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Joint Regulation of Microbial Pesticide Products

Last Modified:

The environmental release of certain micro-organisms is jointly regulated by APHIS and the U.S. Environmental Protection Agency (EPA).

Authorities

EPA has authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to regulate biologically and chemically derived pesticides, including microbial pesticides. Microbial pesticides have micro-organisms (such as a bacterium, fungus, virus, or protozoan) as the pesticide active ingredient. EPA has authority over the [commercial use and field testing of microbial pesticides](#).

APHIS has authority under the Plant Protection Act of 2000 to regulate the importation, interstate movement, and field release of biological control organisms. A biological control organism is defined in the statute as “any enemy, antagonist, or competitor used to control a plant pest or noxious weed.”

APHIS' authority includes genetically engineered organisms whose oversight is administered by [Biotechnology Regulatory Services \(BRS\)](#). Nonengineered organisms are administered by [Plant Protection and Quarantine \(PPQ\)](#).

Frequently Asked Questions

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If I request a PPQ 526 permit for an environmental release of a potential microbial pesticide or commercial distribution of a product containing a potential microbial pesticide, would the permit be withheld if PPQ suspects the product may be regulated under FIFRA?

No. Provided the application meets all of PPQ's requirements, the permit would not be withheld based on any suspected regulation under FIFRA by EPA. PPQ may inform you that the product may be subject to regulation under FIFRA and recommend you contact EPA's Office of Pesticide Programs (OPP), Biopesticides and Pollution Prevention Division (BPPD).

Can I be required to seek a non-FIFRA regulated determination under the M009 Pesticide Registration Improvement Extension Act (PRIA) fee category?

No. That request is voluntary but can help you understand regulatory jurisdiction.

If EPA regulates a microbial product, would a PPQ 526 permit still be required for importation, interstate movement, or environmental release?

No. A PPQ 526 permit would no longer be required for importation, interstate movement, or environmental release, and any existing PPQ 526 permit would be cancelled, if EPA regulates a microbial product under one of the following:

- An EPA experimental use permit or a FIFRA section 18 emergency exemption
- The product is currently registered with EPA as a microbial pesticide product
- The product is being transferred, sold, or distributed in accordance with EPA's regulations in [40 CFR 152.30](#)

**I have an unregistered product that has an equivalent formulation as a registered product by another company.
Do I need a PPQ 526 for my product?**

Yes. You need a PPQ 526 permit for any microbial product lacking an EPA registration unless the product is labeled in accordance with [40 CFR 156](#). The PPQ 526 permit is required until you obtain an EPA product registration.

Does PPQ regulate organisms in off-label research (for example, where an EPA label permits its use on soybean, but the product is applied to citrus) or intermediate products until the final or updated product is developed and registered with EPA?

Yes. You need a PPQ 526 permit for any organism(s) that is in an EPA-registered product if:

- The organism(s) will be used to develop a product, or
- The final product is intended for non-EPA registered product use.

This may necessitate EPA verification by PPQ. The PPQ 526 permit will be required until an EPA product registration is obtained.

Contact Us

[Download contacts](#)

APHIS-PPQ

For questions or more information about APHIS requirements for nonengineered organisms, visit [Regulated Organism and Soil Permits](#) or contact our Pest Permits Team.

For questions about permits for regulated organisms and soil:

Pest Permits Team

Email: pest.permits@usda.gov

Phone: [301-851-2285](tel:301-851-2285)

Alt-Phone: [866-524-5421](tel:866-524-5421)

APHIS-BRS

For questions or more information about APHIS requirements for modified micro-organisms, visit [Biotechnology Permits](#) or contact our BRS staff.

Biotech Microbes

Email: biotechmicrobes@usda.gov

EPA

For questions or more information about EPA requirements, contact EPA's Office of Pesticide Programs, Biopesticides and Pollution Prevention Division. [View EPA Contacts](#)

[Joint Regulation of Microbial Pesticide Products Contacts](#)

Related Resources

- [Animal Product Import and Export](#)
- [Agricultural Select Agents and Toxins](#)
- [Centers for Disease Control and Prevention \(CDC\) Import Permit Program](#)
- [CDC Division of Regulatory Science and Compliance](#)

- [U.S. Food and Drug Administration Food and Cosmetics Information Center](#)
- [U.S. Fish and Wildlife Service](#)

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