

**Comments on RFI: regulatory considerations related to the review of modified organisms
subject to the Plant Protection Act**

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1. Background

After 30 years of genetically modified (GM) organisms in the global market, it is safe to say they are no different from their non-GM counterparts. Since the first risk assessment in 1994, over 4,400 evaluations have been conducted across more than 70 countries for both cultivation and food/feed use. Relative to conventional varieties, not a single increased risk was quantified (Favaratto et al. 2026).

Plant pests (weeds, insects, disease) are a threat to the environment and to all agricultural production. Pests and their host plants co-evolve, which is a natural and ongoing process for any parasitism, parasitoidism, competition, and herbivory dynamics, resulting in species evolving to develop adaptations and counter adaptations against one another in order to survive. When a new exotic plant pest is introduced to an environment, it lacks natural predators, so pests can multiply rapidly, outcompete native species, devastate agriculture, and disrupt local food webs.

According to data from ISAAA (2026a), there are 237 events released for cultivation in several countries where plants were modified to be resistant to pests. GM technology is used to combat pests, not to enhance their devastating power. In fact, there are plants that have been modified to be resistant to more than one pest, such as:

- Soybeans event DAS 44406 x DAS 81419 x GMB151 released in Brazil in 2024, resistant to lepidopteran insects and to nematodes;
- Potato events RBMT15-101, SEMT15-02, and SEMT15-15 resistant to Potato Virus Y (PVY) and coleopteran insects, released in the US since 1998 for food and feed, and since 1999 for cultivation; and
- Potato events RBMT21-129, RBMT21-350, and RBMT22-082 resistant to Potato Leaf Roll Virus (PLRV) and coleopteran insects, released in the US since 1998 for food, feed, and cultivation.

Among the genetically modified plant groups, none of them are cited in the list of plant pests in CRF § 340.2.

Through the use of biotechnologies, bacteria are used in agriculture to enhance production. *Bacillus thuringiensis* is a classical example, widely used as gene donor for plants, to make them resistant to insects (ISAAA 2026b). Another example is *Agrobacterium tumefaciens*, which is classified as a plant pest because it has the capacity to transfer bacterial (T)-DNA into

plant genomes. Besides making it a plant pest, its capacity to transfer bacterial DNA into plant genomes made it one of the most used ways to introduce an exogenous gene into plants (ISAAA 2026c). In fact, after conventional GM breeding, agrobacterium-mediated plant transformation is the most used technique used to produce a GM plant (Favaratto et al. 2026).

There are also many insect species classified as insect pests that have been genetically modified to be less destructive to agriculture. As an example, diamondback moths (*Plutella xylostella*) globally cause an estimated \$4–5 billion annually in damage to growers of brassica vegetables. *P. xylostella* has evolved resistance to over 90 insecticide ingredients globally, forcing farmers to increase insecticide use and further exacerbate resistance. The insect was modified to have half of their offspring die when mating with wild pests (Shelton et al. 2020). Olive fly (*Bactrocera oleae*) was also genetically modified to have a self-limiting effect on females at the larvae or early pupal stage, what could be applied for sustainable pest control (Marubbi et al. 2017). *Drosophila suzukii*, known as spotted wing fly, also identified as an insect pest, was also genetically modified to have the female offspring die on early stages of life (Schetelig et al. 2021).

These examples demonstrate that genetic modification is used to reduce the impacts of plant pests rather than increase them. The modification process itself does not make an organism more harmful or invasive. Instead, plant pest risk depends on the biology of the organism, the introduced trait, and its interaction with the environment.

2. Answers

Question 1: Are there material differences in plant pest risk between conventional and genetically engineered organisms (plants, microorganisms, or insects)? What is the basis, e.g., science-based studies, if such a difference exists? If not, should APHIS continue to distinguish between conventional and genetically engineered organisms in its Plant Protection Act regulations?

Genetically modified organisms do not pose greater risks than their conventional counterparts, according to scientific evidence, and 30 years of GM products being commercially produced in 30 different countries. The risk of a plant pest should be determined by the characteristics of the organism, its biology, ecological interactions, and intended use, rather than by the breeding method. Between 1992 and 2019, there have been 4,485 risk assessments undertaken by expert regulatory scientists in over 70 countries. This establishes a global scientific consensus that genetically modified organisms, regardless of the classification of the organism, do not possess a risk profile that differs from comparable non-GM species or varieties.

Question 5: What would the benefits and challenges of regulating modified organisms under 7 CFR part 330? What changes, if any, would need to be made to 7 CFR part 330 for effective regulation?

It would create a more unified framework for organisms that could be a plant pest risk regardless of the breeding method. The focus on the demonstrated risk would be stronger than focusing on the process used to create the organism. This would bring greater flexibility for new breeding techniques that can benefit both consumers and producers.

Question 7: Did the SECURE rule—and does the current 7 CFR part 340—impose disproportionate burdens on smaller entities developing regulated plants or microorganisms?

Despite the advances SECURE rule brings, compliance, regulatory interpretation, data generation, and uncertainty surrounding jurisdictional determinations still affect the adoption of technology by the smaller entities. Increasing transparency and accessibility of guidance documents, developing simplified application pathways for low-risk organisms and improving timelines and predictability for regulatory determinations could increase the chances of smaller entities developing regulated plants or microorganisms. Large companies usually have a team dedicated to the regulatory part to navigate APHIS requirements, which will probably not be possible for small companies, startups, and universities.

Question 8: Are there any other specific issues or topics APHIS should consider in developing a regulatory framework for assessing the plant pest risk of modified organisms, or possible pathways to commercialization for modified organisms?

The regulatory framework should remain adaptive, science-based, and risk-proportionate, recognizing that biotechnology is a tool whose risks and benefits depend on the organism and trait involved, rather than on the method used to develop it.

3. References

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