Non-approval of various active substances for use in biocidal products

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EU rejects various active substances for use in biocidal products

Commission Implementing Decision (EU) 2024/888 of 22 March 2024 on the non-approval of certain active substances for use in biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

Update

The European Commission has decided not to approve various active substances for use in biocidal products. These include substances currently (directly or indirectly) used in producing and/or preparing food for export to the EU market.

Impacted products

All food sectors in which biocidal products containing these substances are used.

What is changing?

The EU systematically reviews active substances included in biocidal products, taking into consideration information provided by their manufacturers. The European Commission decided that it will not approve the substances potentially relevant to food production listed below, because reapproval was not adequately supported by manufacturers.

Product types (uses of biocides) are shown as numbers in brackets.

* = product types that are less relevant to food production.

- potassium dimethyldithiocarbamate (9*, 11, 12)
- silver-polyethylenimine-chloride (1*, 2, 9*)
- glucoprotamin (2, 4)
- Bardap 26 (2, 4, 10*)
- 2,2-dibromo-2-cyanoacetamide (DBNPA) (2)
- active chlorine generated by electrolysis (2)

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- garlic extract (19)
- brandy (19).

Further details on these substances can be found in the Annex to the Decision.

See Background for more information.

Why?

These specific active substances are not approved for two main reasons.

- Withdrawal or lapse of support: for some active substance/ product-type combinations, the applicant (generally a manufacturer) responsible for supporting their evaluation by the EU withdrew, or were considered to have withdrawn, their support. Without this, the substances cannot be evaluated for safety and efficacy, and therefore cannot be reapproved.
- Lack of new applicant to take over the evaluation: in cases where the initial applicant withdrew, there was an opportunity for other parties to take over the role, but no expressions of interest were submitted.

Timeline

This Decision applies from **15 April 2024**.

What are the major implications for exporting countries?

When exporting food to the European Union, adhering to stringent biocide regulations is crucial. Biocide residues in food products must comply with the EU's established maximum residue levels (MRLs) for pesticides. In cases where no specific MRL is designated for an individual substance, a default limit of 0.01 mg/kg applies.

An example is the potential residue from product type 2 biocides (disinfectants and algaecides not intended for direct application to humans or animals), which might be indirectly associated with food, such as during the cleaning of watering pipes.

For exporting countries, non-compliance with these regulations can lead to products being rejected.

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Background

Biocides are substances or mixtures that are used to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism, by any means other than mere physical or mechanical action.

Biocides are typically classified into four groups based on their intended use:

- disinfectants
- protective products
- products for the control of so-called "harmful" species
- other biocidal products.

The following product types (uses of biocides) may be particularly relevant to food production:

- Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals: used to disinfect surfaces, materials, and equipment.
- Product type 4 – Food and feed area: used to disinfect equipment, containers, consumption utensils, surfaces, or pipework associated with the production, transport, storage, or consumption of food or feed (including drinking water) for humans and animals.
- Product type 11 – Preservatives for liquid-cooling and processing systems: products used to disinfect drinking water.
- Product type 12 – Slimicides: used to prevent or control slime growth on materials, equipment, and structures, used in industrial processes.
- Product type 19 – Repellents and attractants: used to control harmful organisms by repelling or attracting.

Regulation (EU) 1062/2014 established the work programme for the systematic review of active substances contained in biocidal products, and used at the time of adoption of the biocides Regulation 528/2012.

For further information on the EU's regulation of biocides, see Biocides explained.

Resources

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Commission Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012

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European Chemicals Agency (ECHA) Biocides database

EU Pesticide Residues database

EFSA (2020) The 2018 European Union report on pesticide residues in food. EFSA Journal 18(4): e06057.

Sources

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