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COMMENTS OF ITIF

to the

Office of the Secretary
U.S. Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250-1400.

In the Matter of: USDA Request for Information on Modified Organisms Subject to the Plant Protection Act	)	FR Doc. 2026-09833 Docket No: USDA-2026-0133

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INTRODUCTION AND SUMMARY

The Information Technology and Innovation Foundation (ITIF) appreciates the opportunity to offer comments in response to the U.S. Department of Agriculture's request for information (RFI) on modified organisms subject to the Plant Protection Act.[1]

USDA requests comments on the existing regulatory regime for "genetically engineered plants and microbes" under regulations at 7 CFR Parts 330 and 340. USDA asks respondents to indicate whether the existing regime is appropriate, whether it is compliant with the requirements of Executive Order 13874, and how to address defects in the existing regime if they are identified.[2]

In these comments, ITIF first provides an overall analysis, then provides answers to eight specific questions enumerated in USDA's RFI.

OVERALL ANALYSIS

The supplementary information that USDA provides as background for this RFI is instructive, because it makes a compelling case for setting aside the existing regulations rooted in 7 CFR 340 applied to "GE plants and microbes."

The RFI notes:

> A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent is a plant pest or if the Administrator has reason to believe the GE organism is a plant pest.

Moreover, the RFI acknowledges:

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[1] ITIF is an independent 501(c)(3) nonprofit, nonpartisan research and educational institute that has been recognized as the leading think tank for science and technology policy. For more information, see: https://itif.org/about/. These comments pertain to: FR Doc. 2026-09833, "Request for Information on Modified Organisms Subject to the Plant Protection Act," a proposed rule by the U.S. Department of Agriculture, May 15, 2026, https://www.federalregister.gov/documents/2026/05/15/2026-09833/request-for-information-on-modified-organisms-subject-to-the-plant-protection-act.

[2] Executive Order 13874, "Modernizing the Regulatory Framework for Agricultural Biotechnology Products," June 11, 2019, https://www.federalregister.gov/documents/2019/06/14/2019-12802/modernizing-the-regulatory-framework-for-agricultural-biotechnology-products.

> APHIS's decades of experience in evaluating GE plants and microorganisms for plant pest risk have not revealed a materially different or distinct set of risks associated with GE plants and microorganisms when compared to conventional plants and microorganisms. Further, APHIS's regulations do not take clear notice of substantial advances in biotechnology since the late 1980s.

And finally:

> Executive Order 13874… directs the Federal Government to adopt regulatory approaches for the products of agricultural biotechnology that are proportionate to the risks such products pose, and that avoid arbitrary or unjustifiable distinctions across like products developed through different technologies… [it] states that regulatory decisions should be science- and evidence-based, taking economic factors into account as appropriate and consistent with applicable law; that regulatory reviews should be conducted in a timely and efficient manner; and that biotechnology regulations should be transparent, predictable, and consistent.

While it was arguably defensible in 1986 to assert that a lack of experience with "GE" organisms made the hazards they embodied and the risks exposure to those hazards might present justified a presumption of a plant pest risk rebuttable after scrutiny and analysis, this is manifestly not true today. Decades of experience with millions of farmers growing crops improved through biotechnology on many millions of acres in more than thirty countries around the world, producing harvests consumed by billions of livestock animals and humans without a single negative consequence attributable to an unexpected attribute of the biotech improved crop provides a robust falsification of the hazard hypothesis on which the 1986 Coordinated Framework was predicated. The regulations as they are implemented today, and as they have been for decades, are therefore not "science- and evidence-based." As USDA's Animal and Plant Health Inspection Service (APHIS) concedes, there is no "materially different or distinct set of risks associated with GE plants and microorganisms when compared to conventional plants and microorganisms." It is thus not possible to construct a regulatory regime applied to the "regulated articles" as defined that "avoid[s] arbitrary or unjustifiable distinctions across like products developed through different technologies."

By APHIS's own admission, the existing regulations under 7 CFR 340 do nothing to safeguard U.S. agriculture or human or environmental health and safety. They no longer satisfy the criteria under which they were first proposed, nor do they meet the criteria stipulated in Executive Order 13874, nor can any relic of the existing regime be salvaged by reconstitution under 7 CFR 330 as long as the existing definitions of regulated articles and regulatory triggers apply. At this point they constitute nothing but a disincentive and impediment to innovation in agriculture at a time when it is urgently needed. The time to set these regulations aside has arrived.

USDA seeks input into what kind of regulation, if any, might credibly and usefully be stood as an alternative to the existing regime. USDA should issue a new RFI and invite comments on what a science based regulatory regime anchored in a process of hazard identification (the essential prerequisite) might be developed as the basis for risk assessment and management of crops or microbes with hazardous characteristics to which

exposure may create a risk, whether derived from recombinant DNA techniques, classical breeding programs, or other engine of innovation.

Plants grown to produce pharmaceutical compounds for treating human or animal diseases might be a category of potential hazard worthy of pre-market scrutiny. So also might be traits introduced into a crop plant with a wild/weedy relative into which such traits might reasonably be expected to introgress so as to create or exacerbate a plant pest risk, such as herbicide tolerance or pest/disease resistance. We have submitted comments previously as to how such categories might be defined and populated but it is likely that APHIS stakeholders could provide illuminating input to such an RFI.[3]

REPLIES TO USDA'S SPECIFIC QUESTIONS

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?

As vast experience around the world growing genetically engineered crops has shown, and by APHIS' own admission, there are no material differences in plant pest risk between conventionally bred and genetically engineered (or gene edited) organisms. Over many years, proponents of regulation have repeatedly been invited to provide examples of such risk differentials. They have produced none. Given the mandate in EO 13874 there is therefore no justification to continue to discriminate against genetically engineered organisms as the current regime does, and it should be set aside.

2. Describe your experiences of regulation under the SECURE rule. Were there areas that could have been improved? Were there obstacles to performing field trials? What about obstacles advancing from field trials to commercialization? What were the costs incurred complying with and/or navigating the regulatory requirements of the SECURE rule? What areas of the SECURE rule worked well?

Given the preceding summary from APHIS and EO 13874, this question is moot. There is no conceivable response that would overcome the fatal flaws identified in answer 1 and above.

3. Describe your experiences of regulation under the current 7 CFR part 340. Are there areas that could be improved? Are there obstacles to performing field trials? What about obstacles advancing from field trials to commercialization? What are the costs incurred complying with and/or navigating the regulatory requirements of 7 CFR part 340?

The author of these comments has worked for decades with members of the regulated community, helping them to comply with APHIS' regulatory requirements. Many of these requirements made field trials more difficult and costly, protecting against nonexistent risks without contributing to any increase in safety. The

[3] L. Val Giddings, "How the Second Trump Administration Can Boost the Agriculture Economy: A Roadmap to Low-Hanging Fruit," ITIF *Innovation Files* commentary, December 3, 2024, https://itif.org/publications/2024/12/03/how-the-second-trump-administration-can-boost-the-agriculture-economy/; L. Val Giddings, "Biotech Matters: Innovation in Agricultural Biotechnology: The Role and Impact of U.S. Regulations," Center for a New American Security, March 19, 2024, https://www.cnas.org/publications/reports/biotech-matter-innovation-in-agricultural-biotechnology; L. Val Giddings, "Comments to OSTP Regarding Revisions to the Coordinated Framework for the Regulation of Biotechnology," ITIF, January 27, 2023, https://itif.org/publications/2023/01/27/itif-comments-regarding-the-coordinated-framework-for-the-regulation-of-biotechnology/.

requirements also made advancing to commercialization more difficult, slow, and expensive, again without enhancing safety. Myriad opportunities for improvement could be described but given the preceding summary from APHIS of its experience implementing the regulations, and the requirements of EO 13874, they are moot. There are no repairs conceivable that could ameliorate the fatal defects identified above.

4. Could APHIS effectively address plant pest risks of modified organisms by regulating them under 7 CFR part 330 instead of 7 CFR part 340? What should APHIS consider when determining whether 7 CFR part 330 could replace regulation of modified organisms under 7 CFR part 340? For example, what might be the trade implications of a new regulatory framework for modified organisms under the Plant Protection Act?

The fatal flaws intrinsic to the existing regulations under 7 CFR 340 will attach to any other approach similarly predicated on "a materially different or distinct set of risks associated with GE plants and microorganisms when compared to conventional plants and microorganisms" that does not exist whether it be under 7 CFR 330 or otherwise.

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?

If the regulated article remains defined as it has been for the regulations under 7 CFR 340 from 1987 to date, and subject to the same regulatory triggers, the challenges of regulating "modified organisms" under 7 CFR 330 would be no different. They would remain insurmountable, and impossible to reconcile with the findings in APHIS' RFI and EO 13874. There would be no benefit.

6. Describe key elements of a regulatory framework, including oversight of field trials, that would enable a scientifically sound assessment of a modified organism's plant pest risk.

This question suffers from the same fundamental and fatal defect as the existing regulations under 7 CFR 340—without examining or challenging the presupposition, it assumes some undefined hazard peculiar to "GE organisms" distinct from any possessed by "non-GE organisms," which requires risk assessment and management. Yet as APHIS admits in the RFI, they are unable to identify such a hazard. No other entity around the world has succeeded in this effort either.

The best way to enable a scientifically sound assessment of a modified organism's plant pest risk would be to define a category of hazards associated with modified organisms (produced by genetic engineering, gene editing, classical mutagenesis breeding, or whatever mechanism). The characteristics of such organisms presenting hazards will themselves suggest the measures required to ensure the safety of field trials and commercialization through appropriate risk assessment and management or mitigation measures.

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

Clearly, yes. Regulatory burdens were imposed that failed to protect against any defined plant pest risk unique to the regulated articles, or deliver benefits sufficient to justify their costs, putting smaller entities at a competitive disadvantage compared to larger, better capitalized organizations.

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?

Again, the framing of this question rests on an unexamined presupposition of hazardous qualities of modified organisms to which exposure would generate a plant pest risk requiring prevention, mitigation, or management. Until and unless such hazardous characters can be identified, and classes of hazardous modified organisms described with precision, there can be no basis for the assessment and mitigation or management of nonexistent risks.

CONCLUSION

The background information USDA provides in its RFI—including its own historical record and information on regulatory requirements both in regulations and in applicable Executive Orders on regulatory policy—clearly shows that the existing regulations in 7 CFR 340 for "modified" or "genetically engineered plants and microbes" fail to meet the required scientific and regulatory criteria. They presuppose said regulated articles pose a greater risk than organisms with similar characteristics derived through different methods while being unable to demonstrate such a difference in risk. They thus fall short of the requirement that applicable regulations be "proportionate to the risks such products pose, and that avoid arbitrary or unjustifiable distinctions across like products developed through different technologies. Among other things, Executive Order 13874 states that regulatory decisions should be science- and evidence-based." The fatal defects in the regulations under 7 CFR 340 cannot be cured by being recast under 7 CFR 330. The existing regime does nothing to protect American agriculture from any identified or identifiable plant pest risks and must therefore be set aside.

A better approach, as ITIF has proposed, would be to develop science-based, proportionate regulations that identify categories of organisms that carry identifiable hazards (extant or plausible), which could then be subject to risk assessment, management, and mitigation.[4]

Thank you for your consideration.

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[4] Ibid.