EU withdraws approval of acibenzolar-S-methyl

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EU withdraws approval of the pesticide acibenzolar-S-methyl

Commission Implementing Regulation (EU) 2024/1696 of 19 June 2024 withdrawing the approval of the active substance acibenzolar-S-methyl 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) 2016/389

Update

The European Commission has withdrawn its approval of the pesticide acibenzolar-S-methyl due to concerns about its endocrine-disrupting properties. This will oblige EU Member States to withdraw authorisations for products containing this pesticide. Following this decision, the maximum residue levels (MRLs) for acibenzolar-S-methyl are 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), probably in 2026.

What is changing?

The European Commission has withdrawn its approval of acibenzolar-S-methyl, a preventative fungicide used in crops such as leafy vegetables, tobacco, tomatoes, and cotton.

For an overview of all other recent withdrawals, see Latest pesticide non-renewals, withdrawals, restrictions, and non-approvals (2024).

Why?

The approval of acibenzolar-S-methyl was renewed in 2016, but new criteria regarding endocrine-disrupting properties were introduced in 2018. An applicant submitted updated information in 2019, but a review by the European Food Safety Authority (EFSA 2021) found the data insufficient to assess this substance's endocrine-disrupting properties. The European Commission initiated a review and requested additional data by June 2025. However, in September 2023 the applicant ceased further studies and self-classified the substance as toxic for reproduction (under Regulation 1272/2008). The Commission therefore decided to withdraw the approval for acibenzolar-S-methyl.

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Timeline

This Regulation will enter into force on **20 July 2024**.

Existing EU Member State authorisations of products containing acibenzolar-S-methyl will need to be withdrawn by 10 January 2025. EU producers will be permitted to use stocks of products until 10 July 2025.

The European Commission is expected to follow up, most likely in 2026, with proposals to reduce or remove the MRLs for this substance, which will affect its use on crops for export to the EU. Any changes to MRLs are notified to the World Trade Organization Sanitary and Phytosanitary (WTO SPS) Committee, and details will be provided on the AGRINFO website.

What are the major implications for exporting countries?

Following the non-renewal or withdrawal of approvals for pesticide active substances, the EU starts the process of lowering or removing the MRLs. These are typically set at 0.01 mg/kg or the LOD. In most circumstances this means that they can no longer be used on crops for export to the EU.

Recommended Actions

As the EU MRL is likely to be reduced to the LOD, suppliers of agri-food products currently using acibenzolar-S-methyl on crops for export to the EU should review their current good agricultural practices (GAP) and start to look for alternative solutions.

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 EU 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.

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Where an authorisation for an active substance is withdrawn, or expires due to non-approval or non-renewal, the European 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 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).

Resources

EFSA (2021) Peer review of the pesticide risk assessment for the active substance acibenzolar■S■methyl in light of confirmatory data submitted. EFSA Journal, 19(7): 6687.

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.

Sources

Commission Implementing Regulation (EU) 2024/1696 withdrawing the approval of the active substance acibenzolar-S-methyl

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