Approval of biopesticides

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EU updates rules on the approval of micro-organisms used in plant protection products

Commission Regulation (EU) 2022/1438

Commission Regulation (EU) 2022/1439

Commission Regulation (EU) 2022/1440

Commission Regulation (EU) 2022/1441

Update

On 1 September 2022, the EU published four regulations amending its approach to the approval of micro-organisms for use in plant protection products (PPPs). Four Regulations have been amended to establish criteria that are more appropriate to the evaluation of micro-organisms. These four interlinked Regulations change the criteria for approval of micro-organisms as active substances; amend the information to be submitted for approval of active substances and PPPs; and amend the principles for evaluation and authorisation of PPPs by Member States. The EU aims to simplify the risk assessment of micro-organisms and bring biopesticides more quickly to the EU market. This initiative supports the EU's aim to reduce dependency on chemical PPPs, as set out in the Farm to Fork Strategy and Green Deal.

What is changing?

The new legislation updates Regulation (EC) No 1107/2009, with regard to the criteria for the approval of active substances used in PPPs.

Before the adoption of these new rules, the requirements for micro-organisms in biological PPPs were based on principles that were very similar to those for chemically active substances to be used in PPPs.

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Approval of micro-organisms

Commission Regulation (EU) 2022/1438 revises the criteria for the approval of micro-organisms to take into account scientific knowledge on the biological and ecological characteristics of micro-organisms. The Regulation removes for micro-organisms certain criteria that are only relevant to chemicals, such as information on isomers/ diastereo-isomers. It also sets out a different approach to the evaluation of residues, as it does not consider that the presence of micro-organisms constitutes a hazard in terms of residues (Annex, 3.1(b)). Only certain species of fungi and bacteria known to produce toxic metabolites are thought to pose a risk to human and animal health, or to the environment.

Regulation 2022/1438 distinguishes between chemical and micro-organism active substances (Annex, 3.4). It also introduces specific information requirements to define the composition of a micro-organism, in particular:

- accession number of the micro-organism, which must be deposited at an internationally recognised culture collection
- "unequivocally identified" species name
- name of the micro-organism at strain level
- indication of whether micro-organisms are wild types, spontaneous or induced mutants, or genetically modified organisms.

Manufacturing processes

The manufacturing processes of chemical substances and micro-organisms are also different, involving different methods of analysis. The new rules (Annex, 3.5) require validated methods of analysis to:

- identify and quantify active substances that are micro-organisms
- identify relevant contaminating micro-organisms
- determine metabolites of concern and relevant impurities.

Regulation 2022/1438 (Annex, 3.6.6) also requires information demonstrating that:

- the strain of the micro-organism is not pathogenic
- the isolated virus is not infective to humans
- strains of bacteria do not have any known functional and transferable gene coding for resistance to relevant antimicrobial agents.

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Low-risk criteria

The new rules provide more specific criteria to determine whether micro-organisms can be considered as low risk, with a focus on the number of antimicrobial agents against which the micro-organism is demonstrated to be susceptible. Prior to these amendments, baculoviruses were considered as low-risk active substances. The revised rules extend these low-risk criteria to other species of viruses (Annex, 5.2.2). Expanding the number of micro-organisms that can be treated as low risk is significant, as the first approval of the substance lasts 15 years, instead of the 10 year period that normally applies to active substance approvals.

The other three adopted Regulations amend existing rules on different parts of the approval procedure:

- Regulation 2022/1439 amends the data that needs to be submitted to support the approval of a micro-organism as an active substance
- Regulation 2022/1440 amends the data that needs to be submitted to support PPPs containing micro-organisms
- Regulation 2022/1441 amends principles that Member States must apply during the evaluation and authorisation of PPPs containing micro-organisms.

Why?

One objective of the EU's Green Deal and Farm to Fork Strategy is to reduce dependence on chemical PPPs. Biopesticides using micro-organisms provide farmers with an alternative to chemical PPPs that can be used in organic agriculture and contribute to integrated pest management (IPM). In order to allow new biopesticides to more easily reach the EU market, there was a need to streamline the authorisation process and ensure that the information demands of risk assessment were fully relevant to the specific characteristics of biopesticides.

Timeline

Date of publication: 1 September 2022

Date of entry into application: November 2022

What are the major implications for exporting countries?

An increase in the number of non-chemical alternatives permitted in the EU market also provides more potential options for the management of pests on crops for export to the EU. These alternatives must be authorised, available and affordable in the exporting country.

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The CABI BioProtection Portal provides information about registered biocontrol and biopesticide products around the world.

However, some obstacles to the more widespread use of biopesticides have been identified. A survey of Kenyan farmers found that while 87% used chemical pesticides, only 10% used biopesticides. This was explained by the perceived ineffectiveness of biopesticides, or their limited availability and affordability (Constantine et al. 2020). In China, non-availability of appropriate biopesticides has been shown to be a considerable problem (Huang et al. 2022). Limited government support and investment for research into biopesticides is identified as an obstacle in Nigeria (Ivase 2017). In India, significant problems are reported regarding packaging of biopesticides that reduces shelf life and can lead to cross-contamination. Complicated registration processes and data requirements are also a barrier to uptake of biopesticides (Mishra 2019). More than half the biopesticides manufactured globally are being used in Canada, the EU and the USA (Mishra 2019).

Recommended Actions

Countries exporting to the EU are recommended to explore the possible use of micro-organisms as an alternative to chemical pesticides, including in non-organic production systems. Within the EU this trend is expected to accelerate, in large part due to the EU's target to reduce the use and risk of chemical pesticides by 50% by 2030.

Background

Micro-organisms (bacteria, fungi, viruses and protozoa) have long been used in the biological control of pests and plant diseases. Before being permitted for use in the EU, they must be authorised to establish their safety for human and animal health, and for the environment. The EU has a two-tier system: the active substance micro-organism is first approved by the EU under Regulation 1107/2000, followed by approval by individual EU Member States.

These Regulations form part of the Farm to Fork Strategy and reflect the Commission's aims of reducing chemical pesticide use by 50% by 2030.

Resources

Online resources from the European Commission:

- Micro-organisms used in plant protection products
- Farm to Fork: New rules to reduce the risk and use of pesticides in the EU

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- Farm to Fork targets – Progress

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Huang, Y. et al. (2022) Biopesticides extension and rice farmers' adoption behavior: A survey from Rural Hubei Province, China. Environmental Science and Pollution Research, 29: 51744–51757.

Ivase, T.J.P. et al. (2017) Current status, challenges, and prospects of biopesticide utilization in Nigeria. Agriculture and Environment, 9: 95-106.

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Sources

Commission Regulation (EU) 2022/1438 as regards specific criteria for the approval of active substances that are micro-organisms

Commission Regulation (EU) 2022/1439 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms

Commission Regulation (EU) 2022/1440 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms

Commission Regulation (EU) 2022/1441 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms

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

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