June 30, 2026

Michael Poe
Office of the General Counsel
U.S. Department of Agriculture
1400 Independence Ave. SW
Washington, DC 20250

Re: Docket No: USDA-2026-0133, Request for Information on Modified Organisms Subject to the Plant Protection Act

Dear Mr. Poe,

Thank you for the opportunity to comment on the important issue of the regulation of genetically modified organisms subject to the Plant Protection Act. The American Society of Plant Biologists (ASPB), ASM, and the Weed Science Society of America (WSSA), along with its affiliates, the Aquatic Plant Management Society, North Central Weed Science Society, Northeastern Weed Science Society, Southern Weed Science Society, and Western Society of Weed Sciences, are scientific organizations whose members regularly interface with the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA APHIS), both Biotechnology Regulatory Services (BRS) and Plant Protection and Quarantine (PPQ), the two programs directly related to the questions posed for public comment. ASPB is a community of scientists advancing the study of plant biology whose members drive scientific discovery for societal benefit; ASM is a professional life science organization composed of more than 38,000 scientists, educators, and health professionals dedicated to promoting and advancing microbial sciences around the world; and WSSA and its affiliates promote research, education, and extension outreach activities related to weeds and invasive plants.

For more than 40 years, scientists have been fascinated by the promise inherent in the genetic manipulation of plants, insects, livestock, and microorganisms. From the very beginning, biotechnology was used successfully to counter agricultural challenges, such as the devastating threat of papaya ringspot virus to the Hawaiian papaya industry[1]. The very real potential to continue using genetic engineering (GE) to solve challenges relating to agriculture,[2] nutrition,[3] ecosystem recovery,[4] and public health,[5] among many other noble causes, has only grown as the effectiveness of the technology has increased. Moreover, the safety of GE technologies has been demonstrated over nearly 30 years of successful commercialization of biotechnology crops. APHIS should continue a science-based and risk-proportionate approach to regulating these products.

In response to Question 1, “Are there material differences in plant pest risk between conventional and genetically engineered organisms (plant, microorganisms, or insects)?”, the straightforward answer is that the methods for genetic manipulation have consistently shown no inherent increased plant pest risk. The use of *Agrobacterium*-delivered vectors and certain genetic sequences from plant pests, such as promoters from viruses, for example, does not make the resulting GE plant riskier to plant or environmental health. As the RFI noted, decades of evaluations of GE plants and microorganisms have not revealed plant pest risks associated with engineered organisms when compared to conventionally bred organisms.

However, cases in which APHIS may have been consulted on potential modifications that did constitute a risk, and, which, therefore, the developers withdrew from consideration, would never have come to public light. Therefore, although plants, insects, and microorganisms should not be regulated based only on the method by which they were developed, APHIS should continue to maintain a science-based, risk-proportionate oversight of GE plants, insects, and microorganisms that are plant pests, just as APHIS oversees conventionally bred plants, insects, and microorganisms that are plant pests.

Questions 2 and 3 ask about experiences developers have had with the SECURE rule and under the current 7 CFR part 340. The SECURE rule was a significant improvement in science-based regulatory oversight that lowered costs for applicants and was built to allow additional exemptions, though each process has pros and cons.

Part 340 includes an option for notifications, which offer a streamlined alternative to APHIS-BRS permits, enabling pre-commercial activities with GE organisms to run more smoothly. The SECURE rule’s permitting process did not include this option, which was burdensome, especially for relatively small developers.

In addition, Part 340 offered the Am-I-Regulated (AIR) process, which reduces the permitting burden on many gene-edited plants. This process was unavailable when the SECURE rule was in effect.

However, Part 340 is fundamentally flawed in that it is based on regulating the process rather than the product, which is particularly challenging for transgenic plants, regardless of plant pest risk. This is where the SECURE rule was advantageous. *Agrobacterium tumefaciens*, a microorganism and plant pest used to create transgenic plants, for example, can be rendered harmless when its gall tumor-causing genes have been removed (also known as “disarmed *Agrobacterium*”), but permits are still required, under Part 340, to import or ship this microorganism across state lines. By contrast, APHIS-PPQ has determined the wildtype plant pest *A. tumefaciens* so low-risk that it requires no permits to

ship. Transgenic plants produced using *A. tumefaciens*, along with the microorganism itself, should be regulated proportionate with the plant pest risk of the final product and not given extra scrutiny because of the method used to produce them. The SECURE rule regulated these transgenic plants based on their plant pest risk, not the process used in the development of the GE plant, which is a more science-based approach.

Question 4 asks whether APHIS could effectively address plant pest risks of modified organisms under 7 CFR part 330 instead of 7 CFR part 340, the implication being that PPQ could treat GE organisms as it handles conventional ones. Without significant updates to 7 CFR part 330, this would cause a major disruption to the innovation ecosystem of plant and microbial biotechnology and, potentially, international trade. We strongly urge USDA to reconsider this approach as it would be detrimental to the biotech community and offers no pragmatic solutions to current regulatory challenges.

Currently, PPQ maintains authority over the importation and interstate movement of non-modified plant pest organisms, and there are significant obstacles to PPQ taking on the responsibilities currently handled by BRS. For example, PPQ does not have trained staff or expertise in biotechnology regulation. Our members report positive experiences speaking directly with BRS staff, who are knowledgeable with respect to biotechnology and the relevant regulations, often suggesting approaches for shorter paths for regulatory review.

Moreover, unlike BRS, PPQ has no risk-based protocols to assess the impact of importation or interstate movement of the organisms it oversees. If a non-GE organism, for example, a soil microbe, is a plant pest but is also endemic to the area it is proposed to be moved or introduced, PPQ could exempt it from permitting requirements. Often, however, PPQ will not issue an exemption, despite published scientific evidence from other federal agencies (such as the Environmental Protection Agency) or reputable academic institutions (including land-grant institutions) demonstrating the organism's prevalence in the new area. PPQ could determine that the organism is "novel" in the proposed location and require a permit regardless of plant pest risk, with no recourse or appeal process for the developer. Given authority over GE organisms, PPQ could decide all GE microorganisms are novel and require permits even if there is no plant pest risk associated with their movement or introduction, and PPQ permit conditions, which are intended to restrict the spread of known plant pests, are more restrictive. By contrast, BRS utilizes a risk-based framework that exempts modified organisms from regulation if there is no plant pest risk; PPQ does not have a risk-based regulatory pathway in place.

The above comments are primarily concerned with how the transfer of responsibilities for regulatory oversight of GE organisms from BRS to PPQ would cause undue burdens for developers and additional expense and delays in deploying novel crops and

microorganisms to the benefit of farmers and consumers because of the absence of a risk-based regulatory framework at PPQ. APHIS should also consider the potential risks to international trade, public health, and public trust by reducing or significantly altering the oversight of modified plants.

PPQ currently does not have regulatory oversight of GE plants, and 7 CFR part 330 would need to be modified for PPQ to include that authority. This is especially important with respect to plants that produce industrial chemicals. Unlike plants that produce pharmaceuticals, which are regulated by FDA, these plants, though they may not represent a plant pest risk, per se, can be included in the Plant Protection Act's authorities, which include certain risks to public health that underpin BRS's current oversight of such plants. In the absence of 7 CFR part 340, these plants could be released without permitting requirements, and it is feasible they could enter the food system. Therefore, any changes made to the regulatory structure should be considered with respect to the international regulatory community's reliance on the robustness of the U.S. system. Revisions to 7 CFR part 340 would be far less disruptive to international trade than the more abrupt and consequential transfer of BRS responsibilities to PPQ.

To conclude, APHIS has an opportunity, through this RFI, to reaffirm and refine a risk-based approach to the regulation of GE organisms under the Plant Protection Act and Coordinated Framework. We strongly recommend that APHIS (1) continue to maintain risk-based oversight of GE plants, insects, and microorganisms under 7 CFR part 340; (2) refrain from shifting oversight to 7 CFR part 330 unless and until PPQ has developed a transparent, science-based framework comparable to BRS's; and (3) ensure that any future changes to regulatory responsibilities preserve protections for public health, international trade, and public trust while enabling timely deployment of beneficial innovations.

[1] https://www.apsnet.org/edcenter/apsnetfeatures/Pages/PapayaHawaiianRainbow.aspx

[2] https://bteggplant.cornell.edu/bt-eggplant/

[3] https://www.sciencedirect.com/science/article/abs/pii/S0022316625004146

[4] https://pmc.ncbi.nlm.nih.gov/articles/PMC8400010/

[5] https://pmc.ncbi.nlm.nih.gov/articles/PMC5993454/