# BIO ISSUE BRIEF

## USDA Guidance for GE Microbes

Innovations in genetically engineered (GE) microbes can unlock the potential for biology to transform industries. Microbe innovations can foster a more sustainable food system, create the next generation of antibiotics, and make industry and manufacturing more environmentally friendly. But these breakthroughs are dependent on a clear, timely, and science-based regulatory approval process that provides a viable path to market.

### Ambiguity for Non-Plant Genetically Engineered Organism

In May 2020, the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) published a final rule aimed at modernizing biotechnology regulations at 7 CFR Part 340. The final rule marked the first comprehensive revision of the Part 340 regulations since they were established in 1987 for certain GE organisms.

Before the revised rule, developers of non-plant GE organisms could access USDA-APHIS's *Am I Regulated Process* to determine whether a particular non-plant GE organism is subject to regulation under Part 340. Then, based on the answer, they could apply for and obtain permits for movement or release of those organisms from being subject to regulation.

Now, USDA's revised rule only provides new regulatory processes for plants, leaving microbe developers with an opaque and unpredictable pathway to commercialization. Because of this omission, the only option for developers of non-plant GE organisms to determine their regulation status under Part 340 is to apply for a permit and wait for USDA to determine whether one is required.

### Need for Formal Guidance from USDA

Overall, BIO supports the regulatory system for plant biotechnology outlined in the revised rule. However, the final rule did not afford the same predictability and processes for determining the regulatory status of non-plant GE organisms.

BIO continues to urge USDA to take the following actions for developers of GE microbes:

1. **Establish a predictable and science-based regulatory pathway**, including guidance on categories or characteristics of microbes within APHIS's Part 340 scope.
2. **Install a formal, pre-notice consultation process.**
3. **Enable a mechanism for developers to receive confirmation of exemption from regulation under Part 340.**
4. **Identify exemptions for microbes from Part 340 based on clear, risk-based criteria**.

Inaction threatens the pace of research, development, and commercialization of entire categories of innovative products with the potential to present novel and lasting solutions to some of our most pressing challenges.