Review of the existing maximum residue levels for flurochloridone according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance flurochloridone. To assess the occurrence of flurochloridone residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EC) No 33/2008 as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

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Summary

Flurochloridone was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/34/EU and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As flurochloridone was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Spain, the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 20 June 2017 and finalised on 7 September 2017. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 13 October 2017.

Based on the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008 and the additional information provided by the RMS and Member States, EFSA prepared in November 2017 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 6 December 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are reached.

Metabolism in plants was investigated in sunflower (oilseeds/pulses group) and potato (root crop group) using a single spray application of 14C-labelled flurochloridone on the pyrrolidone moiety only applied onto the soil surface, just after sowing/planting. Since cleavage was not observed in environmental fate soil studies which used a second label and were assessed during the peer review, additional studies with labelling of the phenyl moiety are not needed. Identification of metabolites was not possible in sunflower seeds and potato tuber because of the low total radioactive residues (TRRs). The characterisation of residues was only possible in mature sunflower leaves, where flurochloridone accounted for 10–17% TRR (0.15–0.44 mg/kg) and three additional metabolites were identified each representing less than 3% TRR (0.01–0.06 mg/kg).

According to the soil degradation studies evaluated in the framework of the peer review, periods required for 90% dissipation (DT90) values in soil exceeded the trigger value of 100 days and further investigation of residues in rotational crops was required. A confined rotational crop study considered acceptable during the peer review was conducted with 14C-carbonyl-labelled flurochloridone, sprayed uniformly to bare soil (clay loam) at 750 g a.s./ha (corresponding to 1N rate). Following aging of the soil for 33, 131 and 355 days, metabolism was studied in three representative rotational crops (spinach leaf, carrot and wheat).

In mature crops taken at all plant back intervals (PBI), TRRs were very low (max. 0.009 mg eq/kg observed in spinach leaves at a PBI of 33 days), except in wheat straw and chaff (up to 0.049 mg eq/kg). Due to the low TRR, further metabolite identification was not performed. Residues in rotational crops (cereal grain, leafy vegetables and root crops) are expected to remain below the limit of quantification (LOQ) of 0.01 mg/kg, provided that flurochloridone is applied according to the Good Agricultural Practices (GAPs) considered in this review. Further information is still considered desirable for wheat straw and chaff in the present review, to verify whether flurochloridone is to be expected in straw from cereals grown in rotation.

Studies investigating the effect of processing on the nature of the residues are not available. However, as residues of flurochloridone exceeding 0.1 mg/kg are not expected in the treated crops and chronic exposure does not exceed 10% of the acceptable daily intake (ADI), there is no need to investigate the effect of industrial and/or household processing.

Flurochloridone was stable in high water, high oil and dry commodities (alfalfa, almonds, apples, corn, peppers, potatoes, soybeans, wheat grain) when kept stored in the dark at −20°C for a minimum of three years, while in high acid commodities (oranges) for 12 and in wheat straw for 8 months.

Based on the results of the metabolism in primary and rotational crops, the residue definition is defined as flurochloridone (sum of cis and trans isomers) by default for both enforcement and risk assessment. This residue definition is limited to root and tuber corps, pulses and oilseeds following soil treatment. A metabolism study covering the use on cereals is not available and is still required.
Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water, high acid, high oil content and dry commodities with a LOQ of 0.01 mg/kg, respectively.

The available data are considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for maize and wheat where the available data were insufficient to derive MRLs.

A metabolism study in lactating goats was provided during this review where two lactating goats (one for each dose) were dosed twice daily for 7 days with orally administered 14C-phenyl-labelled fluorochloridone at dose levels of 0.002 and 0.49 mg/kg body weight (bw)/day (0.44 N and 109 N compared to the maximum dietary burden calculated for sheep, respectively). Based on the available information, it can be concluded that, at the calculated dietary burden, no significant residues are expected in ruminants and swine tissues and in milk.

The residue definition in animal commodities can be defined as fluorochloridone (cis and trans isomers) by default for both enforcement and risk assessment. A method for enforcement of the proposed residue definition in ruminants and swine tissues and in milk (goat and sheep) is not available. Therefore, the current LOQ of 0.05 mg/kg as reported in the European Union (EU) legislation and considered in this review, should be confirmed by the submission of a fully validated analytical method for enforcement. MRLs for cattle milk, poultry tissues and eggs are not required.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake model (PRIMO). For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 6.0% of the ADI (FR, toddler) and the highest acute exposure amounted to 8.6% of the acute reference dose (ARfD) (carrots).
Table of contents

Abstract .................................................................................................................................................. 1
Summary ................................................................................................................................................ 3
Background .......................................................................................................................................... 6
Terms of Reference ................................................................................................................................. 7
The active substance and its use pattern ............................................................................................... 7
Assessment ............................................................................................................................................ 8
1. Residues in plants .......................................................................................................................... 8
   1.1. Nature of residues and methods of analysis in plants............................................................... 8
       1.1.1. Nature of residues in primary crops .................................................................................... 8
       1.1.2. Nature of residues in rotational crops ................................................................................ 8
       1.1.3. Nature of residues in processed commodities ................................................................. 9
       1.1.4. Methods of analysis in plants ............................................................................................ 9
       1.1.5. Stability of residues in plants ............................................................................................. 9
       1.1.6. Proposed residue definitions ............................................................................................. 9
   1.2. Magnitude of residues in plants ............................................................................................... 9
       1.2.1. Magnitude of residues in primary crops ............................................................................. 9
       1.2.2. Magnitude of residues in rotational crops ......................................................................... 10
       1.2.3. Magnitude of residues in processed commodities .......................................................... 10
       1.2.4. Proposed MRLs .................................................................................................................. 10
2. Residues in livestock ...................................................................................................................... 11
3. Consumer risk assessment ............................................................................................................. 11
Conclusions .......................................................................................................................................... 12
Recommendations ............................................................................................................................... 13
References .......................................................................................................................................... 14
Abbreviations .................................................................................................................................... 15
Appendix A – Summary of authorised uses considered for the review of MRLs .................................. 17
Appendix B – List of end points .......................................................................................................... 19
Appendix C – Pesticide Residue Intake Model (PRIMo) .................................................................... 26
Appendix D – Input values for the exposure calculations ................................................................. 28
Appendix E – Decision tree for deriving MRL recommendations .................................................... 30
Appendix F – Used compound codes ............................................................................................... 32
Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC\(^2\) a reasoned opinion on the review of the existing MRLs for that active substance. As flurochloridone was included in Annex I to Council Directive 91/414/EEC on 1 June 2011 by means of Commission Directive 2011/34/EU\(^3\), and has been deemed to be approved under Regulation (EC) No 1107/2009\(^4\), in accordance with Commission Implementing Regulation (EU) No 540/2011\(^5\), as amended by Commission Implementing Regulation (EU) No 541/2011\(^6\), EFSA initiated the review of all existing MRLs for that active substance.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that, in the framework of Directive 91/414/EEC, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is, therefore, insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

Spain, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC and Commission Regulation (EC) No 33/2008\(^7\) was asked to complete the PROFile for flurochloridone and to prepare a supporting evaluation report. The PROFile was submitted to EFSA on 16 April 2013 while the supporting evaluation report was made available to EFSA on 23 January 2017 and subsequently to the Member States (Spain, 2017a). A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 20 June 2017 and finalised on 7 September 2017. Additional evaluation reports were submitted by France, the Czech Republic, Greece, Hungary, Spain and the EU Reference Laboratories (EURLs) for Pesticide Residues (Czech Republic, 2017; EURL, 2017; France, 2017; Greece, 2017; Hungary, 2017; Spain, 2017b) and, after having considered all the information provided by the RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 13 October 2017. No further clarifications were sought from Member States.

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

\(^{2}\) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

\(^{3}\) Commission Directive 2011/34/EU of 8 March 2011 amending Council Directive 91/414/EEC to include flurochloridone as active substance and amending Commission Decision 2008/934/EC. OJ No L 62, 9.3.2011, p. 27–30.

\(^{4}\) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

\(^{5}\) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

\(^{6}\) Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

\(^{7}\) Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.
Based on the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008 and the additional information provided by the Member States, EFSA prepared in November 2017 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 6 December 2017 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Spain, 2017a) and the evaluation reports submitted by the Member States France, the Czech Republic, Greece, Hungary, Spain and the EURs (Czech Republic, 2017; EURL, 2017; France, 2017; Greece, 2017; Hungary, 2017; Spain, 2017b) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2017a) and the Member States consultation report (EFSA, 2017b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

Flurochloridone is the ISO common name for the mixture of the enantiomeric pairs (3RS,4RS;3RS,4SR)-3-chloro-4-chloromethyl-1-(α, α, α-trifluoro-m-tolyl)-2-pyrrolidone (IUPAC) in the ratio 3:1 of the isomers (3RS,4RS)(trans) and (3RS,4SR)(cis).

However, the isomer ratio of the substance evaluated in the framework of Directive 91/414/EEC and Commission Regulation (EC) No 33/2008 was not exactly 3:1 (the average ratio of trans- to cis-isomer was 3.17:1). Therefore, the company code ‘FLC’ was used during the peer review to identify the substance under consideration. However, in this reasoned opinion, the name flurochloridone is used to identify the active substance.

Flurochloridone is a herbicide that inhibits carotenoid synthesis. It is used in pre-emergence applications. The compound is taken up by the roots of the plant and is quickly translocated from roots to the foliar tissues in susceptible plants. The herbicidal activity takes place in the chloroplasts, where flurochloridone blocks the synthesis of β-carotene, which is responsible for protection of chlorophyll against photo-oxidation by sunlight. Since carotenoids serve as protecting pigments which prevent chlorophyll photodestruction, affected plants are bleached and become necrotic leading to full destruction.

The chemical structure of the active substance and its main metabolites are reported in Appendix F. Flurochloridone was evaluated in the framework of Commission Regulation (EC) No 33/2008 with Spain designated as RMS. The representative uses evaluated under the peer review process was as a pre-emergence herbicide comprising outdoor foliar spray applications against broad leafed and grass weeds in sunflower and potato. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2011/34/EU, which entered into force on 1 June 2011. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, flurochloridone is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as herbicide only.

The EU MRLs for flurochloridone are established in Annex IIIA of Regulation (EC) No 396/2005 and codex maximum residue limits (CXL(s)) for flurochloridone are not available. There are no MRL changes occurred since the entry into force of the Regulation mentioned above.
For the purpose of this MRL review, the critical uses of flurochloridone currently authorised within the EU have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAP(s) for flurochloridone are given in Appendix A. The RMS did not report any use authorised in Third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Spain, 2017a), the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (Spain, 2006), the Additional Report and its addenda prepared under Commission Regulation (EC) No 33/2008 (Spain, 2009, 2010), the conclusion on the peer review of the pesticide risk assessment of the active substance flurochloridone (EFSA, 2010) as well as the evaluation reports submitted during the completeness check (Czech Republic, 2017; EURL, 2017; France, 2017; Greece, 2017; Hungary, 2017; Spain, 2017b). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011\(^8\) and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

Metabolism in plants was investigated in sunflower (oilseeds/pulses group) and potato (root crop group) using a single spray application of \(^14\)C-labelled flurochloridone on the pyrrolidone moiety only applied onto the soil surface, just after sowing/planting.

Identification of metabolites was not possible in sunflower seeds and potato tuber because of the low total radioactive residues (TRRs). The characterisation of residues was only possible in mature sunflower leaves, where flurochloridone accounted for 10–17% TRR (0.15–0.44 mg/kg) and three additional metabolites were identified each representing less than 3% TRR (0.01–0.06 mg/kg).

It is noted that the study was performed with a label on the pyrrolidone moiety only. However, since no cleavage was observed in environmental fate soil studies which used a second label and were assessed during the peer review, additional studies with labelling of the phenyl moiety are not needed (EFSA, 2010).

1.1.2. Nature of residues in rotational crops

According to the soil degradation studies evaluated in the framework of the peer review, periods required for 90% dissipation (DT\(_{90}\)) in soil range between 75 (silty loam) and 515 (sandy loam) days, which is higher than the trigger value of 100 days (EFSA, 2010). Therefore, further investigation of residues in rotational crops was required.

Rotational crop studies were conducted in wheat and sugar beet following bare soil application, at a rate of 300 g a.s./ha (0.4N rate) and plant back intervals (PBIs) of 30, 120 and 365 days. This study does not cover the critical GAP and was not further assessed.

A new study was considered acceptable and was evaluated during the peer review. It was conducted with \(^14\)C-carbonyl-labelled flurochloridone, sprayed uniformly to bare soil (clay loam) at 750 g a.s./ha (corresponding to 1N rate). Following aging of the soil for 33, 131 and 355 days, metabolism was studied in three representative rotational crops (spinach leaf, carrot and wheat).

In mature crops taken at all PBIs, TRRs were very low (max 0.009 mg eq/kg observed in spinach leaves at PBI of 33 days), except in wheat straw and chaff (up to 0.049 mg eq/kg). Due to the low TRR, further metabolite identification was not performed and is not needed.

\(^8\) 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.
1.1.3. Nature of residues in processed commodities

Studies investigating the effect of processing on the nature of the residues are not available. However, as residues of flurochloridone exceeding 0.1 mg/kg are not expected in the treated crops and chronic exposure does not exceed 10% of the acceptable daily intake (ADI) (see also Sections 1.2.1 and 3), there is no need to investigate the effect of industrial and/or household processing.

1.1.4. Methods of analysis in plants

In the framework of this review, a gas chromatography (GC) method with tandem mass spectrometry (MS/MS) detection (GC–MS/MS) was considered suitable for monitoring flurochloridone in high water and high acid commodities, with a limit of quantification (LOQ) of 0.01 mg/kg. The method was validated in potatoes; however, an independent laboratory validation (ILV) was not available (Spain, 2006). A confirmatory GC-MS method with a LOQ of 0.01 mg/kg in high water and high oil content commodities (potatoes and sunflower seeds) was provided during this review (France, 2017).

A GC-MS method with a LOQ of 0.01 mg/kg flurochloridone, validated in sunflower seeds, supported by an ILV and confirmatory method, is available for monitoring in high oil commodities (Spain, 2006; France, 2017).

According to the information provided by the EURLs during the completeness check, a LOQ of 0.01 mg/kg for flurochloridone (validated in high water, high acid, high oil content and dry commodities) is achievable for routine analyses by using a validated liquid chromatography with tandem mass spectrometry (LC-MS/MS) method (EURL, 2017).

1.1.5. Stability of residues in plants

Storage stability of fortified residues of flurochloridone was investigated in high water (alfalfa, apples, peppers and potatoes), high oil (almonds, soybeans), high acid (oranges) and dry (corn, wheat grain and straw) commodities for an overall period of 3 years (Spain, 2006).

The data obtained indicated that flurochloridone was stable in high water, high oil and dry commodities (alfalfa, almonds, apples, corn, peppers, potatoes, soybeans, wheat grain) when kept stored in the dark at –20°C for a minimum of 3 years, while in high acid commodities (oranges) for 12 and in wheat straw for 8 months.

1.1.6. Proposed residue definitions

Based on the results of the metabolism in primary and rotational crops, the residue definition is defined as flurochloridone (sum of cis and trans isomers) by default for both enforcement and risk assessment. This residue definition is limited to root and tuber crops, pulses and oilseeds following soil treatment. A metabolism study covering the use on cereals is not available and is still required. Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water, high acid, high oil content and dry commodities with a LOQ of 0.01 mg/kg, respectively.

EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of flurochloridone and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of flurochloridone residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Spain, 2017a), including residue trials evaluated in the framework of the peer review (Spain, 2006, 2009, 2010; EFSA, 2010) and additional data submitted during the completeness check (France, 2017; Hungary, 2017; Spain, 2017b). All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions. Decline of residues during storage of the trial samples is therefore not expected.
The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Residue trials are not available to support the authorisations on maize and wheat grain and straw. Therefore, MRL or risk assessment values for these crops could not be derived by EFSA and the following data gaps are identified:

- Maize corn and stover: Eight trials on maize compliant with the northern outdoor GAP are required.
- Wheat grain and straw: Eight trials on wheat compliant with the northern outdoor GAP are required.

For all other crops, the available residue trials are sufficient to derive MRL and risk assessment values. However, the following considerations should be taken into account:

- Parsley roots: only 10 overdosed (750 g a.i./ha instead of 500 g a.i./ha) trials on carrots are available to support the northern outdoor GAP. Although tentative MRL and risk assessment values can be derived from the available data, four additional trials compliant with the northern outdoor GAP are required;
- Sunflower seeds: the number of residue trials supporting the northern (four) and southern (six) outdoor GAPs is not compliant with the data requirements. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no-residue situation is expected. Further residue trials are therefore not required;
- Cotton seeds: only six overdosed (750 g a.i./ha instead of 375 g a.i./ha) trials on sunflower seeds are available to support the southern outdoor GAP for cotton seeds. However, since the results of the overdosed and reduced number of trials are all below the LOQ, no additional trials are required to support the southern outdoor GAP.

1.2.2. Magnitude of residues in rotational crops

According to the confined rotational crop study reported in Section 1.1.2, residues in rotational crops (cereal grain, leafy vegetables and root crops) are expected to remain below the LOQ of 0.01 mg/kg, provided that flurochloridone is applied according to the GAPs considered in this review.

On the other hand, it is noticed that, in wheat straw and chaff, residues were found at higher levels and remain stable at all PBIs (max. TRR 0.049 mg eq/kg). As mentioned in Section 1.1.2, further characterisation of the TRR was not performed in these samples. This information is still considered desirable in the present review, in order to verify if flurochloridone is to be expected in straw from cereals grown in rotation.

Considering the critical GAPs reported in this review (one soil application at a rate of 750 g a.i./ha), assuming a soil density of 1.5 g/L, soil depth of 20 cm, no crop interception and considering a DT50 in soil of 65 days, the plateau concentration derived in soil, taking into account accumulation over the years, was calculated as 0.04 mg/kg soil over 2 years (EFSA, 2010).

In this study, limited information on the soil used is available. However, it seems that residues in the soil tested in the confined rotational crop study ranged from 0.76 (immediately after application) to 0.05 mg eq/kg dry soil (411 days after application). Therefore, although uncertainties remain due to the lack of fully characterisation of the soil (soil density, soil ploughing depth), it is concluded that the plateau concentration expected after the use of flurochloridone at the critical GAP (0.04 mg/kg soil) is covered by these studies.

1.2.3. Magnitude of residues in processed commodities

No processing studies were submitted during the peer review or during this review. However, such studies are not required in the present review, as residues of flurochloridone exceeding 0.1 mg/kg are not expected in the treated crops and chronic exposure does not exceed 10% of the ADI (see also Sections 1.2.1 and 3).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for maize and wheat where the available data were insufficient to derive MRLs.
2. **Residues in livestock**

Flurochloridone is authorised for use on potatoes, carrots, sunflower and cotton seeds, wheat and maize corn that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for cattle (all diets), sheep (all diets), sheep (dairy only) and swine were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in ruminants and swine.

It is highlighted that for several feed items, no residue data were available (e.g. maize corn and stover; wheat grain and straw). The animal intake of flurochloridone residues via these commodities has therefore not been assessed and may have been underestimated.

A metabolism study in lactating goats was provided during this review (Spain, 2017b). Two lactating goats (one for each dose) were dosed twice daily for 7 days with orally administered 14C-phenyl-labelled flurochloridone at dose levels of 0.002 and 0.49 mg/kg body weight (bw) per day (0.44 N and 109 N compared to the maximum dietary burden calculated for sheep, respectively). Total residual radioactivity in liver, kidney, muscle and fat was determined and metabolite pattern in milk, muscle, fat, kidney and liver was investigated.

The TRRs in organs and tissues from the lowest dose level group were low (max. 0.003 mg eq/kg in liver) and consisted of multiple metabolites with very low individual amounts. Therefore, it was not possible to perform a complete structural elucidation from the sample material.

In the high dose group, the highest TRR was found in liver (1.01 mg eq/kg) and kidney (0.42 mg eq/kg). Significantly lower TRRs were found in muscle (0.025 mg eq/kg), fat (0.038 mg eq/kg) and milk (0.075 mg eq/kg). Flurochloridone was the main component of the TRR only in fat (53% TRR) and liver (9.2% TRR). Flurochloridone was not found in muscle, kidney and in milk where parent was extensively metabolised in three identified metabolites, none of them accounting for more than 10% of the TRR and not expected to be present at significant levels at the maximum calculated dietary burden. Based on these results a metabolic pathway was proposed involving mono de-hydrogen chloride flurochloridone (M1a), oxidative de-chlorinated flurochloridone (M1b), bis oxidative de-chlorinated, keto metabolite of flurochloridone (M2) and oxidative de-chlorinated, keto metabolite of flurochloridone (M3). These metabolites were identified previously in the rat metabolism study (Spain, 2006). Therefore, the metabolism in rat and ruminants is expected to be similar, and the results from the ruminants study may be extrapolated to swine.

Therefore, based on the available information, it can be concluded that, at the calculated dietary burden, no significant residues are expected in ruminants and swine tissues and in milk. Therefore, the residue definition in these commodities can be defined as flurochloridone (cis and trans isomers) by default for both enforcement and risk assessment. A method for enforcement of the proposed residue definition in ruminants and swine tissues and in milk (goat and sheep) is not available. Therefore, the current LOQ of 0.05 mg/kg as reported in the EU legislation and considered in this review should be confirmed by the submission of a fully validated analytical method for enforcement. MRLs for cattle milk, poultry tissues and eggs are not required.

The log Po/w for flurochloridone is 3.36 which is higher than three; however, in the metabolism study, residues were not accumulated in fat and it is therefore assumed that flurochloridone is not fat soluble.

EFSA emphasises that the above studies do not investigate the possible impact of animal metabolism on the isomer ratio of flurochloridone and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

3. **Consumer risk assessment**

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For those commodities where data were insufficient to derive a MRL in Section 1, EFSA considered the...
The exposure values calculated were compared with the toxicological reference value(s) for flurochloridone, derived by EFSA (2010) under Commission Regulation (EC) No 33/2008. The highest chronic exposure was calculated for FR toddlers, representing 6.0% of the ADI, and the highest acute exposure was calculated for carrots, representing 8.6% of the acute reference dose (ARfD). Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate an unacceptable risk to consumers.

EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of flurochloridone, and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

Conclusions

Metabolism in plants was investigated in sunflower (oilseeds/pulses group) and potato (root crop group) using a single spray application of $^{14}$C-labelled flurochloridone on the pyrrolidone moiety only applied onto the soil surface, just after sowing/planting. Since cleavage was not observed in environmental fate soil studies which used a second label and were assessed during the peer review, additional studies with labelling of the phenyl moiety are not needed. Identification of metabolites was not possible in sunflower seeds and potato tuber because of the low TRRs. The characterisation of residues was only possible in mature sunflower leaves, where flurochloridone accounted for 10–17% TRR (0.15–0.44 mg/kg), and three additional metabolites were identified each representing less than 3% TRR (0.01–0.06 mg/kg).

According to the soil degradation studies evaluated in the framework of the peer review, periods required for DT$_{90}$ values in soil exceeded the trigger value of 100 days and further investigation of residues in rotational crops was required. A confined rotational crop study considered acceptable during the peer review was conducted with $^{14}$C-carbonyl-labelled flurochloridone, sprayed uniformly to bare soil (clay loam) at 750 g a.s./ha (corresponding to 1N rate). Following aging of the soil for 33, 131 and 355 days, metabolism was studied in three representative rotational crops (spinach leaf, carrot and wheat).

In mature crops taken at all PBIs, TRR were very low (max 0.009 mg eq/kg observed in spinach leaves at PBI of 33 days), except in wheat straw and chaff (up to 0.049 mg eq/kg). Due to the low TRR, further metabolite identification was not performed. Residues in rotational crops (cereal grain, leafy vegetables and root crops) are expected to remain below the LOQ of 0.01 mg/kg, provided that flurochloridone is applied according to the GAPs considered in this review. Further information is still considered desirable for wheat straw and chaff in the present review, to verify whether flurochloridone is to be expected in straw from cereals grown in rotation.

Studies investigating the effect of processing on the nature of the residues are not available. However, as residues of flurochloridone exceeding 0.1 mg/kg are not expected in the treated crops and chronic exposure does not exceed 10% of the ADI, there is no need to investigate the effect of industrial and/or household processing.

Flurochloridone was stable in high water, high oil and dry commodities (alfalfa, almonds, apples, corn, peppers, potatoes, soybeans, wheat grain) when kept stored in the dark at $\pm 20^\circ C$ for a minimum of three years, and in high acid commodities (oranges) for 12 and in wheat straw for 8 months.

Based on the results of the metabolism in primary and rotational crops, the residue definition is defined as flurochloridone (sum of cis and trans isomers) by default for both enforcement and risk assessment. This residue definition is limited to root and tuber corps, pulses and oilseeds following soil treatment. A metabolism study covering the use on cereals is not available and is still required.

Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water, high acid, high oil content and dry commodities with a LOQ of 0.01 mg/kg, respectively.

The available data are considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for maize and wheat where the available data were insufficient to derive MRLs.
A metabolism study in lactating goats was provided during this review where two lactating goats (one for each dose) were dosed twice daily for 7 days with orally administered $^{14}$C-phenyl-labelled flurochloridone at dose levels of 0.002 and 0.49 mg/kg bw per day (0.44 N and 109 N compared to the maximum dietary burden calculated for sheep, respectively). Based on the available information, it can be concluded that, at the calculated dietary burden, no significant residues are expected in ruminants and swine tissues and in milk.

The residue definition in animal commodities can be defined as flurochloridone ($\text{cis}$ and $\text{trans}$ isomers) by default for both enforcement and risk assessment. A method for enforcement of the proposed residue definition in ruminants and swine tissues and in milk (goat and sheep) is not available. Therefore, the current LOQ of 0.05 mg/kg as reported in the EU legislation and considered in this review should be confirmed by the submission of a fully validated analytical method for enforcement. MRLs for cattle milk, poultry tissues and eggs are not required.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 6.0% of the ADI (FR, toddler) and the highest acute exposure amounted to 8.6% of the ARfD (carrots).

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 1). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 1 footnotes for details). In particular, some tentative MRLs and existing EU MRLs need to be confirmed by the following data:

- Metabolism study in cereals;
- Residue trials supporting the authorisations on maize and wheat;
- Four additional trials compliant with the northern outdoor GAP on parsley roots;
- A fully validated analytical method for enforcement in all animal commodities.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment, but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- Further information on the characterisation of the residues in wheat straw and chaff from the confined rotational crop study.

**Table 1:** Summary table

| Code number(a) | Commodity                          | Existing EU MRL (mg/kg) | Outcome of the review |
|----------------|------------------------------------|------------------------|-----------------------|
|                |                                    | MRL (mg/kg)            | Comment              |
| **Enforcement residue definition (existing): Flurochloridone** |                       |                        |                       |
| 211000         | Potatoes                           | 0.1*                   | Recommended(b)       |
| 213020         | Carrots                            | 0.1*                   | Recommended(b)       |
| 213030         | Celeriacs/turnip rooted celeries   | 0.1*                   | Recommended(b)       |
| 213060         | Parsnips                           | 0.1*                   | Recommended(b)       |
| 213070         | Parsley roots/Hamburg roots parsley| 0.1*                   | Further consideration needed(c) |
| 401050         | Sunflower seeds                    | 0.1*                   | Recommended(b)       |
| 401090         | Cotton seeds                       | 0.1*                   | Recommended(b)       |
| 500030         | Maize/corn grains                  | 0.1*                   | Further consideration needed(d) |

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(a) Bold code numbers indicate changes to existing MRLs.

(b) Recommended is based on the proposed residue definition.

(c) Further consideration was recommended in the reasoned opinion.

(d) Further consideration is recommended for the following reasons:
- Tentative MRLs and existing EU MRLs need to be confirmed by the following data:
  - Metabolism study results for cereals;
  - Residue trials supporting the authorisations on maize and wheat;
  - Four additional trials compliant with the northern outdoor GAP on parsley roots;
  - A fully validated analytical method for enforcement in all animal commodities.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.
## References

Czech Republic, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for flurochloridone, August 2017. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance flurochloridone. EFSA Journal 2010;8(12):1869, 66 pp. https://doi.org/10.2903/j.efsa.2010.1869

EFSA (European Food Safety Authority), 2017a. Completeness check report on the review of the existing MRLs of flurochloridone prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 12 October 2017. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2017b. Member States consultation report on the review of the existing MRLs of flurochloridone prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 13 December 2017. Available online: www.efsa.europa.eu

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| Code number(a) | Commodity | Existing EU MRL (mg/kg) | Outcome of the review |
|----------------|-----------|-------------------------|-----------------------|
| 500090         | Wheat grains | 0.1* (b)                | MRL (mg/kg)          |
| 500090         | Wheat grains | 0.1* (b)                | 0.1* (c,d)           |
| 1011010        | Swine muscle | 0.05* (b)               | Further consideration needed (c) |
| 1011020        | Swine fat tissue | 0.05* (b)              | Further consideration needed (c) |
| 1011030        | Swine liver | 0.05* (b)               | Further consideration needed (c) |
| 1011040        | Swine kidney | 0.05* (b)               | Further consideration needed (c) |
| 1012010        | Bovine muscle | 0.05* (b)              | Further consideration needed (c) |
| 1012020        | Bovine fat tissue | 0.05* (b)         | Further consideration needed (c) |
| 1012030        | Bovine liver | 0.05* (b)               | Further consideration needed (c) |
| 1012040        | Bovine kidney | 0.05* (b)              | Further consideration needed (c) |
| 1013010        | Sheep muscle | 0.05* (b)               | Further consideration needed (c) |
| 1013020        | Sheep fat tissue | 0.05* (b)            | Further consideration needed (c) |
| 1013030        | Sheep liver | 0.05* (b)               | Further consideration needed (c) |
| 1013040        | Sheep kidney | 0.05* (b)               | Further consideration needed (c) |
| 1014010        | Goat muscle | 0.05* (b)               | Further consideration needed (c) |
| 1014020        | Goat fat tissue | 0.05* (b)             | Further consideration needed (c) |
| 1014030        | Goat liver | 0.05* (b)               | Further consideration needed (c) |
| 1014040        | Goat kidney | 0.05* (b)               | Further consideration needed (c) |
| 1015010        | Equine muscle | 0.05* (b)              | Further consideration needed (c) |
| 1015020        | Equine fat tissue | 0.05* (b)           | Further consideration needed (c) |
| 1015030        | Equine liver | 0.05* (b)               | Further consideration needed (c) |
| 1015040        | Equine kidney | 0.05* (b)              | Further consideration needed (c) |
| 1020020        | Sheep milk | 0.05* (b)               | Further consideration needed (c) |
| 1020030        | Goat milk | 0.05* (b)               | Further consideration needed (c) |
| –              | Other commodities of plant and animal origin | See Regulation (EC) No 149/2008 | – | Further consideration needed (e) |

MRL: maximum residue level.
*: Indicates that the MRL is set/proposed at the limit of quantification.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(c): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(d): GAP evaluated at EU level is not supported by data, but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(e): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
Review of the existing MRLs for flurochloridone

EURL (European Union Reference Laboratories for Pesticide Residues), 2017. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for flurochloridone. July 2017. Available online: www.efsa.europa.eu

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414/EEC. SANCO/3029/99-rev. 4.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Edition. FAO Plant Production and Protection Paper 197, 264 pp.

France, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for flurochloridone, August 2017. Available online: www.efsa.europa.eu

Greece, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for flurochloridone, August 2017. Available online: www.efsa.europa.eu

Hungary, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for flurochloridone, August 2017. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.

Spain, 2006. Draft Assessment Report (DAR) on the active substance flurochloridone prepared by the rapporteur Member State Spain in the framework of Directive 91/414/EEC, February 2006.

Spain, 2009. Additional Report to the Draft Assessment Report on the active substance flurochloridone, prepared by the rapporteur Member State Spain in the framework of Commission Regulation (EC) No 33/2008, October 2009. Available online: www.efsa.europa.eu

Spain, 2010. Final Addendum to the Additional Report on flurochloridone, compiled by EFSA, August 2010. Available online: www.efsa.europa.eu

Spain, 2017a. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for flurochloridone, January 2017. Available online: www.efsa.europa.eu

Spain, 2017b. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for flurochloridone, September 2017. Available online: www.efsa.europa.eu

Abbreviations

a.i. active ingredient

a.s. active substance

ADI acceptable daily intake

ARfD acute reference dose

BBCH growth stages of mono- and dicotyledonous plants
bw  body weight
CS  capsule suspension
CXL  codex maximum residue limit
DAR  draft assessment report
DM  dry matter
DT₉₀  period required for 90% dissipation (define method of estimation)
EC  emulsifiable concentrate
eq  residue expressed as a.s. equivalent
ESI  electrospray ionization
EURLs  European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO  Food and Agriculture Organization of the United Nations
GAP  Good Agricultural Practice
GC  gas chromatography
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 Standardization
IUPAC  International Union of Pure and Applied Chemistry
LC  liquid chromatography
LC–MS/MS  liquid chromatography with tandem mass spectrometry
LC-QqQ-MS/MS  liquid chromatography with triple quadrupole tandem mass spectrometry
LOQ  limit of quantification
Mo  monitoring
MRL  maximum residue level
MS  mass spectrometry detector
MS/MS  tandem mass spectrometry detector
NEU  northern European Union
OECD  Organisation for Economic Co-operation and Development
PBI  plant back interval
PF  processing factor
PHI  preharvest interval
P₀₀w  partition coefficient between n-octanol and water
PRIMo  (EFSA) Pesticide Residues Intake Model
PROFile  (EFSA) Pesticide Residues Overview File
RA  risk assessment
RD  residue definition
RMS  rapporteur Member State
SANCO  Directorate-General for Health and Consumers
SEU  southern European Union
SMILES  simplified molecular-input line-entry system
STMR  supervised trials median residue
TRR  total radioactive residue
WHO  World Health Organization
## Appendix A – Summary of authorised uses considered for the review of MRLs

| Crop | Common name | Scientific name | Region | Pest controlled | Formulation | Application | PHI or waiting period (days) | PHI or waiting period (days) | Comments (max. 250 characters) |
|-------|-------------|-----------------|--------|----------------|-------------|-------------|-----------------------------|-----------------------------|--------------------------------|
| **Critical outdoor GAPs for Northern Europe** | | | | | | | | | |
| Potatoes | Solanum tuberosum subsp. tuberosum | NEU | Outdoor | AT, CZ | Broad-leaved weeds and grass weeds | EC | 250.0 g/L Soil treatment – spraying | 0 | 5 | 1 | 375.00 | 750.00 | n.a. | Concentration: 93.8 – 375 g a.i./L Water: 200 – 400 L/ha [FR, HU less critical GAPs] |
| Carrots | Daucus carota subsp. sativa | NEU | Outdoor | FR | Broad-leaved weeds and grass weeds | CS | 250.0 g/L Seed treatment – spraying | 0 | 9 | 1 | 750.00 | g a.i./ha | n.a. | HU less critical GAP |
| Celeriacs | Apium graveolens var. rapaceum | NEU | Outdoor | FR | Broad-leaved weeds and grass weeds | CS | 250.0 g/L Soil treatment – spraying | 0 | 9 | 1 | 750.00 | g a.i./ha | n.a. |
| Parsnips | Pastinaca sativa | NEU | Outdoor | FR | Broad-leaved weeds and grass weeds | CS | 250.0 g/L Soil treatment – spraying | 0 | 9 | 1 | 750.00 | g a.i./ha | n.a. |
| Parsley roots | Petroselinum crispum convar. radiatum | NEU | Outdoor | HU | Broad-leaved weeds and grass weeds | EC | 250.0 g/L Soil treatment – spraying | 0 | 9 | 1 | 500.00 | g a.i./ha | 90 |
| Sunflower seeds | Helianthus annuus | NEU | Outdoor | AT, CZ, HU, FR | Broad-leaved weeds and grass weeds | EC | 250.0 g/L Soil treatment – spraying | 0 | 7 | 1 | 500.00 | 750.00 | g a.i./ha | APPLICATION RATE Concentration: 125 – 375 g a.i./L Water: 200 – 400 L/ha |
| Maize | Zea mays | NEU | Outdoor | CZ | Broad-leaved weeds and grass weeds | EC | 250.0 g/L Soil treatment – spraying | 0 | 7 | 1 | 83.00 | 160.00 | g a.i./ha | n.a. |
| Wheat | Triticum aestivum | NEU | Outdoor | CZ | Broad-leaved weeds and grass weeds | EC | 250.0 g/L Soil treatment – spraying | 0 | 7 | 1 | 83.00 | 160.00 | g a.i./ha | n.a. |
| **Critical outdoor GAPs for Southern Europe** | | | | | | | | | |
| Potatoes | Solanum tuberosum subsp. tuberosum | SEU | Outdoor | ES | Broad-leaved weeds and grass weeds | CS | 250.0 g/L Soil treatment – spraying | 0 | 5 | 1 | 625.00 | 875.00 | g a.i./ha | n.a. | Concentration: 93.8 – 375 g a.i./L Water: 200 – 400 L/ha [EL, FR less critical GAPs] |
| Crop | Scientific name | Region | Outdoor/ indoor | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|-----------------|--------|-----------------|-----------------|-------------|-------------|-----------------------------|--------------------------------|
| Carrots | Daucus carota subsp. sativus | SEU | Outdoor | EL, ES, FR | Broad-leaved weeds and grass weeds, pre-emergence | CS 250.0 g/L Soil treatment – spraying | 0 9 1 375.00 750.00 g a.i./ha | n.a. |
| Celeriacs | Apium graveolens var. rapaceum | SEU | Outdoor | EL, ES | Broad-leaved weeds and grass weeds, pre-emergence | CS 250.0 g/L Soil treatment – spraying | 0 9 1 375.00 750.00 g a.i./ha | n.a. |
| Parsnips | Pastinaca sativa | SEU | Outdoor | FR | Broad-leaved weeds and grass weeds, pre-emergence | CS 250.0 g/L Soil treatment – spraying | 0 9 1 375.00 750.00 g a.i./ha | n.a. |
| Sunflower seeds | Helianthus annuus | SEU | Outdoor | EL, ES, FR, PT | Broad-leaved weeds and grass weeds | CS 250.0 g/L Soil treatment – spraying | 0 7 1 500.00 750.00 g a.i./ha | n.a. |
| Cotton seeds | Gossypium barbadense; Gossypium herbaceum | SEU | Outdoor | EL, ES | Broad-leaved weeds and grass weeds, pre-emergence | CS 250.0 g/L Soil treatment – spraying | 0 9 1 250.00 375.00 g a.i./ha | n.a. |

n.a.: not applicable; MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; EC: emulsifiable concentrate; CS: capsule suspension; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; a.i.: active ingredient.
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) |
|-----------------------------------|-------------|--------|----------------|----------------|
| Root crops                        | Potatoes    | Bare soil, 615.1 g a.s./ha | 68, 130         |
| Pulses/oilseeds                  | Sunflower seeds | Bare soil, 300 g a.s./ha     | 30, 119        |
|                                  |             | Bare soil, 600 g a.s./ha     | 30, 119        |
| Source: Spain (2006)             |             |                                  |                |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|--------------------------------------|-------------|--------|----------------|-----------|
| Root/tuber crops                     | Sugar beet  | Bare soil, 300 g a.s./ha | 30, 120, 365 |
|                                      | Carrots     | Bare soil, 750 g a.s./ha  | 33, 131, 355 |
| Leafy crops                          | Spinach     | Bare soil, 750 g a.s./ha  | 33, 131, 355 |
| Cereal (small grain)                 | Wheat       | Bare soil, 300 g a.s./ha  | 30, 120, 365 |
|                                      | Wheat       | Bare soil, 750 g a.s./ha  | 33, 131, 355 |
| Source: Spain (2006, 2009)          |             |                                  |                |

| Processed commodities (hydrolysis study) | Conditions | Investigated? |
|-----------------------------------------|------------|---------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4) | No            |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5) | No            |
|                                        | Sterilisation (20 min, 120°C, pH 6) | No            |
|                                        | Studies are not required |                |

Can a general residue definition be proposed for primary crops? No
Rotational crop and primary crop metabolism similar? Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities? Not triggered
Plant residue definition for monitoring (RD-Mo) Limited to root and tuber crops, pulses and oilseeds following soil treatment: Flurochloridone (sum cis and trans isomers) by default
Plant residue definition for risk assessment (RD-RA) Limited to root and tuber crops, pulses and oilseeds following soil treatment: Flurochloridone (sum cis and trans isomers) by default
Conversion factor (monitoring to risk assessment) Not applicable
### Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

| High water and high acid commodities: |
|--------------------------------------|
| • GC–MS/MS, LOQ: 0.01 mg/kg for fluorochloridone; validation data in potatoes, however ILV not available (Spain, 2006). Confirmatory GC–MS method with LOQ: 0.01 mg/kg available (France, 2017). |
| • EURLs provided a LC-MS/MS method with a LOQ of 0.01 mg/kg; validation data available (cucumber, orange juice) (EURL, 2017). |

| High oil commodities: |
|-----------------------|
| • GC–MS, LOQ: 0.01 mg/kg fluorochloridone, validated in sunflower seeds, ILV and confirmatory method available (Spain, 2006; France, 2017). |
| • LC-MS/MS ESI-neg, LOQ: 0.01 mg/kg for fluorochloridone in high oil commodities, validation data available (almonds) (EURL, 2017). |

| Dry commodities: |
|------------------|
| • LC-QqQ-MS/MS, LOQ: 0.01 mg/kg for fluorochloridone in dry commodities, validation data available for a GC-QqQ-MS/MS, LOQ: 0.01 mg/kg for fluorochloridone in dry commodities (oat, rye, wheat, rice and barley) (EURL, 2017). |

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

| Plant products (available studies) | Category | Commodity | T (°C) | Stability (months) |
|-----------------------------------|----------|-----------|--------|--------------------|
| High water content                | Alfalfa  | –20       | 72     |
|                                  | Apples   | –20       | 72     |
|                                  | Peppers  | –20       | 72     |
|                                  | Potatoes | –20       | 72     |
| High oil content                  | Soybean seeds | –20 | 72 |
|                                  | Almonds  | –20       | 72     |
| High acid content                 | Oranges  | –20       | 12     |
| Dry commodity                     | Corn     | –20       | 72     |
|                                  | Wheat grain | –20 | 72 |
|                                  | Wheat straw | –20 | 8 |

Source: Spain (2006)
## B.1.2. Magnitude of residues in plants

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

| Crop                      | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|---------------------------|------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------|---------------|-----------------|
| Potatoes                  | NEU              | 8 × < 0.01                                                                                     | GAP compliant trials on potatoes (Spain, 2006, 2017a)                                                                 | 0.01*                | 0.01          | 0.01            |
|                           | SEU              | 8 × < 0.01                                                                                     | GAP compliant trials on potatoes (Spain, 2006, 2017a)                                                                 | 0.01*                | 0.01          | 0.01            |
| Sunflower seeds           | NEU              | 4 × < 0.01                                                                                     | GAP compliant trials on sunflower (Spain, 2006, 2017a)                                                            | 0.01*                | 0.01          | 0.01            |
|                           | SEU              | 6 × < 0.01                                                                                     | GAP compliant trials on sunflower (Spain, 2006, 2017a)                                                            | 0.01*                | 0.01          | 0.01            |
| Cotton seeds              | SEU              | 6 × < 0.01                                                                                     | Trials on sunflower seeds with an application rate of 750 g a.i./ha instead of 375 g a.i./ha. (Spain, 2006, 2017a) | 0.01*                | 0.01          | 0.01            |
| Carrots Celeriacs/turnip rooted celeries, Parsnips | NEU | 7 × < 0.01; 0.011; 0.024; 0.054 | GAP compliant trials on carrot extrapolated to celeriacs and parsnips (France, 2017; Hungary, 2017; Spain, 2017b) \  MRL\textsubscript{OECD} = 0.07 | 0.08                | 0.05          | 0.01            |
|                           | SEU              | 4 × < 0.01; 0.016; 0.023; 0.033; 0.044                                                       | GAP compliant trials on carrots extrapolated to celeriacs and parsnips (France, 2017; Spain, 2017b) \  MRL\textsubscript{OECD} = 0.07 | 0.08                | 0.04          | 0.01            |
| Maize/corn grains         | NEU              | –                                                                                               | No trials available                                                                                              | –                    | –             | –               |
| Wheat grains              | NEU              | –                                                                                               | No trials available                                                                                              | –                    | –             | –               |
| Maize/corn stover         | NEU              | –                                                                                               | No trials available                                                                                              | –                    | –             | –               |
| Wheat straw               | NEU              | –                                                                                               | No trials available                                                                                              | –                    | –             | –               |
| Parsley roots/Hamburg roots parsley | NEU | 7 × < 0.01; 0.011; 0.024; 0.054 | Trials on carrot with an application rate of 750 g a.i./ha instead of 500 g a.i./ha extrapolated to parsley roots (France, 2017; Hungary, 2017; Spain, 2017b) \  MRL\textsubscript{OECD} = 0.07 | 0.08 (tentative)(d) | 0.05          | 0.01            |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.

*: 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 according to the residue definition.

(c): Supervised trials median residue according to the residue definition.

(d): A tentative MRL is derived on the basis of overdosed trials.
B.1.2.2. Residues in succeeding crops

| Confined rotational crop study (quantitative aspect) | Residues in mature rotated crops relevant for human consumption are not expected to be present above the LOQ, except in wheat straw and chaff, provided that flurochloridone is applied according to the GAPs considered in this review |
| Field rotational crop study | Not available |

B.1.2.3. Processing factors

Studies are not available and are not required.

B.2. Residues in livestock

Relevant groups

| Dietary burden expressed in | Most critical diet\(^{(a)}\) | Most critical commodity\(^{(a)}\) | Trigger exceeded (Y/N) |
|-----------------------------|-----------------------------|-------------------------------|------------------------|
| mg/kg bw per day            | mg/kg DM                    |                               |                        |
| Med. | Max. | Med. | Max. | Med. | Max. |                       |                        |
| Cattle (all diets)          | 0.0016 | 0.0036 | 0.05 | 0.10 | Cattle (beef) | Carrot, culls | Yes |
| Cattle (dairy only)         | 0.0016 | 0.0036 | 0.04 | 0.09 | Cattle (dairy) | Carrot, culls | No |
| Sheep (all diets)           | 0.0018 | 0.0045 | 0.06 | 0.12 | Sheep (lamb) | Carrot, culls | Yes |
| Sheep (ewe only)            | 0.0018 | 0.0041 | 0.06 | 0.12 | Sheep (ram/ewe) | Carrot, culls | Yes |
| Swine (all diets)           | 0.0010 | 0.0034 | 0.04 | 0.13 | Swine (finishing) | Carrot, culls | Yes |
| Poultry (all diets)         | 0.0009 | 0.0033 | 0.01 | 0.05 | Poultry (broiler) | Carrot, culls | No |
| Poultry (layer only)        | 0.0009 | 0.0032 | 0.01 | 0.05 | Poultry (layer) | Carrot, culls | No |

bw: body weight; DM: dry matter.

\(^{(a)}\): Calculated for the maximum dietary burden.

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

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

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | N rate/comment |
|-------------------------------|--------|-------------------------|-----------------|----------------|
|                               | Lactating goat | 0.002 0.49 | 7 7 | 0.44N/compared to the maximum dietary burden calculated for sheep 109N/compared to the maximum dietary burden calculated for sheep |

Source: Spain (2017b)

Time needed to reach a plateau concentration in milk and eggs (days) 3-4 days

Metabolism in rat and ruminant similar (Yes/No) Yes

Animal residue definition for monitoring (RD-Mo) Flurochloridone (sum cis + trans isomers) by default

Animal residue definition for risk assessment (RD-RA) Flurochloridone (sum cis + trans isomers) by default

Conversion factor (monitoring to risk assessment) Not applicable

Fat soluble residues (Yes/No) No

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) Not available and required
### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal Commodity | T (°C) | Stability (months/years) |
|-------------------------------------|------------------|-------|-------------------------|
|                                     |                  |       |                         |
| Not available and not required      |                  |       |                         |

### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) | MRL proposal (mg/kg) |
|------------------|-----------------------------------------------|-------------------------------------------|----------------------|
|                  | Mean | Highest | STMR<sup>(a)</sup> | HR<sup>(b)</sup> |                     |

- **Cattle (all diets)**
  - Based on the metabolism study, at the calculated dietary burden, no residues above the LOQ are expected in tissues
  - Muscle: 0.05
  - Fat: 0.05
  - Liver: 0.05
  - Kidney: 0.05

- **Cattle (dairy only)**
  - MRLs for cattle milk are not required (calculated dietary burdens below 0.1 mg/kg DM)
  - Milk: 0.05

- **Sheep (all diets)**
  - Based on the metabolism study, at the calculated dietary burden, no residues above the LOQ are expected in tissues
  - Muscle: 0.05
  - Fat: 0.05
  - Liver: 0.05
  - Kidney: 0.05

- **Sheep (dairy only)**
  - Based on the metabolism study, at the calculated dietary burden, no residues above the LOQ are expected in milk
  - Milk: 0.05

- **Swine**
  - Based on the metabolism study, at the calculated dietary burden, no residues above the LOQ are expected in tissues
  - Muscle: 0.05
  - Fat: 0.05
  - Liver: 0.05
  - Kidney: 0.05

- **Poultry (all diets)**
  - Studies on poultry are not available and are not required (calculated dietary burdens below 0.1 mg/kg DM)
  - Muscle: 0.05
  - Fat: 0.05
  - Liver: 0.05
  - Kidney: 0.05

- **Poultry (layer only)**
  - Studies on poultry are not available and are not required (calculated dietary burdens below 0.1 mg/kg DM)
  - Muscle: 0.05
  - Fat: 0.05
  - Liver: 0.05
  - Kidney: 0.05

**STMR:** supervised trials median residue; **HR:** highest residue.

- **:** Indicates that the MRL is proposed at the limit of quantification.
- (a): The mean residue levels for milk and tissues measured in the metabolism studies were recalculated at the 1N rate for the median dietary burden.
- (b): The mean residue level in milk and the highest residue levels in tissues measured in the metabolism studies were recalculated at the 1N rate for the maximum dietary burden.
- (c): In the absence of a fully validated analytical method for enforcement, the proposed MRL is tentative only.
B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs

| ADI | 0.04 mg/kg bw per day (EFSA, 2010) |
|-------------------------------|----------------------------------|
| Highest IEDI, according to EFSA PRIMo | 6.0% ADI (FR, toddler) |

**Assumptions made for the calculations**
The calculation is based on the median residue levels in the raw agricultural commodities. For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The contributions of commodities, where no GAP was reported in the framework of this review, were not included in the calculation.

| ARfD | 0.04 mg/kg bw (EFSA, 2010) |
|---------------------------------|-----------------------------|
| Highest IESTI, according to EFSA PRIMo | 8.6% ARfD (carrots) |

**Assumptions made for the calculations**
The calculation is based on the highest residue levels in the raw agricultural commodities. For those commodities, where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation.

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ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; ARfD: acute reference dose; IESTI: international estimated short-term intake.

B.4. Proposed MRLs

| Code number(a) Commodity | Existing EU MRL (mg/kg) | MRL (mg/kg) | Comment |
|--------------------------|------------------------|-------------|---------|
| Enforcement residue definition (existing): Flurochloridone |
| Enforcement residue definition (proposed): Flurochloridone (sum of cis and trans isomers) |
| 211000 Potatoes | 0.1* | 0.01* | Recommended(b) |
| 213020 Carrots | 0.1* | 0.08 | Recommended(b) |
| 213030 Celeriacs/turnip rooted celeries | 0.1* | 0.08 | Recommended(b) |
| 213060 Parsnips | 0.1* | 0.08 | Recommended(b) |
| 213070 Parsley roots/Hamburg roots parsley | 0.1* | 0.08 | Further consideration needed(c) |
| 401050 Sunflower seeds | 0.1* | 0.01* | Recommended(b) |
| 401090 Cotton seeds | 0.1* | 0.01* | Recommended(b) |
| 500030 Maize/corn grains | 0.1* | 0.1* | Further consideration needed(d) |
| 500090 Wheat grains | 0.1* | 0.1* | Further consideration needed(d) |
| 1011010 Swine muscle | 0.05* | 0.05* | Further consideration needed(c) |
| 1011020 Swine fat tissue | 0.05* | 0.05* | Further consideration needed(c) |
| 1011030 Swine liver | 0.05* | 0.05* | Further consideration needed(c) |
| 1011040 Swine kidney | 0.05* | 0.05* | Further consideration needed(c) |
| 1012010 Bovine muscle | 0.05* | 0.05* | Further consideration needed(c) |
| 1012020 Bovine fat tissue | 0.05* | 0.05* | Further consideration needed(c) |
| 1012030 Bovine liver | 0.05* | 0.05* | Further consideration needed(c) |
| 1012040 Bovine kidney | 0.05* | 0.05* | Further consideration needed(c) |
| 1013010 Sheep muscle | 0.05* | 0.05* | Further consideration needed(c) |
| 1013020 Sheep fat tissue | 0.05* | 0.05* | Further consideration needed(c) |
| 1013030 Sheep liver | 0.05* | 0.05* | Further consideration needed(c) |
| 1013040 Sheep kidney | 0.05* | 0.05* | Further consideration needed(c) |
| Code number\(^{(a)}\) | Commodity       | Existing EU MRL (mg/kg) | Outcome of the review | Comment                                      |
|----------------------|-----------------|-------------------------|-----------------------|----------------------------------------------|
|                     |                 |                         | MRL (mg/kg)           | Comment                                      |
| 1014010              | Goat muscle     | 0.05*                   | 0.05*                 | Further consideration needed\(^{(c)}\)       |
| 1014020              | Goat fat tissue | 0.05*                   | 0.05*                 | Further consideration needed\(^{(c)}\)       |
| 1014030              | Goat liver      | 0.05*                   | 0.05*                 | Further consideration needed\(^{(c)}\)       |
| 1014040              | Goat kidney     | 0.05*                   | 0.05*                 | Further consideration needed\(^{(c)}\)       |
| 1015010              | Equine muscle   | 0.05*                   | 0.05*                 | Further consideration needed\(^{(c)}\)       |
| 1015020              | Equine fat tissue | 0.05*              | 0.05*                 | Further consideration needed\(^{(c)}\)       |
| 1015030              | Equine liver    | 0.05*                   | 0.05*                 | Further consideration needed\(^{(c)}\)       |
| 1015040              | Equine kidney   | 0.05*                   | 0.05*                 | Further consideration needed\(^{(c)}\)       |
| 1020020              | Sheep milk      | 0.05*                   | 0.05*                 | Further consideration needed\(^{(c)}\)       |
| 1020030              | Goat milk       | 0.05*                   | 0.05*                 | Further consideration needed\(^{(c)}\)       |
| –                    | Other commodities of plant and animal origin | See Regulation (EC) No 149/2008 | –                              | Further consideration needed\(^{(e)}\)       |

**MRL**: maximum residue level.  
\(^{*}\): Indicates that the MRL is set/proposed at the limit of quantification.  
\(^{(a)}\): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.  
\(^{(b)}\): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).  
\(^{(c)}\): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).  
\(^{(d)}\): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).  
\(^{(e)}\): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
Appendix C – Pesticide Residue Intake Model (PRIMo)

- **PRIMo(EU)**

### Flurochloridone

| Scenario | TMDI (mg/kg bw per day) | Source of ADI | Source of ARfD | Year of evaluation | Year of evaluation |
|----------|-------------------------|---------------|----------------|-------------------|-------------------|
| EU       | 0.04                    | EFSA          | EFSA           | 2010              | 2010              |

| Toxicological end points | LOQ (mg/kg bw) | LOQ (mg/kg bw) |
|--------------------------|----------------|----------------|
| ADI                      | 0.04           | 0.04           |
| ARfD                     |                |                |

#### PRIMo(EU)

| Code no. | LOQ (mg/kg bw): 0.01 proposed LOQ: | Source of ADI: | Source of ARfD: | Year of evaluation: | Year of evaluation: |
|----------|-----------------------------------|----------------|----------------|-------------------|-------------------|
|          | 0.04                              | EFSA           | EFSA           | 2010              | 2010              |

| Status of the active substance: | included |
|---------------------------------|----------|
| Code no. | LOQ (mg/kg bw): 0.01 proposed LOQ: | Source of ADI: | Source of ARfD: | Year of evaluation: | Year of evaluation: |
|----------|-----------------------------------|----------------|----------------|-------------------|-------------------|
|          | 0.04                              | EFSA           | EFSA           | 2010              | 2010              |

### Flurochloridone

| Toxicological end points | LOQ (mg/kg bw) | LOQ (mg/kg bw) |
|--------------------------|----------------|----------------|
| ADI                      | 0.04           | 0.04           |
| ARfD                     |                |                |

#### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI | No of diets exceeding ADI: |
|--------------------------------|-------------------------|---------------------------|
|                                | Minimum – Maximum       |                           |
|                                |                         | 0                         |
|                                |                         | 6                         |

| TMDI values in % of ADI | MS Diet | Highest contributor to MS diet | Commodity/group of commodities | 2nd contributor to MS diet | Commodity/group of commodities | 3rd contributor to MS diet | Commodity/group of commodities | pTMRLs at LOQ (in % of ADI) |
|-------------------------|---------|--------------------------------|-------------------------------|---------------------------|-------------------------------|---------------------------|-------------------------------|-----------------------------|
| 6.0                     | FR toddler | 5.0       | Milk and cream | 0.7 | Wheat | 0.2 | Bovine: meat | 0.1 |
| 5.9                     | UK Infant | 4.8       | Milk and cream | 0.7 | Wheat | 0.3 | Maize | 0.1 |
| 5.4                     | NL child | 3.7       | Milk and cream | 1.2 | Wheat | 0.2 | Swine: meat | 0.1 |
| 3.7                     | FR infant | 3.2       | Milk and cream | 0.2 | Wheat | 0.1 | Potatoes | 0.1 |
| 3.7                     | UK Toddler | 2.6       | Milk and cream | 1.0 | Wheat | 0.1 | Potatoes | 0.1 |
| 3.5                     | WHO Cluster diet B | 2.1       | Wheat | 0.6 | Maize | 0.4 | Milk and cream | 0.1 |
| 3.2                     | ES child | 1.6       | Milk and cream | 1.1 | Wheat | 0.2 | Bovine: meat | 0.0 |
| 3.1                     | DK child | 1.6       | Milk and cream | 1.4 | Wheat | 0.1 | Potatoes | 0.1 |
| 3.1                     | DE child | 1.8       | Milk and cream | 1.0 | Wheat | 0.1 | Potatoes | 0.1 |
| 2.6                     | WHO cluster diet D | 1.6       | Wheat | 0.6 | Milk and cream | 0.1 | Maize | 0.1 |
| 2.5                     | SE general population 90th percentile | 1.5       | Milk and cream | 0.8 | Wheat | 0.1 | Potatoes | 0.1 |
| 2.5                     | WHO regional European diet | 0.7       | Wheat | 0.6 | Milk and cream | 0.2 | Swine: meat | 0.1 |
| 2.5                     | WHO cluster diet E | 1.0       | Wheat | 0.4 | Milk and cream | 0.1 | Maize | 0.1 |
| 2.5                     | WHO Cluster diet F | 0.9       | Wheat | 0.5 | Milk and cream | 0.1 | Swine: meat | 0.1 |
| 2.5                     | IE adult | 0.6       | Maize | 0.3 | Milk and cream | 0.3 | Maize | 0.1 |
| 2.5                     | IT kids/toddler | 1.7       | Wheat | 0.0 | Potatoes | 0.0 | Maize | 0.0 |
| 2.5                     | NL general | 0.8       | Milk and cream | 0.5 | Wheat | 0.1 | Swine: meat | 0.1 |
| 2.5                     | ES adult | 0.6       | Milk and cream | 0.6 | Wheat | 0.1 | Bovine: meat | 0.0 |
| 2.5                     | FR all population | 0.8       | Wheat | 0.3 | Milk and cream | 0.1 | Bovine: meat | 0.0 |
| 2.5                     | DH adult | 0.7       | Milk and cream | 0.5 | Wheat | 0.1 | Swine: meat | 0.0 |
| 2.5                     | PT General population | 1.0       | Wheat | 0.1 | Potatoes | 0.1 | Maize | 0.1 |
| 2.5                     | IT adult | 1.0       | Wheat | 0.0 | Potatoes | 0.0 | Carrots | 0.0 |
| 2.5                     | LT adult | 0.5       | Milk and cream | 0.3 | Wheat | 0.1 | Swine: meat | 0.1 |
| 2.5                     | FI adult | 0.7       | Milk and cream | 0.2 | Wheat | 0.0 | Potatoes | 0.0 |
| 2.5                     | UK vegetarian | 0.5       | Wheat | 0.4 | Milk and cream | 0.0 | Potatoes | 0.0 |
| 2.5                     | UK Adult | 0.4       | Wheat | 0.4 | Milk and cream | 0.0 | Potatoes | 0.0 |
| 2.5                     | PL general population | 0.1       | Potatoes | 0.0 | Carrots | 0.0 | Parsley root | 0.1 |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Flurochloridone 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.

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | --- |
|---|---|---|---|---|---|---|---|
| Highest % of ARfD/ADI Commodity | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodity | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodity | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodity | pTMRL/ threshold MRL (mg/kg) |
| 6.6 Carrots 0.054/- | 7.5 Celeriac 0.054/- | 2.3 Celeriac 0.054/- | 2.3 Celeriac 0.054/- | 2.0 Wheat 0.1/- | 2.0 Wheat 0.1/- | 1.3 Carrots 0.054/- |
| 7.5 Celeriac 0.054/- | 6.1 Carrots 0.054/- | 2.0 Wheat 0.1/- | 1.4 Parsnips 0.054/- | 1.6 Carrots 0.054/- | 0.8 Milk and milk products 0.05/- | 0.8 Milk and milk products 0.05/- |
| 4.9 Parsnips 0.054/- | 3.6 Wheat 0.1/- | 1.9 Parsnips 0.054/- | 0.8 Milk and milk products 0.05/- |
| 3.8 Potatoes 0.054/- | 3.5 Parsnips 0.054/- | 1.6 Carrots 0.054/- |
| 3.6 Wheat 0.1/- | 3.0 Milk and milk 0.05/- |
| 5.8 Carrot, juice 0.054/- | 1.1 Bread/pizza 0.1/- | 0.1 Maize flour 0.1/- |
| 3.0 Wheat flour 0.1/- | 0.0 Potato uree (flakes) 0.01/- |
| 1.8 Potato flour 0.054/- |
| 1.1 Maize flour 0.1/- |
| 0.3 Potato puree (flakes) 0.01/- |

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

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For flurochloridone, 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.

For processed commodities, no exceedance of the ARfD/ADI was identified.
### Appendix D – Input values for the exposure calculations

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

| Feed commodity       | Median dietary burden | Maximum dietary burden |
|----------------------|-----------------------|------------------------|
|                      | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| **Risk assessment residue definition** flurochloridone (sum of cis and trans isomers) | | |
| Potato, culls        | 0.01* STMR            | HR                     | 0.01* STMR            | HR                     |
| Potato, process waste| 0.01* STMR           | HR                     | 0.01* STMR           | HR                     |
| Potato, dried pulp   | 0.01* STMR           | HR                     | 0.01* STMR           | HR                     |
| Carrot, culls        | 0.01 STMR             | HR                     | 0.01 STMR             | HR                     |
| Sunflower, meal      | 0.01* STMR           | HR                     | 0.01* STMR           | HR                     |
| Cotton, undelinted seed | 0.01* STMR       | HR                     | 0.01* STMR       | HR                     |
| Cotton, meal         | 0.01* STMR           | HR                     | 0.01* STMR           | HR                     |

STMR: supervised trials median residue; HR: highest residue.
* Indicates that the input value is proposed at the limit of quantification.
(a): For potatoes and sunflower, cotton meals no default processing factor was applied because flurochloridone is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

#### D.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity                          | Chronic risk assessment | Acute risk assessment |
|------------------------------------|-------------------------|-----------------------|
|                                    | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| **Risk assessment residue definition** flurochloridone (sum of cis and trans isomers) | | |
| Potatoes                           | 0.01* STMR             | HR                    | 0.01* HR                |
| Carrots                            | 0.01 STMR              | HR                    | 0.05 HR                 |
| Celeriacs/turnip rooted celeries    | 0.01 STMR              | HR                    | 0.05 HR                 |
| Parsnips                           | 0.01 STMR              | HR                    | 0.05 HR                 |
| Parsley roots/ Hamburg roots parsley | 0.01 STMR (tentative) | HR (tentative)        | 0.05 HR (tentative)     |
| Sunflower seeds                    | 0.01* STMR             | HR                    | 0.01* HR                |
| Cotton seeds                       | 0.01* STMR             | HR                    | 0.01* HR                |
| Maize/corn grains                  | 0.1* EU MRL            | EU MRL                | 0.1* EU MRL             |
| Wheat grains                       | 0.1* EU MRL            | EU MRL                | 0.1* EU MRL             |
| Bovine meat                        | 0.05* 0.8 × STMR muscle + 0.2 × STMR fat (tentative) | 0.05* 0.8 × HR muscle + 0.2 × HR fat (tentative) |
| Bovine fat tissue                  | 0.05* STMR (tentative) | HR (tentative)        | 0.05* HR (tentative)    |
| Bovine liver                       | 0.05* STMR (tentative) | HR (tentative)        | 0.05* HR (tentative)    |
| Bovine kidney                      | 0.05* STMR (tentative) | HR (tentative)        | 0.05* HR (tentative)    |
| Sheep meat                         | 0.05* 0.8 × STMR muscle + 0.2 × STMR fat (tentative) | 0.05* 0.8 × HR muscle + 0.2 × HR fat (tentative) |
| Sheep fat tissue                   | 0.05* STMR (tentative) | HR (tentative)        | 0.05* HR (tentative)    |
| Sheep liver                        | 0.05* STMR (tentative) | HR (tentative)        | 0.05* HR (tentative)    |
| Sheep kidney                       | 0.05* STMR (tentative) | HR (tentative)        | 0.05* HR (tentative)    |
| Goat meat                          | 0.05* 0.8 × STMR muscle + 0.2 × STMR fat (tentative) | 0.05* 0.8 × HR muscle + 0.2 × HR fat (tentative) |
| Goat fat tissue                    | 0.05* STMR (tentative) | HR (tentative)        | 0.05* HR (tentative)    |
| Commodity          | Chronic risk assessment | Acute risk assessment |
|-------------------|-------------------------|-----------------------|
|                   | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Goat liver        | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Goat kidney       | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Equine meat       | 0.05*                   | 0.8 × STMR muscle + 0.2 × STMR fat (tentative) | 0.05*               | 0.8 × HR muscle + 0.2 × HR fat (tentative) |
| Equine fat tissue | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Equine liver      | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Equine kidney     | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Goat milk         | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |
| Sheep milk        | 0.05*                   | STMR (tentative)      | 0.05*               | HR (tentative)        |

STMR: supervised trials median residue; HR: highest residue.
*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg DM in EU?
  - No
  - MRL derived in Section 3?
    - No
    - MRL fully supported by data?
      - No
      - MRL is recommended.
    - Yes
      - Median/highest values are included in the RA.
  - Yes
    - MRL derived in Section 3?
      - No
      - MRL fully supported by data?
        - No
        - MRL is recommended.
        - Yes
        - Tentative median/highest values are included in the RA.
      - Yes
        - Tentative median/highest values are included in the RA.

Consumer risk assessment for GAPs evaluated at EU level - EU scenarios

- Risk identified?
  - Yes
    - Median/highest values are included in the RA.
  - No
    - Not considered for the RA.

- Fall-back MRL available?
  - Yes
    - Median/highest values are included in the RA.
  - No
    - Fall-back MRL available?
      - Yes
        - Median/highest values are included in the RA.
      - No
        - Fall-back MRL is recommended.

Recommendations resulting from EU authorisations and import tolerances

- (A) Specific LOQ or default MRL?
  - No
    - (B) Specific LOQ or default MRL?
      - No
        - (C) Maintain current EU MRL?
          - No
            - (D) Specific LOQ or default MRL?
              - No
                - (E) Establish tentative EU MRL?
                  - No
                    - (F) Specific LOQ or default MRL?
                      - No
                        - (G) MRL is recommended.
                      - Yes
                        - Comparison with CXLs
                    - Yes
                      - Median/highest values are included in the RA.
                  - Yes
                    - Recommendations resulting from EU authorisations and import tolerances
                - Yes
                  - Tentative median/highest values are included in the RA.
              - Yes
                - Tentative median/highest values are included in the RA.
          - Yes
            - Tentative median/highest values are included in the RA.
        - Yes
          - Tentative median/highest values are included in the RA.
      - No
        - Fall-back MRL available?
          - Yes
            - Median/highest values are included in the RA.
          - No
            - Fall-back MRL available?
              - Yes
                - Median/highest values are included in the RA.
              - No
                - Fall-back MRL is recommended.

- No
  - (A) Specific LOQ or default MRL?
    - No
      - (B) Specific LOQ or default MRL?
        - No
          - (C) Maintain current EU MRL?
            - No
              - (D) Specific LOQ or default MRL?
                - No
                  - (E) Establish tentative EU MRL?
                    - No
                      - (F) Specific LOQ or default MRL?
                        - No
                          - (G) MRL is recommended.
                        - Yes
                          - Comparison with CXLs
                      - Yes
                        - Median/highest values are included in the RA.
                    - Yes
                      - Tentative median/highest values are included in the RA.
                - Yes
                  - Tentative median/highest values are included in the RA.
            - Yes
              - Tentative median/highest values are included in the RA.
        - Yes
          - Tentative median/highest values are included in the RA.
    - Yes
      - Tentative median/highest values are included in the RA.
  - Yes
    - Tentative median/highest values are included in the RA.
Review of the existing MRLs for flurochloridone

Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes
            - Maintain EU recommendation indicating that no CXL is available.
          - No
        - No
          - Maintain EU recommendation indicating CXL is not compatible.
      - No
        - Maintain EU recommendation indicating that CXL is covered.
  - No
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes
            - Maintain EU recommendation indicating CXL is not compatible.
          - No
        - No
          - Maintain EU recommendation indicating that CXL is covered.
      - No
        - Maintain EU recommendation indicating CXL is not safe for consumer.

Consumer risk assessment with consideration of the existing CXL

- CXL supported by data?
  - Yes
    - CXL is included in the RA.
      - Risk identified?
        - Yes
          - Maintain EU recommendation indicating that no CXL is available.
        - No
          - Maintain EU recommendation indicating CXL is not compatible.
    - No
      - Risk identified?
        - Yes
          - Maintain EU recommendation indicating that no CXL is available.
        - No
          - Maintain EU recommendation indicating CXL is not compatible.

Recommendations with consideration of the existing CXL

- Maintain current CXL or EU recommendation?
  - Yes
    - Maintain EU recommendation: higher CXL is not safe for consumer.
  - No
    - Maintain EU recommendation: higher CXL is not safe for consumer.

- CXL is recommended; EU recommendation is covered as well.
## Appendix F – Used compound codes

| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|-------------------|--------------------------------|-------------------|
| Flurochloridone   | (3RS,4RS;3RS,4SR)-3-chloro-4-chloromethyl-1-(α,α,α-trifluoro-m-toly)-2-pyrrolidone | ![Structural formula](image1) |
|                   | FC(F)(F)c1ccc(c1)N2CC(CCl)C(Cl)C2=O | ![Structural formula](image2) |
| trans Isomers     | (3R,4R)-3-chloro-4-chloromethyl-1-(α,α,α-trifluoro-m-toly)-2-pyrrolidone | ![Structural formula](image3) |
|                   | FC(F)(F)c1ccc(c1)N2[C@H][CCl][C@H]C(C)C2=O | ![Structural formula](image4) |
|                   | (3S,4S)-3-chloro-4-chloromethyl-1-(α,α,α-trifluoro-m-toly)-2-pyrrolidone | ![Structural formula](image5) |
|                   | FC(F)(F)c1ccc(c1)N2[C@H][CCl][C@H]C(Cl)C2=O | ![Structural formula](image6) |
| cis Isomers       | (3R,4S)-3-chloro-4-chloromethyl-1-(α,α,α-trifluoro-m-toly)-2-pyrrolidone | ![Structural formula](image7) |
|                   | FC(F)(F)c1ccc(c1)N2[C@H][C[C@@H]C](Cl)C2=O | ![Structural formula](image8) |
|                   | (3S,4R)-3-chloro-4-chloromethyl-1-(α,α,α-trifluoro-m-toly)-2-pyrrolidone | ![Structural formula](image9) |
|                   | FC(F)(F)c1ccc(c1)N2[C@H][C[C@@H]C]C(Cl)C2=O | ![Structural formula](image10) |
| mono de-hydrogen chloride flurochloridone (M1a) | 4-(choloromethyl)-1-[3-(trifluoromethyl)phenyl]-1,5-dihydro-2H-pyrrol-2-one | ![Structural formula](image11) |
|                   | FC(F)(F)c1ccc(c1)N2CC(=CC2=O)Cl | ![Structural formula](image12) |
|                   | or (3RS)-3-chloro-4-methylidene-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one | ![Structural formula](image13) |
|                   | FC(F)(F)c1ccc(c1)N2CC(=C(C)O)C2=O | ![Structural formula](image14) |
| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|------------------|--------------------------------|--------------------|
| oxidative       | (3RS,4RS)-4-(chloromethyl)-3-hydroxy-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one<br>FC(F)(F)c1cccc(c1)N2CC(CCl)C(O)C2=O or (3RS,4RS)-3-chloro-4-(hydroxymethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one<br>FC(F)(F)c1cccc(c1)N2CC(CO)C(Cl)C2=O | ![Structural formula image 1](image1.png) |
| de-chlorinated   |                             | ![Structural formula image 2](image2.png) |
| flurochloridone  |                             | ![Structural formula image 3](image3.png) |
| (M1b)            |                             | ![Structural formula image 4](image4.png) |
|                   | (4RS)-4-(hydroxymethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidine-2,3-dione<br>FC(F)(F)c1cccc(c1)N2CC(CO)=O C2=O or (3RS,4RS)-4-hydroxy-5-oxo-1-[3-(trifluoromethyl)phenyl]pyrrolidine-3-carbaldehyde<br>FC(F)(F)c1cccc(c1)N2CC(C=O)C(O)C2=O | ![Structural formula image 5](image5.png) |
|                  | (3RS,4RS)-3-chloro-4-(hydroxymethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidine-2,5-dione<br>FC(F)(F)c1cccc(c1)N2CC(=O)C(CO)C(Cl)C2=O or (3RS,4RS)-3-(chloromethyl)-4-hydroxy-1-[3-(trifluoromethyl)phenyl]pyrrolidine-2,5-dione<br>FC(F)(F)c1cccc(c1)N2CC(=O)C(CCl)C(O)C2=O | ![Structural formula image 6](image6.png) |
|                  | (3RS,4RS)-3-chloro-4-(hydroxymethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidine-2,5-dione<br>FC(F)(F)c1cccc(c1)N2CC(=O)C(CO)C(Cl)C2=O or (3RS,4RS)-3-(chloromethyl)-4-hydroxy-1-[3-(trifluoromethyl)phenyl]pyrrolidine-2,5-dione<br>FC(F)(F)c1cccc(c1)N2CC(=O)C(CCl)C(O)C2=O | ![Structural formula image 7](image7.png) |

SMILES: simplified molecular-input line-entry system.