EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the non-renewal of approval of the active substance fenamidone, 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)

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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 2003/68/EC[2] included fenamidone as an 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 fenamidone, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2018.

(4) An application for the renewal of the approval of fenamidone 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.

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

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1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2003/68/EC of 11 July 2003 amending Council Directive 91/414/EEC to include trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone and isoxaflutole as active substances (OJ L 177, 16.7.2003, p. 12).

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 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).

(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 ('the Authority') and the Commission on 12 February 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 11 February 2016 the Authority communicated to the Commission its conclusion[6] on whether fenamidone can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Autority identified specific concerns. In particular, it was not possible to conclude on the genotoxic potential of fenamidone and no health-based reference values could be set. Consequently, the consumer and non-dietary risk asessements could not be conducted. Furthermore, a high potential for groundwater contamination above the parametric drinking water limit of 0.1 μg/L by a toxicologically relevant metabolite (RPA 412708) was indicated in all pertinent scenarios for crops grown in soils of predominantly pH 7 or above. In addition, the Authority concluded that the consumer risk assessment for exposure to another groundwater metabolite (RPA 412636) which is also found in food of plant and animal origin could not be finalised. Furtermore, the residue definitions for risk assessment in plant and livestock commodities are not finalised in terms of the inclusion of potentially relevant metabolites. Finally, the Authority concluded that the risk assessment for wild mammals could not be finalised and a high risk to aquatic organisms from exposure to the metabolite acetophone could not be excluded based on the available information.

(10) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EC) No 844/2012, the Commission invited the applicant to submit comments on the draft renewal report. The applicant submitted its comments, which have been carefully examined.

(11) However, despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.

(12) 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 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance fenamidone in accordance with Article 20(1)(b) of that Regulation.

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

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

(15) For plant protection products containing fenamidone, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that

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

period should, at the latest, expire on *[Office of Publications please insert date 15 months from the date of entry into force]*.

(16) Commission Implementing Regulation (EU) 2017/841[7] extended the expiry date of fenamidone to 31 July 2018 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision is taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

(17) This Regulation does not prevent the submission of a further application for the approval of fenamidone pursuant to 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 fenamidone is not renewed.

Article 2
Amendments to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 62, on fenamidone, is deleted.

Article 3
Transitional measures

Member States shall withdraw authorisations for plant protection products containing fenamidone as active substance by [*Office of Publications please insert date 6 months from the date of entry into force*] at the latest.

[7] Commission Implementing Regulation (EU) 2017/841 of 17 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, Ampelomyces quisqualis strain: aq 10, benalaxyl, bentazone, bifenazate, bromoxynil, carfentrazone ethyl, chlorpropham, cyazofamid, desmedipham, diquat, DPX KE 459 (flupyrsulfuron-methyl), etoxazole, famoxadone, fenamidone, flumioxazine, foramsulfuron, Gliocladium catenulatum strain: j1446, imazamox, imazosulfuron, isoxaflutole, laminarin, metalaxyl-m, methoxyfenozide, milbemectin, oxasulfuron, pendimethalin, phenmedipham, pymetrozine, s-metolachlor, and trifloxystrobin. (OJ L 125, 18.5.2017, p. 12.).

Article 4
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 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