**Flurtamone**

SANTE/11585/2016 Rev 3
24 October 2018

**Final Renewal report for the active substance flurtamone**
finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 24 October 2018
in view of the non-renewal of the approval of flurtamone as active substance
in accordance with Regulation (EC) No 1107/2009

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1. **Procedure followed for the re-evaluation process**

This renewal report has been established as a result of the evaluation of **flurtamone**, in accordance with Regulation (EC) No 1107/2009 and Commission Implementing Regulation (EU) No 844/2012 following the submission of an application to renew the approval of this active substance expiring in October 2018.


An application for renewal of the approval of flurtamone was submitted by Bayer CropScience AG in accordance with Article 1 of Regulation 844/2012.

Commission Implementing Regulation 2016/950 extended until 31 October 2017 the period of approval of flurtamone to allow the completion of its review.

Commission Implementing Regulation 2017/1511 extended until 31 October 2018 the period of approval of flurtamone to allow the completion of its review.

Commission Implementing Regulation 2018/1262 extended until 31 October 2019 the period of approval of flurtamone to allow the completion of its review.

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1. Renewal report established in accordance with Article 14 of Regulation (EU) No 844/2012; does not necessarily represent the views of the European Commission.
Commission Implementing Regulation (EU) No 686/2012\(^9\) designated the rapporteur Member States and the co-rapporteur Member States which had to submit the relevant renewal assessment reports and recommendations to the European Food Safety Authority (EFSA).

For flurtamone the rapporteur Member State was Czech Republic and the co-rapporteur Member State was Ireland.

Czech Republic finalised in May 2015 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and the European Food Safety Authority on 29 May 2015 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of flurtamone for the supported uses.

In accordance with Article 13 of Implementing Regulation (EU) No 844/2012, the EFSA organised an intensive consultation of technical experts from Member States, to review the renewal assessment report and the comments received thereon (peer review).

The EFSA sent to the Commission its conclusion on the risk assessment (Conclusions regarding the peer review of the pesticide risk assessment of the active substance)\(^10\) on 13 May 2016. Following a mandate\(^11\) to EFSA from the European Commission an updated Conclusion was sent to the Commission on 10 August 2017\(^12\). This conclusion refers to several background documents: the renewal assessment report including its addendum and the peer review report.

According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report to the Standing Committee on Plants, Animals, Food and Feed, for examination on 7 October 2016. The draft renewal report was finalised in the meeting of the Standing Committee on 20 July 2018.

The present renewal report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and its background documents, these documents are also considered to be part of this renewal report.

2. Purposes of this renewal report

This renewal report, including the background documents has been developed and finalised in support of Commission Implementing Regulation (EU) 2018/1917\(^13\) concerning the non-renewal of approval of flurtamone as active substance under Regulation (EC) No 1107/2009.

This renewal report will be made available to the public.

The information in this renewal report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this renewal report would not be accepted to support any registration

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outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this renewal report is based.

3. **Overall conclusion in the context of Regulation (EC) No 1107/2009**

As part of the updated evaluation of flurtamone reference values could not be established as a mutagenic potential of flurtamone has not been excluded. However, the experts considered the possible values that could apply if a mutagenic potential was excluded. These are provided for completeness below:

- **ADI**: 0.03 mg/kg bw per day - provisional pending the exclusion of mutagenic potential of flurtamone;
- **ARfd**: 0.5 mg/kg bw - provisional pending the exclusion of mutagenic potential of flurtamone;
- **AOEL**: 0.05 mg/kg bw per day - provisional pending the exclusion of mutagenic potential of flurtamone;
- **AAOEL**: 0.17 mg/kg bw - provisional pending the exclusion of mutagenic potential of flurtamone.

To note, during the first EU review of flurtamone an ADI of 0.03 mg/kg bw per day and an AOEL of 0.02 mg/kg bw per day were established. An ARfd and AAOEL were not considered necessary at that time.

The overall conclusion of this evaluation, based on the information available and the proposed conditions of use, is that:

- **the information available indicates that the approval criteria** as set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009 are not satisfied as concerns were identified with regards to:
  - Health-based reference values could not be set for flurtamone as a mutagenic potential of flurtamone has not been excluded;
  - The consumer and the non-dietary risk assessments cannot be conducted as health-based reference values could not be established.

- **the information available is insufficient** to satisfy the requirements set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009, in particular with regard to:
  - The metabolite TFA (trifluoroacetic acid) is predicted to be present in groundwater at concentrations exceeding 0.1 μg/L in all the relevant FOCUS groundwater scenarios. In fact the predicted levels of TFA are above 0.75 μg/L in all scenarios (in the range of 3.62-22.13 μg/L). Based on the studies assessed EFSA suggested that flurtamone should be classified as a category 2 carcinogen, however, a harmonised classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council\(^\text{14}\) does not currently exist for carcinogenicity. The presence of this metabolite in groundwater is therefore of concern since it has not been demonstrated that

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it does not share the same intrinsic properties as flurtamone. Therefore it cannot currently be established that the presence of the metabolite in groundwater will not result in unacceptable effects on groundwater or in harmful effects on human health; furthermore, the risk to consumers from total exposure to TFA cannot be concluded due to data gaps identified in the residues area – see below;

- The endocrine disrupting potential of flurtamone. Flurtamone does meet the conditions listed in Annex II, Point 3.6.5 of Regulation (EU) No 1107/2009 to be considered an endocrine disruptor, however, with regards to the screening of endocrine-disrupting properties for flurtamone, as sensitive end points were not all addressed in the original studies submitted, further investigations are required according to the OECD Conceptual Framework (OECD, 2012) and the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors (EFSA Scientific Committee, 2013);

- The consumer risk assessment cannot be finalised with regard to flurtamone and the major plant metabolite TFA included in the residue definition for risk assessment considering the incomplete toxicological data package for flurtamone and the identified data gaps with regards to TFA in the area of residues;

- For some scenarios a high risk to aquatic organisms was identified (5 out of 9 FOCUS scenarios).

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

The approval of flurtamone in accordance with Regulation (EC) No 1107/2009 should therefore not be renewed.