Data requirements for EU approval of pesticides

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EU to update data requirements for authorisation of pesticides

Draft Commission Regulation amending Commission Regulation (EU) No 283/2013 as regards the information to be submitted for active substances; Draft Annex

Draft Commission Regulation amending Commission Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products; Draft Annex

Draft Commission Regulation amending Commission Regulation (EU) No 546/2011 as regards uniform principles for evaluation and authorisation of plant protection products with regard to birds, mammals, bees and drinking water; Draft Annex

Update

The European Commission has informed the World Trade Organization Technical Barriers to Trade (WTO TBT) Committee that it intends to update the data requirements for authorising active substances used in pesticide products in the European Union (G/TBT/N/EU/1162) and the approval of plant protection products by EU Member States (G/TBT/N/EU/1164). These changes reflect the development of new approaches to risk assessment.

These developments also necessitate a change to the rules for the approval of products in relation to birds, mammals, bees, and drinking water (G/TBT/N/EU/1161).

The WTO consultation on these proposals closed on 30 November 2025.

What is changing?

The EU is proposing to update the requirements for risk assessment (and the associated information) as follows.

- For active substances (Regulation 283/2013): to reflect new approaches to conducting risk assessments, in particular in relation to risks to birds, mammals, and bees, and the impact of water treatment processes on pesticide residues. The detailed amendments to the requirements are set out in the Annex to the proposal.
- For plant protection products (Regulation 284/2013): to reflect new methodologies for conducting risk assessments in particular protocols, including minimising and developing alternatives to testing on animals (vertebrates). New approaches have also been developed

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in relation to substances of biological origin. The detailed amendments to the requirements are set out in the Annex to the proposal.

Given these new approaches and methodologies, the Commission also proposes updating Regulation 546/2011 concerning the principles for evaluating and authorising plant protection products specifically in relation to birds, mammals, bees, and drinking water.

Why?

For active substances, the proposed amendments are in line with changes to European Food Safety Authority (EFSA) Guidance Documents on conducting risk assessments for birds and mammals (EFSA 2023a) and bees (EFSA 2023b), and EFSA's guidance on the impact of water treatment on pesticide residues (EFSA 2023c). EFSA's bee guidance led to the inclusion of additional tests in the requirements for plant protection products.

Timeline

These Regulations are expected to be adopted in the second quarter of 2026. The new requirements will apply 2 years after publication of the Regulation (approximately the second quarter of 2028). Applications for active substances or plant protection products before that date may still submit data in accordance with current requirements.

Background

To ensure the safety of plant protection products, only active substances that have a clear benefit for plant production, and are not expected to have a harmful effect on human or animal health or the environment, may be used in these products. All active substances are assessed for use across the EU through an approval procedure based on standardised data requirements (Regulation 1007/2009, Art. 7).

Plant protection products can be formulated in many ways for use on a variety of plants in different agricultural conditions. Authorisations for plant protection products are granted by individual EU Member States. However, to ensure high standards of protection, the EU sets standardised conditions for their authorisation (Regulation 1007/2009, Art. 29).

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Resources

Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances,

Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products

Commission Regulation (EU) No 546/2011 as regards uniform principles for evaluation and authorisation of plant protection products

Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market

EFSA (2023a) Guidance on the risk assessment for birds and mammals. EFSA Journal, 21(2): 7790.

EFSA (2023b) Revised guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal, 21(5): 7989.

EFSA (2023c) Guidance document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water. EFSA Journal, 21(8): e08194.

Sources

Draft Commission Regulation as regards the information to be submitted for active substances; Draft Annex

Draft Commission Regulation as regards the information to be submitted for plant protection products; Draft Annex

Draft Commission Regulation as regards uniform principles for evaluation and authorisation of plant protection products with regard to birds, mammals, bees and drinking water; Draft Annex

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