Commission Implementing Regulation (EU) 2018/1501 of 9 October 2018 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1501

of 9 October 2018

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)

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 2019.

(4) An application for the renewal of the approval of pymetrozine 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 (‘the Authority’) and the Commission on 28 June 2013.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1501. 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 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 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) Additionally, the Authority concluded that 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 by the Authority based on the information available in the dossier.

(10) 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.

(11) However, despite the arguments put forward by the applicant, the concerns related to the 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 pymetrozine 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 allowed sufficient time to withdraw authorisations for plant protection products containing pymetrozine.

(15) 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 30 January 2020.

(16) Commission Implementing Regulation (EU) 2018/917[(7)] extended the expiry date of pymetrozine to 30 June 2019 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision

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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 pymetrozine pursuant to Article 7 of Regulation (EC) No 1107/2009.

(18) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

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

Amendment 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 30 April 2019 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 30 January 2020.

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.