



Animal and Plant Health Inspection Service  
U.S. DEPARTMENT OF AGRICULTURE

# Microbe Efforts

APHIS

Biotechnology Regulatory Services

Plant Protection and Quarantine

A wooden sign with the text 'Microbe Efforts' is mounted on a post. The sign is weathered and has a rustic appearance. It is positioned on a dirt path that curves through a green field. In the background, there are rolling hills and a sun setting or rising behind a line of trees, creating a warm, golden glow.

Microbe  
Efforts

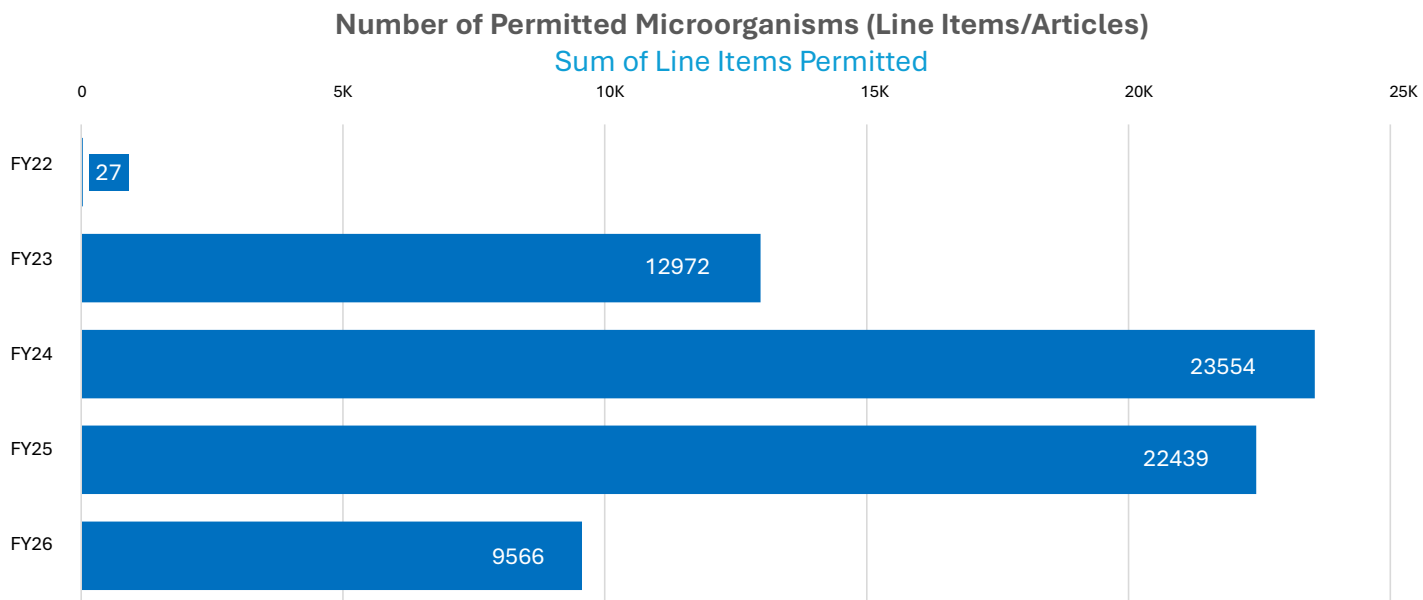


# New Microbial Biotechnologies

- **Drivers:** Genomics, genome editing, automation, AI – driven discovery and development; biotechnology as a national priority.
- **Uses:** Plant health and nutrition (pesticides, fertilizers, biostimulants), food, fuels, chemicals, materials, etc.
- **Impact:** Increase in APHIS permit applications.

# PPQ Permitted Microorganisms

Over 7,300 unique microorganisms evaluated and permitted



# BRS Permitted Microorganisms

Over 4,600 unique modified microorganisms permitted

	FY 21	FY 22	FY 23	FY 24	FY 25
Movement	65	446	1551	2654	2151
Release		14	38	67	283
Total	65	460	1589	2721	2434



# Concerns We've Heard

BRS and PPQ lack a harmonized approach to microbe regulation for plant health

There are no clear, predictable pathways for *commercialization* of modified microbes regulated by BRS

BRS permit conditions for field releases of modified microbes are not risk-based and fit-for-purpose

# Developing a Harmonized APHIS Framework for Microbe Regulation

Established the core principle for the framework.



Established the foundation of APHIS's harmonized framework.



Jointly defined scientific criteria to assess microbes under a harmonized framework.



# Core Principle

For an organism to be regulated as a plant pest, there must be demonstrated evidence or a plausible hypothesis that the organism can cause direct or indirect harm to plants.

# Examples of Microbes Regulated by APHIS

The foundation of the harmonized framework and some of the key scientific criteria

## Plant Pathogens

- A microbe is regulated if there is evidence demonstrating the microbe's ability to infect and cause disease in a plant; even a single credible report indicating pathogenic potential could meet the threshold.



## Insecticidal Microbes

- A microbe is regulated if there is evidence that it harms or could plausibly harm a beneficial insect and could lead to plant harm.

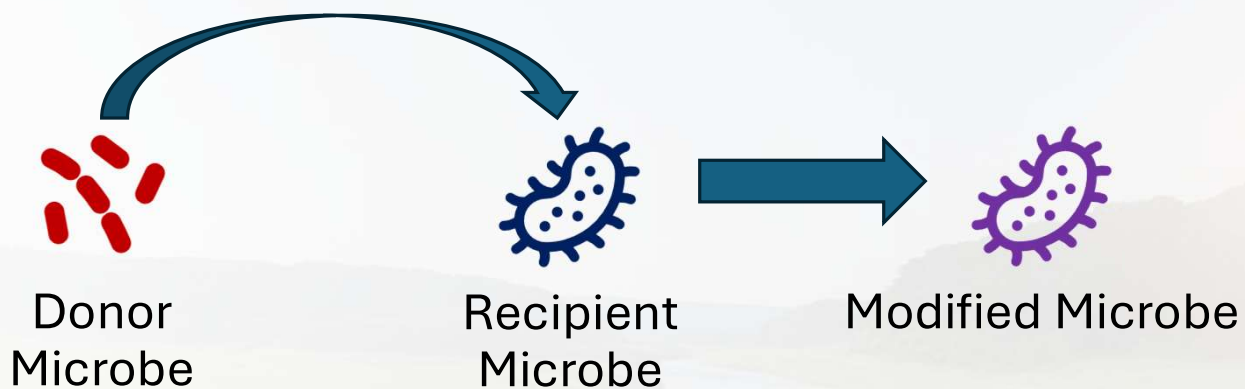


## Anti-microbial Microbes

- A microbe is regulated when evidence indicates its antimicrobial properties could plausibly lead to indirect plant harm; the mere production of antimicrobial compounds does not meet that threshold.



# How Will This Framework Apply to Modified Microbes?



If either the donor microbe or the recipient microbe are known to or could plausibly harm plants, then the modified microbe would be subject to regulation.

# Advancing the Microbial Harmonization Framework: Future Directions and Implementation



Finalize scientific criteria



Implement harmonized framework



Stakeholder engagement and guidance

# Thank You!

A scenic landscape featuring a river flowing through a valley. A wooden bridge with railings spans across the river in the foreground. A dirt path curves along the right bank of the river. A wooden signpost stands on the path, displaying the text "Microbe Efforts". The sun is visible in the background, creating a warm, golden glow over the scene. The sky is clear and blue.

Microbe  
Efforts