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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

withdrawing the approval of the active substance isopyrazam 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, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Implementing Regulation (EU) No 1037/2012

(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/EEC¹, and in particular Article 21(3) and Article 78(2) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 1037/2012² approved isopyrazam as an active substance in accordance with Regulation (EC) No 1107/2009 and listed it in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011³.
- (2) On 10 December 2020, the Committee for Risk Assessment of the European Chemicals Agency adopted an opinion⁴ in accordance with Article 37(4) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁵ in which it concluded that isopyrazam meets the criteria to be classified as toxic for reproduction category 1B and carcinogenic category 2.
- (3) Commission Delegated Regulation (EU) **.../...** [*Office of Publications: Please insert in the text the number of the Delegated Regulation and insert the number, date, title*

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Implementing Regulation (EU) No 1037/2012 of 7 November 2012 approving the active substance isopyrazam, 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 308, 8.11.2012, p. 15).

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 Committee for Risk Assessment, Opinion proposing harmonised classification and labelling at EU level of Reaction mass of 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9RS)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide and 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9SR)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide [$>78\%$ *syn* isomers $<15\%$ *anti* isomers relative content]; isopyrazam. EC Number: - CAS Number: 881685-58-1 CLH-O-0000006915-65-01/F, adopted on 10 December 2020.

⁵ 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).

and OJ reference of that Regulation in the footnote]⁶ consequently amended Annex VI to Regulation (EC) No 1272/2008 and classified isopyrazam as toxic for reproduction category 1B.

- (4) Under point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 an active substance is only to be approved if it is not or has not to be classified in accordance with the provisions of Regulation (EC) No 1272/2008 as toxic for reproduction category 1B, unless the exposure of humans to that substance in a plant protection product under realistic proposed conditions of use is negligible.
- (5) For the representative uses of isopyrazam, residues of isopyrazam on food and feed exceed the default value within the meaning of Article 18(1), point (b), of Regulation (EC) No 396/2005, therefore the condition of negligible exposure with respect to dietary exposure is not met.
- (6) Consequently, isopyrazam no longer fulfils the criterion for approval laid down in point 3.6.4 of Annex II to Regulation (EC) No 1107/2009.
- (7) In accordance with Article 21(1) of Regulation (EC) No 1107/2009, the Commission informed the Member States, the European Food Safety Authority and the applicant that it considered the approval criterion laid down in point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 may no longer be met given that isopyrazam meets the criteria to be classified as toxic for reproduction category 1B and invited the applicant to submit its comments.
- (8) The applicant neither provided any information to demonstrate negligible exposure nor any evidence that the conditions of Article 4(7) of Regulation (EC) No 1107/2009, concerning substances which are needed to control a serious danger to plant health that cannot be contained by other available means, are fulfilled.
- (9) Consequently, it is appropriate to withdraw the approval of isopyrazam.
- (10) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly and Implementing Regulation (EU) No 1037/2012 should be repealed.
- (11) Member States should be provided with sufficient time to withdraw authorisations for plant protection products containing isopyrazam.
- (12) For plant protection products containing isopyrazam, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should be as short as possible and expire no later than 6 months from the date of entry into force of this Regulation.
- (13) This Regulation does not prevent the submission of a further application for the approval of isopyrazam pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (14) 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
Withdrawal of approval

The approval of the active substance isopyrazam is withdrawn.

⁶ Commission Delegated Regulation (EU) .../... (OJ ..., p. ...).

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

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, row 27 on isopyrazam is deleted.

Article 3
Transitional measures

Member States shall withdraw authorisations for plant protection products containing isopyrazam as active substance by ... [*Office of Publications: please insert date 3 months after entry into force of this Regulation*].

Article 4
Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by ... [*Office of Publications: please insert date 6 months from the date of entry into force of this Regulation*].

Article 5
Repeal

Implementing Regulation (EU) No 1037/2012 is repealed.

Article 6
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