COMMISSION IMPLEMENTING REGULATION (EU) 2023/939

of 10 May 2023

withdrawing the approval of the active substance ipconazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Commission Implementing Regulation (EU) No 571/2014

(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 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 571/2014 ([2]) approved ipconazole 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 540/2011 ([3]).

(2) Following the submission of confirmatory data on the long-term risk to granivorous birds, as required by Article 1 in conjunction with Annex I to Implementing Regulation (EU) No 571/2014, the original rapporteur Member State, the United Kingdom ([4]), carried out an evaluation of the data, which was reviewed by Member States and the European Food Safety Authority ('the Authority'). Based on the information submitted, the Authority concluded that there is a high long-term risk to birds for the representative uses of ipconazole ([5]).

(3) On 9 March 2018, the Committee for Risk Assessment of the European Chemicals Agency adopted an opinion ([6]) in accordance with Article 37(4) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([7]) in which it concluded, amongst others, that ipconazole meets the criteria to be classified as toxic for reproduction category 1B.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Implementing Regulation (EU) No 571/2014 of 26 May 2014 approving the active substance ipconazole, 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 157, 27.5.2014, p. 96).

([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]) Following the withdrawal of the United Kingdom from the Union, Belgium was designated as the rapporteur Member State for ipconazole by Commission Implementing Regulation (EU) 2018/155 of 31 January 2018 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of active substances (OJ L 29, 1.2.2018, p. 8).

([5]) EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for ipconazole in light of confirmatory data. EFSA supporting publication 2017:EN-1260.; doi:10.2903/sp.efsa.2017.EN-1260

([6]) Committee for Risk Assessment, Opinion proposing harmonised classification and labelling at EU level of ipconazole (ISO); (1RS,2SR,5RS;1RS,2SR,5SR)-2-(4-chlorobenzyl)-5-isopropyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol [CAS No 125225-28-7 (all stereoisomers); CAS No 115850-69-6 (cis-cis racemate); CAS No 115937-89-8 (cis-trans racemate)] EC Number: – CAS Number: – CLH-O-0000001412-86-198/F.

([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).

(4) Commission Delegated Regulation (EU) 2020/1182 ([8]) consequently amended Annex VI to Regulation (EC) No 1272/2008 and classified ipconazole as toxic for reproduction category 1B.

(5) In accordance with Article 4(3), point (e)(ii), of Regulation (EC) No 1107/2009, an active substance can only be approved if a plant protection product containing it does not have unacceptable effects on the environment, in particular on non-target species, which includes birds.

(6) 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.

(7) In accordance with Article 21(1) of Regulation (EC) No 1107/2009, the Commission informed the Member States, the Authority and the applicant that it considered the approval criteria laid down in Article 4(3), point (e)(ii), of that Regulation and in point 3.6.4 of Annex II to that Regulation may no longer be met given that a high long-term risk to birds was identified and ipconazole is classified as toxic for reproduction category 1B. The Commission invited the applicant to submit comments.

(8) The applicant provided comments and additional information which were considered and assessed by the new rapporteur Member State, Belgium.

(9) The Commission requested the Authority to consider the information provided by the applicant, taking into consideration the assessment by the new rapporteur Member State, and specifically to consider the risks posed to birds from representative uses of ipconazole and whether the requirements regarding negligible exposure for humans (dietary and non-dietary exposure) set out in point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 may be considered satisfied.

(10) On 1 February 2022, the Authority communicated to the Commission its statement ([9]) in which it indicated that although residues of ipconazole in food are below the default value of 0,01 mg/kg and hence dietary exposure to ipconazole is expected to be negligible, there are uncertainties about exposure to operators and workers due to limitations in the studies submitted. In particular, for operators, measurements of exposure during equipment cleaning were not included in the study and the exposure during bagging was minimised due to a highly automated process, therefore limiting the representativeness of the study when considering the commonly used seed treatment practices across the Union. Thus, the study was of limited use. Furthermore, concerning workers, the study provided was of limited value since it only included data for two workers. Moreover, for one of those workers, exposure could not be considered negligible, even taking into account the use of personal protective equipment.

(11) In addition, the Authority concluded that there is a high long-term risk to birds from the representative uses of ipconazole even after taking into account all appropriate refinements in the risk assessment.

(12) The Commission invited the applicant to submit its comments on the statement of the Authority and on its proposal to withdraw the approval of ipconazole due to the concerns identified by the Authority. The applicant submitted its comments, which have been carefully examined.

(13) The Commission considers that ipconazole no longer fulfils the criteria for approval laid down in Article 4(3), point (e)(ii), of Regulation (EC) No 1107/2009 and in point 3.6.4 of Annex II to that Regulation.

(14) It is therefore appropriate to withdraw the approval of ipconazole.

([8]) Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 261, 11.8.2020, p. 2).

([9]) EFSA Panel (European Food Safety Authority), 2022. Statement concerning the review of the approval of the active substance ipconazole. *EFSA Journal* 2022;20(8):7133, https://doi.org/10.2903/j.efsa.2022.7133

(15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly and Implementing Regulation (EU) No 571/2014 should be repealed.

(16) Member States should be provided with sufficient time to withdraw authorisations for plant protection products containing ipconazole.

(17) For plant protection products containing ipconazole, 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 9 months from the date of entry into force of this Regulation.

(18) This Regulation does not prevent the submission of a new application for the approval of ipconazole pursuant to Article 7 of Regulation (EC) No 1107/2009.

(19) 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 ipconazole is withdrawn.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, row 73 on ipconazole is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing ipconazole as active substance by 31 August 2023.

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 29 February 2024.

Article 5

Repeal

Implementing Regulation (EU) No 571/2014 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, 10 May 2023.

For the Commission
The President
Ursula VON DER LEYEN