Ipconazole: withdrawal of approval

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EU withdraws approval of active substance ipconazole

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

Update

The European Commission has withdrawn its approval of the active substance ipconazole. This is due to concerns about its impact on the environment and risks to agricultural workers. EU Member States must withdraw authorisations for products containing ipconazole by 31 August 2023. This decision should have no impact on exports.

What is changing?

The European Commission has withdrawn its approval for the active substance ipconazole. European farmers will therefore no longer be able to use pesticides containing this substance. Ipconazole is a fungicide used to control a range of soil and seed borne seed diseases (various fungal pathogens including Zygomycetes, Ascomycetes, Basidiomycetes and Deuteromycetes) in a wide range of crops.

For an overview of all other recent withdrawals, see Latest pesticide non-renewals, withdrawals and restrictions.

Why?

In 2018, the European Chemicals Agency (ECHA) adopted an opinion that concluded that ipconazole should be classified as “toxic for reproduction category B” (ECHA RAC 2018). This means that the substance has unacceptable effects on the environment, in particular on non-target species including birds. An EFSA evaluation concluded that workers risk exposure to ipconazole, even taking into account use of personal protective equipment. It also found high long-term risks to birds (EFSA 2022). The Commission therefore proposes to withdraw the substance.

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Timeline

This Regulation entered into force on 21 May 2023.

EU Member States' authorisations of products containing ipconazole were withdrawn by 31 August 2023.

EU producers were permitted to use stocks of products containing ipconazole until 29 February 2024.

What are the major implications for exporting countries?

EU decisions not to renew or withdraw approvals for pesticide active substances primarily impact EU producers.

MRLs for ipconazole are already set at the limit of determination (LOD – the lowest level that can be detected using the most modern and reliable analytical methods). Suppliers exporting to the EU may continue to use ipconazole provided residues do not exceed existing MRLs (0.01–0.05 mg/kg).

Background

Pesticide active substances are approved for up to a maximum period of 15 years. Manufacturers may apply for reapproval for a period not exceeding 15 years. Work programmes have been developed by Member State authorities and EFSA to allow for the systematic review of active substances. In some instances, active substances are not reapproved or manufacturers do not seek reapproval, and the substance ceases to be authorised after the expiry date.

The approval of active substances is sometimes withdrawn prior to the approval expiry date where specific consumer health or environmental issues are identified. In some cases, active substances are not withdrawn but their use may be restricted.

Where an authorisation for an active substance is withdrawn or expires due to non-approval or non-renewal, the Commission will prepare a draft measure to delete the relevant existing MRLs. In practice, the Commission starts this procedure once all existing authorisations for that active substance have been revoked. MRLs are either set to a default value of 0.01 mg/kg, or at a the appropriate limit of quantification (based on specific data on analytical feasibility). MRLs based on the Codex MRLs (CXLs) are not deleted where there is no risk to EU consumers. Changes to MRLs are always notified to the WTO Sanitary and Phytosanitary (SPS) Committee.

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The timing of changes to MRLs as a result of the withdrawal or non-approval of active substances is difficult to predict. In its review of pesticide policy, the Commission committed to "enhance communication efforts on the impacts of the PPP Regulation on MRLs as well as the timing of the various procedures to make the EU system more predictable for non-EU countries, including for the cut-off criteria" (European Commission 2020).

Import tolerances can be requested in anticipation of potential changes to MRLs (see European Commission, Overview of import tolerances): applicants must demonstrate the existence of relevant good agricultural practices (GAP) in the country of origin, and the safety of the proposed MRLs. Guidelines are available on the requirements and process for the establishment of MRLs including import tolerances (European Commission 2021).

Resources

ECHA RAC (2018) Opinion proposing harmonised classification and labelling at EU level of ipconazole. European Chemicals Agency, Committee for Risk Assessment.

EFSA (2022) Statement concerning the review of the approval of the active substance ipconazole. EFSA Journal, 20(8): e07133.

European Commission (2020) Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides.

European Commission (2021) Technical Guidelines: MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005 and Article 8 of Regulation (EC) No 1107/2009.

European Commission (nd) Overview of import tolerances 2009–2020.

Sources

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