EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the non-renewal of approval of the active substance linuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2003/31/EC[2] included linuron as active substance in Annex I to Council Directive 91/414/EEC[3].

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[4].

(3) The approval of the active substance linuron, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2017.

(4) An application for the renewal of the approval of linuron was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[5] within the time period provided for in that Article.

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1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2003/31/EC of 11 April 2003 amending Council Directive 91/414/EEC to include 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide and pendimethalin as active substances (OJ L 101, 23.4.2003, p. 3).

3 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).

4 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 amending 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).

5 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 15 April 2015.

(7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(8) On 8 June 2016 the Authority communicated to the Commission its conclusion[6] on whether linuron can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. Specific concerns were identified, in particular, child resident exposure is above the toxicological reference value ('AOEL') and operator exposure considering handheld sprayer application is also in exceedance of the AOEL even when personal protective equipment is used. Furthermore, a high risk to birds and wild mammals, non-target arthropods and non-target soil macro-organisms was identified. The consumer risk assesment could not be finalised due to a number of serious deficiencies in the data package. In addition, the exposure and risk assessment for several environmental compartments including groundwater could also not be finalised.

(9) Linuron is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008[7]. 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.

(10) 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 detailed in

[6] EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance linuron. EFSA Journal 2016;14(2):4406, 173 pp. doi:10.2903/j.efsa.2016.4406. Available online: www.efsa.europa.eu.

[7] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 **(**OJ L 353, 31.12.2008, p. 1).

recital 9. 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.

(11) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with third paragraph of Article 14 of Implementing Regulation (EC) No 844/2012, the Commission invited the applicant to submit comments on the renewal report. The applicant submitted its comments, which have been carefully examined.

(12) However, despite the arguments put forward by the applicant, the concerns related to the substance could not be eliminated.

(13) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 are satisfied. The approval of the active substance linuron should therefore not be renewed.

(14) Commission Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(15) Member States should be provided with time to withdraw authorisations for plant protection products containing linuron.

(16) For plant protection products containing linuron, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on *[insert date 15 months from the date of entry into force]*.

(17) Commission Implementing Regulation (EU) 2016/950[8] extended the expiry date of linuron to 31 July 2017 in order to allow the renewal process to be completed before the expiry of the approval of that substance. Given that a decision is taken ahead of this extended expiry date, this Regulation should apply as soon as possible.

(18) This Regulation does not prejudice the submission of a further application for the approval of linuron in accordance with Article 7 of Regulation (EC) No 1107/2009.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Non-renewal of approval of active substance

The approval of the active substance linuron is not renewed.

[8] Commission Implementing Regulation (EU) 2016/950 of 15 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-DB, beta-cyfluthrin, carfentrazone ethyl, *Coniothyrium minitans* Strain CON/M/91-08 (DSM 9660), cyazofamid, deltamethrin, dimethenamid-P, ethofumesate, fenamidone, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mesotrione, oxasulfuron, pendimethalin, picoxystrobin, silthiofam and trifloxystrobin (OJ L 159, 16.6.2016, p. 3).

Article 2

Transitional measures

Member States shall withdraw authorisations for plant protection products containing linuron as active substance by [*Office of Publications please insert date 3 months from the date of entry into force*] at the latest.

Article 3

Grace Period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by *[insert date 15 months from the date of entry into force]* at the latest.

Article 4

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 51, on linuron, is deleted.

Article 5

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER