Metiram: approval not renewed by EU

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EU has not renewed approval of the active substance metiram

Commission Implementing Regulation (EU) 2023/2455 concerning the non-renewal of the approval of the active substance metiram, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011

Update

The European Commission has published its decision not to renew approval of the active substance metiram. This is due to concerns about potential adverse effects on human health, and high risks to the health of aquatic organisms. EU Member States will have to withdraw authorisations for products containing metiram. A review of maximum residue levels (MRLs) for dithiocarbamates, which include metiram, is under way.

What is changing?

The Commission has decided not to renew its approval for the active substance metiram. European farmers will therefore no longer be able to use pesticides containing metiram.

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

Why?

Approval for use of the active substance metiram in the EU was set to expire on 31 January 2024. An application to renew the approval was submitted and evaluated.

EFSA (2023a) identified several concerns, particularly human health risks (endocrine-disrupting properties) to consumers, operators, and bystanders; and environmental risks to non-target arthropods and aquatic organisms.

The Commission has therefore decided not to renew its approval of this substance.

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Timeline

This Regulation will enter into force on 28 November 2023.

EU producers will be permitted to use stocks of products containing metiram until 28 November 2024.

A revision of MRLs for dithiocarbamates, including metiram, is under way. New MRLs are expected to be set in late 2024.

What are the major implications for exporting countries?

Where active substances are not reapproved, or are withdrawn or restricted, the European Commission usually also lowers or removes MRLs. Metiram is included in combined MRLs for dithiocarbamates.

EFSA published its safety evaluation of MRLs for dithiocarbamates in May 2023 (EFSA 2023b). The Commission's review of the MRLs commenced in autumn 2023.

Recommended Actions

As the EU MRL is likely to be reduced to the limit of determination (LOD, the lowest level that can be detected using the most modern and reliable analytical methods), suppliers of agri-food products currently using metiram on crops for export to the EU should review their current good agricultural practices (GAP) and start to look for alternative solutions.

Any interested party can request import tolerances from an EU Member State competent authority (see Background).

Background

Pesticide active substances are approved for up to a maximum of 15 years. Manufacturers may apply for reapproval for a period not exceeding 15 years. Work programmes have been developed by EU Member State authorities and EFSA for the systematic review of active substances. In some cases, active substances are not reapproved or manufacturers do not seek reapproval, so the substance is no longer authorised after the expiry date.

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

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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 maximum residue levels (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 to the appropriate limit of quantification (based on specific data on analytical feasibility). MRLs based on the Codex MRLs (CXLs) are not deleted if there is no risk to EU consumers. Changes to MRLs are always notified to the WTO Sanitary and Phytosanitary (SPS) Committee.

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 the Commission's 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

EFSA (2023a) Peer review of the pesticide risk assessment of the active substance metiram. EFSA Journal, 21(4): 7937.

EFSA (2023b) Review of the existing maximum residue levels for dithiocarbamates. EFSA Journal, 21(5): 7987.

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.

Sources

Commission Implementing Regulation (EU) 2023/2455 concerning the non-renewal of the approval of the active substance metiram

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