Commission Implementing Regulation (EU) 2016/871 of 1 June 2016 concerning the non-renewal of approval of the active substance amitrole, 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 Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/871

of 1 June 2016

concerning the non-renewal of approval of the active substance amitrole, 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 Commission Implementing Regulation (EU) No 540/2011

(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 2001/21/EC[(2)] included amitrole 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 amitrole, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 June 2016.

(4) An application for the renewal of the inclusion of amitrole in Annex I to Directive 91/414/EEC was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010[(5)] within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. 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 2 April 2014.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/871. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(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 19 June 2014 the Authority communicated to the Commission its conclusion[6] on whether amitrole can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority concluded that there is a high potential for the representative uses assessed to result in groundwater exposure above the parametric drinking water limit of 0,1 μg/l by a relevant metabolite of amitrole in situations represented by all pertinent groundwater scenarios. In addition, a high risk to operators, workers and bystanders from the use of amitrole was identified.

(9) Based on these identified risks, 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 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of amitrole in accordance with Article 20(1)(b) of Regulation (EC) No 1107/2009.

(10) Additionally, amitrole is classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[7] as toxic for reproduction category 2 and it has toxic effects on endocrine organs. Therefore, and taking into account the conclusion of the Authority, amitrole should be considered to have endocrine disrupting properties pursuant to the interim provisions of the fourth paragraph of point 3.6.5 of Annex II to Regulation (EC) No 1107/2009. However, given that the identified risks referred to in recital 8 preclude approval of amitrole, it was not appropriate to consider whether exposure to amitrole under realistic proposed conditions of use is negligible. Therefore, it could not be concluded whether amitrole meets the approval criteria related to endocrine disrupting properties as outlined in the first paragraph of point 3.6.5 of Annex II to Regulation (EC) No 1107/2009.

(11) Furthermore, in the conclusion of the Authority, it is indicated that during the peer review it was proposed that amitrole should be re-classified as toxic for reproduction category 1B.

(12) Given the concerns detailed in recital 8, the derogation provided for in Article 4(7) to Regulation (EC) No 1107/2009 does not apply. The application of that derogation is also excluded on the grounds that it has not been established that any of the criteria set out in point 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are not satisfied.

(13) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 17(1) of Regulation (EU) No 1141/2010, on the draft review report. The applicant submitted its comments, which have been carefully examined.

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

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/871. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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

(16) For plant protection products containing amitrole, 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 30 September 2017.

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

(18) 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 amitrole is not renewed.

Article 2

Transitional measures

Member States shall withdraw authorisations for plant protection products containing amitrole as active substance by 30 September 2016.

Article 3

Grace periods

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 on 30 September 2017 at the latest.

Article 4

Amendments to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 14 on amitrole is deleted.

Article 5

Entry into force

This Regulation shall enter into force on 1 July 2016.