COMMISSION STAFF WORKING DOCUMENT

Linuron
SANTE/10944/2016 Rev 1
7 December 2016

Final
Renewal report for the active substance linuron
finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 7 December 2016
in view of the non-renewal of the approval of linuron as active substance in accordance with Regulation (EC) No 1107/2009

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the evaluation of linuron, 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 July 2017.


An application for renewal of the approval of linuron was submitted by Adama Agriculture B.V. in accordance with Article 1 of Regulation 844/2012.

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

Commission Implementing Regulation (EU) No 686/2012 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).

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1. Does not necessarily represent the views of the Commission services.
4. OJ L 101, 24.4.2003, p. 3 - 9
For linuron the rapporteur Member State was Italy and the co-rapporteur Member State was Germany. Italy finalised in April 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 15 April 2015 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of linuron 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)\(^8\) on 11 February 2016. This conclusion refers to background document A (final revised version of the renewal assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 12 July 2016. The draft renewal report was finalised in the meeting of the Standing Committee on 7 December 2016.

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 the comments and clarifications submitted after the conclusion of the EFSA, these documents are also considered to be part of this review report.

### 2. Purposes of this review report

This renewal report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Implementing Regulation (EU) 2017/244\(^9\) concerning the non-renewal of approval of linuron as active substance under Regulation (EC) No 1107/2009.

This review report will be made available to the public.

The information in this review 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 review report would not be accepted to support any registration 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 review report is based.

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

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:

  - Linuron is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008\(^{10}\). Child resident exposure is above the AOEL for the proposed uses. To demonstrate negligible exposure of humans to the substance under realistic proposed conditions of use, exposure cannot be above the AOEL, therefore use of linuron under realistic proposed conditions of use so that exposure of humans to the substance is negligible, is excluded. In addition, a further requirement to demonstrate negligible exposure is that residues of the active substance shall not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005. A Maximum Residue Level could not be derived from the available data for the proposed use of linuron, however, the available residue trial data for the proposed uses indicate that residues of linuron above the default value would be expected and therefore this condition is not fulfilled. Based on these considerations, the requirements set out in Point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 are not fulfilled.

  - Furthermore, in addition to the classification of linuron as toxic for reproduction category 1B, linuron is also classified as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008 and therefore shall be considered to have endocrine disrupting properties in accordance with the third paragraph of Point 3.6.5 of Annex II to Regulation (EC) No 1107/2009. In addition, the available scientific evidence shows that linuron has endocrine disrupting properties that may cause adverse effects on endocrine organs in humans and non-target organisms. Negligible exposure of humans to linuron under realistic conditions of use is excluded for the reasons above. Based on these considerations, the requirements set out in the first paragraph of Point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 are not fulfilled.

  - Child resident exposure is above the AOEL.

  - Operator exposure considering hand held sprayer application outdoors to low crops is above the Acceptable Operator Exposure Level (AOEL) even with the use of personal protective equipment.

  - A high risk was identified for birds, mammals, non-target arthropods and soil macro-organisms (except earthworms).

- **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 basis for setting an Acute Reference Dose (ARfD) could not be established since developmental endpoints from an additional rabbit study not submitted during the peer review might be more critical compared to available developmental toxicity study in rabbits.

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- The consumer risk assessment could not be finalised due to a number of deficiencies in the data package, as follows:
  - the toxicological profile of the metabolite 3,4-dichloroaniline formed under all processing conditions could not be defined;
  - the metabolic profile of linuron in roots could not be elucidated;
  - an MRL for carrots could not be derived;
  - an ARfD could not be derived so no acute consumer risk assessment was possible.
- The consumer risk assessment from consumption of drinking water could not be finalised whilst the nature of residues in drinking water following water treatment had not been addressed.
- Environmental exposure assessment could not be finalised for soil, aquatic and groundwater compartments due to the lack of reliable information on the route and rate of degradation of linuron in soil and other data gaps identified to complete the necessary information for fate and behaviour in the environment.
- The aquatic risk assessment could not be finalised.
- The risk assessment for non-target terrestrial plants could not be finalised.

The applicant submitted comments related to the endocrine disrupting properties of linuron, stating that they believe the effects seen in rodents are not relevant for humans and that there are no endocrine adverse effects in birds and fish. During the peer review of the assessment of linuron, experts from Member States and EFSA discussed whether linuron has endocrine disrupting properties and concluded that the available scientific evidence shows that linuron is antiandrogenic and has adverse effects on different endocrine organs at the lowest doses tested. It was concluded that there was human relevance for the effects seen.

Furthermore, there were indications from open literature that linuron possess anti-androgenic properties in fish and in birds.

Therefore the concern that linuron has endocrine disrupting properties that may cause adverse effects on endocrine organs in humans and non-target organisms remains based on the information and assessment available.

It must be also be reiterated that linuron shall be considered to have endocrine disrupting properties based on its harmonised classification as toxic for reproduction category 1B and carcinogenic category 2 in accordance with the legally applicable interim criteria as laid down in the third paragraph of Point 3.6.5 of Annex II to Regulation (EC) No 1107/2009.

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 linuron in accordance with Regulation (EC) No 1107/2009 should therefore not be renewed.