EUROPEAN
COMMISSION

Brussels, XXX
SANTE/00102/2015 Rev 1
[…](2018) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the non-renewal of approval of the active substance pymetrozine, 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 2001 /87/EC[2] included pymetrozine 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 pymetrozine, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 June 2018.

(4) An application for the renewal of the approval of pymetrozine 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 2001/87/EC of 12 October 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine and pyraflufen-ethyl as active substances **(**OJ L 276, 19.10.2001, p. 17).

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).

(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 28 June 2013.

(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 28 August 2014 the Authority communicated to the Commission its conclusion[6] on whether pymetrozine 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 the toxicologically relevant metabolite CGA371075 in all pertinent groundwater scenarios. The Authority further concluded that several other toxicologically relevant metabolites of pymetrozine are also predicted to occur above 0.1 μg/L in some or all pertinent groundwater scenarios for the representative uses evaluated. It also concluded that the toxicological profile of metabolites included in the plant residue definition for risk assessment could not be confirmed based and that the assessment of the risk to aquatic organisms from exposure to metabolite M3MF could not be finalised for all representative uses considered based on the information available in the dossier.

(9) In addition, pymetrozine is classified as carcinogen category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[7], while in the conclusion of the Authority it is indicated that pymetrozine is also to be classified as toxic for reproduction category 2. Moreover, on 30 May 2017 the rapporteur Member State submitted a dossier with a proposal for harmonised classification of pymetrozine in accordance with Article 37 of Regulation (EC) No 1272/2008. It proposed to have a classification in category 2 for the hazard class on reproductive toxicity and to maintain the classification in category 2 for the hazard class on carcinogenicity.Therefore pymetrozine shall be considered to have endocrine disrupting properties in accordance with the interim criteria set out in the third subparagraph of point 3.6.5 of Annex II to Regulation (EC) No 1107/2009. Moreover, pymetrozine caused adverse effects on endocrine organs across different species and timelines, however, the scientific assessment for potential endocrine disruption properties of pymetrozine could not be finalised based on the information available in the dossier. Given the concerns mentioned in recital 8, a conclusion on whether the requirements set out in Point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 with respect to negligible exposure are satisfied or not was not considered necessary.

(10) Given the concerns mentioned in recital 8, the derogation provided for in Article 4(7) of Regulation (EC) No 1107/2009 cannot apply. The application of that derogation is also excluded as it has not been established that any of the criteria set out in points 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.

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6 EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance pymetrozine. EFSA Journal 2014;12(9):3817, 102 pp. doi:10.2903/j.efsa.2014.3817.

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).

(11) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1) of Implementing Regulation (EC) No 844/2012, on the draft 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 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance pymetrozine in accordance with Article 20(1)(b) of that Regulation.

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

(15) Member States should be allowed sufficient time to withdraw authorisations for plant protection products containing pymetrozine.

(16) For plant protection products containing pymetrozine, 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 *[Office of Publications please insert date 15 months from the date of entry into force]*.

(17) This Regulation does not prevent the submission of a further application for the approval of pymetrozine 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 pymetrozine 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 23, on pymetrozine, is deleted.

Article 3
Transitional measures

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

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 *[Office of Publications please 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