

## *Microbial Permitting and Importation Process in the United States*



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## *Global Regulatory*



# USDA APHIS PPQ Regulatory Authority

- The Plant Protection Act of 2000 (PPA)
- Regulation 7 CFR 330 (Federal Plant Pest Regulation)
- USDA APHIS PPQ is tasked with regulating the movement of plant pests, biological control organisms, and associated articles

# What are Microbials?

- USDA considers microbes (or microorganisms) to be organisms that are too small to be seen by the unaided eye.
- Includes bacteria, fungi, protozoa, microalgae, and viruses



# What are Microbials (Legally)?

“Biological control organism” – “any enemy, antagonist, or competitor used to control a plant pest or noxious weed.

Definition amended/clarified in the regulation:

- Microbial pathogens used to control invertebrate plant pests
- Microbial pathogens used to control noxious weeds
- Microbial parasites used to control plant pathogens
- Any other types of biological control organisms, as determined by APHIS



# Microbes that are not Biocontrol Organisms

USDA defines the term Plant Growth Enhancers (PGEs) as:

- Materials that typically are added to soil, plants, or the plant-growth environment to enhance plant growth
- These include fertilizers, compost, sludge, manure, microbes, additives, and others or combinations thereof

PGEs have the potential to contain pests or plants and plant parts that present a risk to American agriculture and the environment. Therefore, release of these commodities into the environment could be detrimental to U.S. agriculture and the environment. APHIS regulates living organisms that could impact animal and plant health

# What is NOT regulated by USDA APHIS PPQ?

1. Biological control organisms that have undergone genetic engineering
2. Products that are currently under an EPA experimental use permit, (FIFRA) section 18 emergency exemption, or currently registered with the EPA

# When is an APHIS PPQ Permit needed?

Importing, interstate movement, or environmental release of any microbe that is:

1. A known or potential plant pest or pathogen
2. A known or potential biocontrol organism
3. An organism of unknown risk

*Products that only require state registration (biostimulants, microbes) still must have USDA permits even after registration by the states.*

Check the Agricultural Commodity Import Requirements (ACIR – Pest organism permitting) database. Three outcomes when you search:

1. No jurisdiction – no application needs (for that species)
2. Submit a 526 movement application
3. Species not found (which will require a permit application as well)

# Responsible Parties associated with a PPQ 526 Permit

## The Applicant

- Filing the permit with USDA

## The Permittee

- Overall responsible for the compliance conditions of the permit

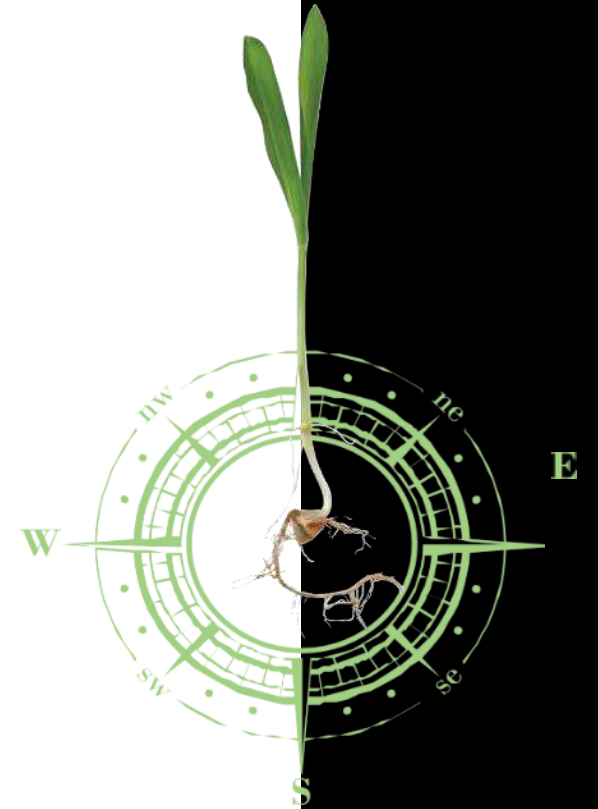
## Primary Contacts

- Specified for each location where the product will be stored or shipped



# What is needed to apply for a 526 permit?

1. Taxonomy to the species level
2. Original country and environment of isolation
3. Mode of Action with data or literature support
4. Certificate of Analysis showing the microbe in your product and the methods used
5. Any information to show the microbe(s) are not pathogenic to plants, humans, animals, and non-target organisms likely to be present in the environment where the material will be released, if applicable
6. Composition
7. Manufacturing process
8. For foreign isolates – need to show prevalence in the US of an identical species
9. For field release permits – information about the field test site including preliminary endangered species review



# 526 Permit Timelines

| Step   | Application Status                  | Time Range   |
|--|-------------------------------------|--------------|
| Application review for completeness and assignment to permit scientist.                                    | Submitted                           | 1- 2 Weeks   |
| Application technical review – Risk analysis   | Review Initiated                    | 1- 6 Weeks   |
| Evaluation of containment facility, if necessary.  | Pending Containment Facility Review | 1- 19 Weeks  |
| Determination of permit conditions to mitigate risk.   | In Review                           | 1- 2 Weeks   |
| Consultation of draft permit with the State.   | Pending State Review                | 1- 2 Weeks   |
| Evaluation State response.   | Pending APHIS Review                | 1- 2 Weeks   |
| Review of draft permit conditions by applicant.  | Applicant Action Required           | 1- 4 Weeks   |
| Review of Applicant’s response and issuance of the Permit (Official Letter(s) may be issued if necessary). | Pending APHIS Review                | 1- 2 Weeks   |
| Issuance of Permit   | Processed                           | 8 - 39 Weeks |

# Outcomes from a 526 Permit Application

1. Approval and issuance of a permit with conditions
2. Denial of the permit with the reasons listed
3. Letter of non-jurisdiction



# Microbial Logistics - USDA

- USDA Permit
- Red and White label on the outside of the package for importation
- USDA plant inspection stations at port of entry (unless “all ports” is shown on permit)
- Hand carry permitted, must designate on the permit at the time of application





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## Microbial Logistics – EPA Registered

- Label – “For Research and Development Only, Not For Sale”
- Notice of Arrival – must be filed before entering into the US
  - Issued by EPA regional office for port of entry
- Certificate of Origin statement
- Intended Purpose Letter/EPA Addendum
- Toxic Substance Control Act (TSCA) Certificate

## DOCUMENTATION

All documentation related to the field trial itself or the movement of the material to the facility – the CRO and permittee need records.



## INSPECTION

Will likely ask to see the permit, protocols, the field, the storage facility. Potentially anything that is related to what was submitted to USDA to support the permit could be asked for.

## QUESTIONS

They can ask about anything to confirm the CRO is complying with the conditions of the permit

Questions?



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