyfop, its esters, salts and conjugates                   | EFSA (2009)    |
| High oil content                  | Soya beans, cotton seeds | –20            | 17     | Months                 |      | Haloxyfop, its esters, salts and conjugates                   |                |
| Dry/High starch                   | Rice         | –20                        | 7      | Months                 |      |                                                              |                |

DAT: days after treatment; PBI: plant-back interval; LOQ: limit of quantification; GC-ECD: gas chromatography with electron capture detector; ILV: independent laboratory validation.
### 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) |
|-----------------|--------------------------|----------------------------------------------------------------|-----------------|------------------------|-----------------------|-----------------------|
| Canola (oilseed rape) | Non-EU          | **Mo = RA:** 6\(\times\) < 0.05; 0.07\(^{(1)}\)  
Scaled residue values: 7\(\times\) < 0.05 | Residue trials on rapeseeds overdosed or compliant with GAP.  
In one overdosed trial, downscaling was applied (Scaling factor: 0.5). Reduced number of trials is sufficient since residues are expected to be below the LOQ. | 0.05* | 0.05 | 0.05 |
| Linseed         | Non-EU          | **Mo = RA:** 7\(\times\) < 0.05 | Possible extrapolation from rapeseeds to linseeds according to the SANCO Guideline 7525/VI/95-rev. 10.3 | 0.05* | 0.05 | 0.05 |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: Monitoring; RA: risk assessment; LOQ: limit of quantification.

*\(^{+}\): 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 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.

\(^{(e)}\): Supervised trials median residue according to the residue definition for monitoring.

\(^{(1)}\): Overdosed residue trial (2N).
B.1.2.2. Residues in rotational crops

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | Comment/source |
|---------------------|---------------------------|------------------------|----------------|
|                     |                           | Individual values      | Median PF      | source |                   |
| Rapeseeds, meal     | 3                         | 0.9, 0.9, 0.9          | 0.9            | EFSA   | (2009)            |
| Rapeseeds, crude oil| 3                         | 1.4, 2.0, 1.8          | 1.8            | EFSA   | (2009)            |
| Rapeseeds, refined oil | 3                     | 1.1, 2.2, 1.9          | 1.9            | EFSA   | (2009)            |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | Comment/source |
|---------------------|---------------------------|------------------------|----------------|
|                     |                           | Individual values      | Median PF      | source |                   |
| Rapeseeds, meal     | 3                         | 0.9, 0.9, 0.9          | 0.9            | EFSA   | (2009)            |
| Rapeseeds, crude oil| 3                         | 1.4, 2.0, 1.8          | 1.8            | EFSA   | (2009)            |
| Rapeseeds, refined oil | 3                     | 1.1, 2.2, 1.9          | 1.9            | EFSA   | (2009)            |

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|-----------------------------|-----------------------------|---------------------------|---------------------------|------------------------|
|                             | mg/kg bw per day | mg/kg DM |                         |                          |                        |
|                             | Median | Maximum | Median | Maximum |                          |                          |                        |
| Cattle (all diets)          | 0.010  | 0.013   | 0.26   | 0.36    | Cattle (dairy)            | Beet, sugar, molasses   | Yes                     |
| Cattle (dairy only)         | 0.010  | 0.013   | 0.26   | 0.33    | Cattle (dairy)            | Beet, sugar, molasses   | Yes                     |
| Sheep (all diets)           | 0.012  | 0.015   | 0.28   | 0.36    | Sheep (lamb)              | Beet, sugar, tops       | Yes                     |
| Sheep (ewe only)            | 0.009  | 0.012   | 0.28   | 0.36    | Sheep (ram/ewe)           | Beet, sugar, tops       | Yes                     |
| Swine (all diets)           | 0.004  | 0.006   | 0.16   | 0.28    | Swine (breeding)          | Beet, mangel, fodder    | Yes                     |
| Poultry (all diets)         | 0.004  | 0.006   | 0.05   | 0.09    | Poultry (layer)           | Beet, sugar, tops       | No                      |
| Poultry (layer only)        | 0.004  | 0.006   | 0.05   | 0.09    | Poultry (layer)           | Beet, sugar, tops       | No                      |

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 expressed as ‘mg/kg bw per day’.

The contribution of haloxyfop-P residues in the crops under consideration in this MRL application to the total livestock exposure was insignificant; the estimated animal intakes remained the same irrespective whether linseed and rapeseed were included in the calculations or not. Therefore, there is no need to reconsider the livestock exposure assessment in regards to linseeds and rapeseeds.
### B.3. Consumer risk assessment

| ARFD | 0.075 mg/kg bw (EFSA, 2009) |
|------|---------------------------|
| Highest IESTI, according to EFSA PRIMO | Rapeseeds: 0.1% of ARFD Linseeds: 0.1% of ARFD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities |

| ADI | 0.00065 mg/kg bw per day (EFSA, 2009) |
|------|--------------------------------------|
| Highest IEDI, according to EFSA PRIMO | 90.2% ADI (UK infant) Contribution of crops assessed: rapeseed: 4.6% of ADI linseed: 1.1% of ADI |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities, except for sugar beet where the refined input value for white sugar was applied The contributions of commodities where no GAP was reported in the framework of the Art. 12 MRL review were not included in the calculation |

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; GAP: Good Agricultural Practice; MRL: maximum residue level.

### B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|------------|------------------------|-------------------------|-----------------------|
| 401010  | Linseeds   | 0.01*                  | 0.05*                   | The submitted data are sufficient to derive an import tolerance (Australia GAP). Risk for consumers unlikely. It is noted that the MRL in the country of origin is 0.1 mg/kg |
| 401060  | Rapeseeds/canola seeds | 0.2(ft)       | 0.05* Further risk management considerations required | The submitted data are sufficient to derive an import tolerance (Australia GAP). Risk for consumers unlikely. It is noted that the MRL in the country of origin is 0.1 mg/kg The assessment of data that were identified as missing during the MRL review under Regulation (EC) No 396/2005 has not yet been performed. Thus, further risk management considerations are required before a decision on the lowering of the existing MRL is taken |

MRL: maximum residue level; GAP: Good Agricultural Practice.

*: 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.
(ft): The European Food Safety Authority identified some information on analytical methods, nature of residues in processed commodities, residue trials, storage conditions used in the residue trials, analytical methods used in the residue trials, analytical methods used in the storage stability studies and the northern Good Agricultural Practice as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or, if that information is not submitted by that date, the lack of it.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Haloxyfop-P

**Status of the active substance:**
- Code no.
- LOQ (mg/kg bw):
- Toxicological endpoints
- ADI (mg/kg bw per day):
- Proposed ADI:
- ARfD (mg/kg bw):
- Proposed ARfD:
- Year of evaluation:

| Source of ADI | EFSA |
|---------------|------|
| Source of ARfD | EFSA |

#### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI |
|-------------------------------|-------------------------|
| Minimum – maximum              |                         |

| Commodity/group of commodities | Highest contributor to MS diet | 2nd contributor to MS diet | 3rd contributor to MS diet |
|-------------------------------|--------------------------------|---------------------------|---------------------------|
|                               | (in % of ADI)                  | (in % of ADI)              | (in % of ADI)              |
| Milk and cream                |                                |                           |                           |
| Sugar beet (root)             | 1.5                            | 3.1                       | Carrots                   |
| Bovine: Meat                 | 2.1                            |                           |                           |
| Bears                        | 2.4                            |                           |                           |
| Milk and cream                | 1.5                            | 2.0                       | Pork: Meat                |
| Milk and cream                | 2.0                            |                           |                           |
| Milk and cream                | 1.5                            | 2.0                       | Carrots                   |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI) based on pTMRLs were below the ADI. A long-term intake of residues of haloxyfop-P is unlikely to present a public health concern.
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.

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.

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

### Acute risk assessment/children – refined calculations

| Commodity     | IESTI 1 | IESTI 2 | No of critical MRLs (IESTI 1) | No of critical MRLs (IESTI 2) |
|---------------|---------|---------|------------------------------|------------------------------|
| Rapeseed      | 0.1     | 0.1     | 0.05/-                       | 0.05/-                       |
| Linseed       | 0.1     | 0.1     | 0.05/-                       | 0.05/-                       |

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

| Commodity     | IESTI 1 | IESTI 2 | No of critical MRLs (IESTI 1) | No of critical MRLs (IESTI 2) |
|---------------|---------|---------|------------------------------|------------------------------|
| Carrot, juice | 2.9     | 2.9     | 0.05/-                       | 0.05/-                       |

### Conclusion:

For haloxyfop-P, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity. No exceedance of the ARfD/ADI was identified for any processed commodity.
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 |
| Carrot, culls                   | 0.02                  | STMR     | 0.05                | HR      |
| Bean, seed (dry)                | 0.02                  | STMR     | 0.02                | STMR    |
| Cowpea, seed                    | 0.02                  | STMR     | 0.02                | STMR    |
| Pea (Field pea), seed (dry)     | 0.02                  | STMR     | 0.02                | STMR    |
| Flaxseed/Linseed, meal          | 0.05                  | STMR     | 0.05                | STMR    |
| Sunflower, meal<sup>(a)</sup>   | 0.07                  | STMR × PF (0.9)       | 0.07                | STMR × PF (0.9) |
| Canola (Rape seed), meal        | 0.05                  | STMR     | 0.05                | STMR    |
| Soybean, seed                   | 0.04                  | STMR     | 0.04                | STMR    |
| Soybean, meal<sup>(b)</sup>     | 0.05                  | STMR × default PF (1.3) | 0.05 | STMR × default PF (1.3) |
| Soybean, hulls<sup>(c)</sup>    | 0.03                  | STMR × PF (0.7)       | 0.03                | STMR × PF (0.7) |
| Beet, sugar, dried pulp<sup>(d)</sup> | 0.81            | STMR × PF (8)         | 0.81                | STMR × PF (8) |
| Beet, sugar, ensiled pulp<sup>(d)</sup> | 0.14            | STMR × PF (0.4)       | 0.14                | STMR × PF (0.4) |
| Beet, sugar, molasses<sup>(d)</sup> | 1.26            | STMR × PF (18)        | 1.26                | STMR × PF (18) |
| Beet, mangel, roots             | 0.05                  | STMR     | 0.09                | HR      |
| Beet, mangel, tops              | 0.10                  | STMR     | 0.12                | HR      |
| Beet, sugar, tops               | 0.10                  | STMR     | 0.12                | HR      |

Risk assessment residue definition: sum of haloxyfop, its esters, salts and conjugates expressed as haloxyfop (sum of the R- and S-isomers at any ratio)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): For by products, where processing factors supported by data were tentatively derived in the framework of the MRL review (EFSA, 2014a), these processing factors as indicated in the table were included in the calculation.

(b): For by products, in the absence of processing factors supported by data, default processing factors as indicated in the table were included in the calculation to consider the potential concentration of residues in these commodities.

(c): For soybean hulls, the processing factors derived in an import tolerance application (EFSA, 2016a,b), as indicated in the table, were included in the calculation.

(d): For sugar beet by-products, processing factors derived in the DAR were used (Denmark, 2004).

### D.2. Consumer risk assessment

| Commodity                      | Chronic risk assessment | Acute risk assessment |
|--------------------------------|-------------------------|-----------------------|
|                                | Input value (mg/kg)     | Comment | Input value (mg/kg) | Comment |
| Linseeds                       | 0.05                    | STMR     | 0.05                | STMR    |
| Rapeseeds/canola seeds         | 0.05                    | STMR     | 0.05                | STMR    |
| Carrots                        | 0.02                    | STMR (EFSA, 2014a)   |                  |         |
| Parsley roots/Hamburg roots parsley | 0.02               | STMR (EFSA, 2016b)   |                  |         |
| Onions                         | 0.04                    | STMR (EFSA, 2014a)   |                  |         |
| Leeks                          | 0.01                    | STMR (EFSA, 2016b)   |                  |         |
| Beans (dry)                    | 0.02                    | STMR (EFSA, 2014a)   |                  |         |
| Peas (dry)                     | 0.02                    | STMR (EFSA, 2014a)   |                  |         |
| Sunflower seeds                | 0.08                    | STMR (EFSA, 2014a)   |                  |         |
| Soya beans                     | 0.04                    | STMR (EFSA, 2016a)   |                  |         |
| Sugar beet roots               | 0.01                    | Refined input value: residues in white sugar. (EFSA, 2014a) | | |
| Commodity       | Input value (mg/kg) | Chronic risk assessment | Acute risk assessment |
|-----------------|---------------------|-------------------------|-----------------------|
| Pig meat<sup>(a)</sup> | 0.01                | 0.8 × median muscle + 0.2 × median fat (EFSA, 2014a) |                       |
| Pig fat         | 0.01                | STMR (EFSA, 2014a)      |                       |
| Pig liver       | 0.02                | STMR (EFSA, 2014a)      |                       |
| Pig kidney      | 0.04                | STMR (EFSA, 2014a)      |                       |
| Ruminant meat<sup>(a)</sup> | 0.01*             | 0.8 × median muscle + 0.2 × median fat (EFSA, 2014a) |                       |
| Ruminant fat    | 0.01*               | STMR (EFSA, 2014a)      |                       |
| Ruminant liver  | 0.018               | STMR (EFSA, 2014a)      |                       |
| Ruminant kidney | 0.044               | STMR (EFSA, 2014a)      |                       |
| Poultry meat<sup>(a)</sup> | 0.01*            | 0.8 × median muscle + 0.2 × median fat (EFSA, 2014a) |                       |
| Poultry fat     | 0.010               | STMR (EFSA, 2014a)      |                       |
| Poultry liver   | 0.016               | STMR (EFSA, 2014a)      |                       |
| Ruminant milk   | 0.011               | STMR (EFSA, 2014a)      |                       |
| Eggs            | 0.01*               | STMR (EFSA, 2014a)      |                       |

STMR: supervised trials median residue.

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

<sup>(a)</sup>: Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticides, STMR 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 | IUPAC name/SMILES notation/InChiKey | Structural formula |
|-------------------|------------------------------------|--------------------|
| Haloxyfop-P       | (R)-2-((4-[3-chloro-5-(trifluoromethyl)-2-pyridyloxy]phenoxy)propionic acid\nO=C(O)[C@@H](C)Oc1ccc(cc1)Oc2ncc\n(cc2C)(C(F)(F))F\nGOCUAJOYBLQRH-MRVPVSSYSA-N | ![Structural formula of Haloxyfop-P](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChIKey: International Chemical Identifier Key.