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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulations (EU) No 540/2011 and (EU) No 820/2011 as regards the conditions of approval of the active substance terbuthylazine

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

Whereas:

(1) Commission Implementing Regulation (EU) No 820/2011[2] provides for the approval of the active substance terbuthylazine and the resulting insertion of terbuthylazine in the Annex to Commission Implementing Regulation (EU) No 540/2011[3].

(2) Implementing Regulation (EU) No 820/2011 also provides for the submission of further confirmatory information on the specification of the technical material, as commercially manufactured including information on the relevance of the impurities, the equivalence between the specifications of the technical material, as commercially manufactured, and the specifications of the test material used in the toxicity studies and the groundwater exposure assessment for the unidentified metabolites LM1, LM2, LM3, LM4, LM5 and LM6.

(3) In addition, Implementing Regulation (EU) No 820/2011 required the applicant to submit confirmatory information as regards the relevance of the metabolites MT1 MT 13, MT14 and of the unidentified metabolites LM1, LM2, LM3, LM4, LM5 and LM6 with respect to cancer, if terbuthylazine was classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council[4] as 'suspected of causing cancer'.

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1 OJ L 309, 24.11.2009, p. 1.

2 Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011 approving the active substance terbuthylazine, 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 and Commission Decision 2008/934/EC (OJ L 209, 17.8.2011, p. 18).

3 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).

4 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).

(4) The applicant submitted additional information within the periods provided for in Implementing Regulation (EU) No 820/2011. With regard to the relevance of specified metabolites of terbuthylazine if terbuthylazine was classified under Regulation (EC) No 1272/2008 as 'suspected of causing cancer', the Risk Assessment Committee of the European Chemicals Agency adopted on 5 June 2015 an opinion[5] confirming that terbuthylazine is not to be classified as 'suspected of causing cancer', rendering the corresponding confirmatory information unnecessary.

(5) The rapporteur Member State, the United Kingdom, assessed the additional information submitted by the applicant. It submitted its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission, and the European Food Safety Authority ('the Authority') on 6 August 2015.

(6) The rapporteur Member State consulted the other Member States, the applicant and the Authority and asked them to provide comments on the addendum to the draft assessment report. The Authority published a technical report[6] summarising the outcome of this consultation for terbuthylazine on 20 January 2016.

(7) Taking into account the assessment of the rapporteur Member State and the technical report the Commission considers that the requirement to submit confirmatory information on the specification of the technical material, as commercially manufactured, including information on the relevance of the impurities, and on the equivalence between the specifications of the technical material, as commercially manufactured, and the specifications of the test material used in the toxicity studies can be considered addressed, provided the currently established maximum levels for the relevant impurities propazine and simazine in the technical material as manufactured are lowered.

(8) The Commission further consulted the Authority in relation to the exposure of groundwater to metabolites of terbuthylazine. The Authority published its updated conclusions on the assessment of the additional information on 29 June 2017[7] and 19 September 2019[8]. The Authority identified a risk to infants and toddlers under some conditions of use from exposure to metabolites of terbuthylazine through food and drinking water, according to the additional information provided by the applicant and based on the use of terbuthylazine at a rate of 850 g/ha each year on the same field. Furthermore, where terbuthylazine is applied every year at a maximum rate of 850 g/ha, two metabolites of terbuthylazine, LM3 and LM6, are predicted to occur in groundwater above 0.75 µg/L in all scenarios, triggering the need for a consumer risk assessment which, however, could not be carried out since health-based reference values could not be derived based on the available data.

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5 Opinion proposing harmonised classification and labelling at EU level of Terbuthylazine (ISO); N-tert-butyl-6-chloro-N'-ethyl-1,3,5-triazine-2,4-diamine EC Number: 227-637-9 CAS Number: 5915-41-3 CLH-O-0000001412-86-66/F.

6 EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for terbuthylazine in light of confirmatory data. EFSA supporting publication 2016:EN-919. 54 pp.

7 EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment for the active substance terbuthylazine in light of confirmatory data submitted. EFSA Journal 2017;15(6):4868, 20 pp. https://doi.org/10.2903/j.efsa.2017.4868

8 EFSA (European Food Safety Authority), 2019. Conclusion on the updated peer review of the pesticide risk assessment for the active substance terbuthylazine in light of confirmatory data submitted. EFSA Journal 2019;17(9):5817, 21 pp. https://doi.org/10.2903/j.efsa.2019.5817

(9) The draft assessment report, the addendum to the draft assessment report and the conclusions of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on XX XXXX 2021 in the format of the updated review report for terbuthylazine.

(10) The applicant was given the possibility to submit comments on the updated review report.

(11) The Commission has concluded that the additional information provided by the applicant is not sufficient to exclude a risk to consumers from exposure to metabolites of terbuthylazine where it is applied every year in the same field at a maximum rate of 850 g/ha.

(12) Therefore, it is necessary and appropriate to restrict the approval of terbuthylazine to use only every third year on the same field at a maximum rate of 850 g/ha. It is also necessary to amend the maximum levels of the relevant impurities propazine and simazine that are permitted in the technical material as commercially manufactured.

(13) Implementing Regulations (EU) No 820/2011 and (EU) No 540/2011 should therefore be amended accordingly.

(14) Member States should be provided with time to withdraw or amend authorisations for plant protection products containing terbuthylazine which do not comply with the restricted conditions of approval.

(15) For plant protection products containing terbuthylazine, 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 12 months after the entry into force of this Regulation.

(16) 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 820/2011

Annex I to Implementing Regulation (EU) No 820/2011 is amended in accordance with Annex I to this Regulation.

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

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

Article 3
Transitional measures

Member States shall, where necessary, withdraw or amend authorisations for plant protection products containing terbuthylazine as an active substance by … [*Office of Publications please insert date 6 months from the date of entry into force*].

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 12 months from the date of entry into force*].

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
Ursula VON DER LEYEN