EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10424/2020
[…](2020) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance fenpyrazamine

(Text with EEA relevance)

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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 the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 595/2012[2] approved fenpyrazamine as an active substance in accordance with Regulation (EC) No 1107/2009 subject to certain conditions, requiring, in particular, the examining Member State to inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.

(2) In December 2013, the applicant submitted an updated dossier intended to provide the information on specification of the technical material as commercially manufactured to the rapporteur Member State Austria within the time period provided for its submission. The updated dossier was evaluated by the rapporteur Member State in the form of an Addendum to the Draft Assessment Report.

(3) On 23 April 2014, Austria distributed the addendum to the Member States, the applicant and the European Food Safety Authority ('the Authority') for comments, collated together with all comments in the format of a reporting table, which was submitted to the Authority on 7 July 2014. The Authority added its scientific views on the specific points raised during the commenting phase in the reporting table.

(4) On 13 August 2014, the Authority published a technical report[3] summarising the outcome of this consultation process for fenpyrazamine.

(5) The draft assessment report, the addendum and the technical report were reviewed by the Member States and the Commission within the Standing Committee on Plants,

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1 OJ L 309, 24.11.2009, p. 1.

2 Commission Implementing Regulation (EU) No 595/2012 of 5 July 2012 approving the active substance fenpyrazamine, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 176, 6.7.2012, p. 46).

3 EFSA (European Food Safety Authority), 2015. Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment of confirmatory data for the active substance fenpyrazamine. EFSA supporting publication 2014:EN-630.

Animals, Food and Feed and finalised on 18 May 2020 in the format of the Commission review report for fenpyrazamine.

(6) The Commission invited the applicant to submit its comments on the Commission review report for fenpyrazamine.

(7) In its review report the Commission considered that the technical specification proposed in the approval of fenpyrazamine needs to be changed from pilot to commercial production. The impurity hydrazine, a starting material, has been identified during the assessment as a relevant impurity, since it was detected in the reanalysed pilot plant batches as well as in the commercial plant batches. Bearing in mind that the relevant impurity hydrazine is of toxicological concern, the Commission has concluded that a maximum content of this impurity in the technical material should not exceed 0.0001% (1 mg/kg).

(8) In order to ensure a high level of protection for consumers it is, therefore, appropriate to establish a maximum level for this impurity in the commercially manufactured active substance.

(9) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(10) Member States should be allowed sufficient time to amend or withdraw authorisations for plant protection products containing fenpyrazamine, which are not complying with the specification of the technical material as commercially manufactured and the restricted conditions of approval.

(11) For plant protection products containing fenpyrazamine, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should expire, at the latest, 15 months after the entry into force of this Regulation.

(12) 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
Amendment to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2
Transitional measures

Member States shall, where necessary, amend or withdraw existing authorisations for plant protection products containing fenpyrazamine 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 *[Office of Publications please insert date 15 months from the date of entry into force]* at the latest.

Article 4
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
Ursula VON DER LEYEN