Clofentezine: approval not renewed by EU

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EU has not renewed approval of clofentezine

Commission Implementing Regulation (EU) 2023/2456 of 7 November 2023 concerning the non-renewal of the approval of the active substance clofentezine, 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 clofentezine. This is due to concerns about adverse effects on human health, and high long-term environmental risks to birds and wild mammals. EU Member States will have to withdraw authorisations for products containing clofentezine.

A reduction in the maximum residue levels (MRLs) for clofentezine to the limit of determination (LOD, the lowest level that can be detected using the most modern and reliable analytical methods) is expected in 2025, with potential impacts on exporters of fruit.

What is changing?

The Commission has not renewed approval for the active substance clofentezine. European farmers will therefore no longer be able to use pesticides containing clofentezine.

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

Why?

Approval for use of the active substance clofentezine in the EU was set to expire on 31 December 2023. An application to renew the approval was submitted and evaluated.

EFSA (2021) identified several concerns, particularly endocrine-disrupting properties that may cause adverse effects in humans, and high long-term environmental risks to birds and wild mammals.

The Commission therefore decided not to renew approval for this substance.

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Timeline

This Regulation will enter into force on 11 November 2023.

EU producers will be permitted to use stocks of products containing clofentezine until 11 November 2024.

A revision of clofentezine MRLs is expected in 2025.

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Where active substances are not reapproved, or are withdrawn or restricted, the European Commission usually also lowers or removes MRLs. These are typically set at the LOD or default level of 0.01 mg/kg. Decisions on active substances serve as an early indication of upcoming MRL changes and the need to adapt agricultural practices for produce exported to the EU. There are currently MRLs above the LOD for clofentezine on a wide range of fruits, so growers using this substance are likely to be affected.

Recommended Actions

Suppliers of fruit currently using clofentezine should review current agricultural practices and start to seek alternative solutions in anticipation of changes to EU MRLs.

Import tolerance MRLs for specific products can be requested (see Background), although the process is complex and requires a lot of data.

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 (2021) Peer review of the pesticide risk assessment of the active substance clofentezeine. EFSA Journal, 19(8): 6817.

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) 2023/2456 concerning the non-renewal of the approval of the active substance clofentezine

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