BREAKTHROUGH INSTITUTE

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Michael Poe
Office of the General Counsel
United States Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250-1400

SUBMITTED VIA REGULATIONS.GOV

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

The Breakthrough Institute[1] writes to commend the efforts of USDA and the White House to streamline regulation of agricultural biotechnology. The current regulatory approach fails to allocate resources based on the risks posed by genetically engineered organisms, thus imposing regulatory costs and delays for small and large developers alike without providing public benefit.

We urge USDA to overhaul its approach, regulating based on the hazard posed by a product's traits and the risk created through exposure to that hazard, rather than based on the types of genetic changes or the technology used to make them. In particular, USDA should build a tiered, risk-proportionate regulatory system that presumes that no premarket regulation is needed for most new organisms, and that requires review only of organisms with high-risk traits, regardless of how they were developed.[2] Experience with conventionally-bred and genetically engineered crops to date provides enough evidence to treat a wide variety of traits as low-risk.[3] Such an approach would more efficiently use government resources to assess risks in a scalable and proportional manner, as recommended by the National Academies of Sciences; would support innovation by streamlining commercialization of low-risk products; and would provide a regulatory framework that can more easily adapt to new technologies.[4]

A more risk-proportionate system could be implemented by withdrawing 7 CFR Part 340 and modifying 7 CFR Part 330. Withdrawal of Part 340 would align APHIS regulations with regulatory and scientific findings that the process of genetic engineering itself has not made and does not make organisms function as plant pests, even when the donor organism, vector, or vector agent is or contains a plant pest.[5]

[1] The Breakthrough Institute is an independent 501(c)(3) global research center that identifies and promotes technological solutions to environmental and human development challenges. Breakthrough's Food and Agriculture program advocates for policies and strategies to improve productivity growth in U.S. agriculture.
[2] Marchant, G. E., & Stevens, Y. A. (2015). A new window of opportunity to reject process-based biotechnology regulation. *GM crops & food*, *6*(4), 233-242. https://doi.org/10.1080/21645698.2015.1134406
[3] Bradford, K. J., Van Deynze, A., Gutterson, N., Parrott, W., & Strauss, S. H. (2005). Regulating transgenic crops sensibly: lessons from plant breeding, biotechnology and genomics. Nature biotechnology, 23(4), 439-444. https://www.nature.com/articles/nbt1084
[4] National Academies of Sciences, Engineering, and Medicine (NASEM, 2017). *Preparing for Future Products of Biotechnology*. National Academies Press. https://doi.org/10.17226/24605
[5] National Academies of Sciences, Engineering, and Medicine (NASEM, 2016). *Genetically engineered crops: experiences and prospects*. National Academies Press. https://doi.org/10.17226/23395

Nevertheless, withdrawing Part 340 would create new challenges APHIS must carefully address. APHIS must revise the plant pest exemption process under Part 330 to stop requiring permits for strains or lines of plant pests that are attenuated, disarmed, or otherwise do not pose a plant pest risk. In addition, plants that produce plant-made pharmaceuticals and industrials (PMPIs) or are used for phytoremediation can pose a non-negligible risk if they enter the feed or food supply. APHIS has previously said it lacks substantial experience with this area and PMPIs have previously required enforcement action for non-compliance.[6,7] New varieties of herbicide-tolerant crops—regardless of breeding method—can also increase the weediness of wild or feral relatives with which they can interbreed. These risks are not currently managed by Part 330 per se and warrant changes to the rule.

Below, we detail these claims, recommendations, and concerns in response to the questions in the RFI.

Thank you for your consideration.

Sincerely,

Dan Blaustein-Rejto, Director, Food & Agriculture
The Breakthrough Institute

Emily Bass, Director of Federal Policy, Food & Agriculture
The Breakthrough Institute

[6] Movement of Certain Genetically Engineered Organisms, 85 Fed. Reg. 29790, 29819 (May 18, 2020). https://www.federalregister.gov/d/2020-10638/p-379
[7] Fox, J. L. (2003). Puzzling industry response to ProdiGene fiasco. *Nature Biotechnology*. https://doi.org/10.1038/nbt0103-3b

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?

The latest scientific reviews and consensus reports do not indicate there is a material difference in plant pest risk between genetically engineered and non-genetically engineered organisms.

The Plant Protection Act defines a plant pest as any living stage of a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus, pathogen or similar or allied article "that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[8] Any method of plant breeding could theoretically increase plant pest risk (that is, the risk of introduction or dissemination of a plant pest) through several pathways including:

- increased host suitability, reservoir capacity, or transmissibility such as by reducing basal immunity, sustaining higher pest reproduction, or expanding the seasonal window for vector spread;
- affecting non-target organisms, such as by reducing populations of biological control organisms;
- selection-driven pest adaptation, such as selection for insecticide-resistant insects;
- increased persistence, volunteerism, or weediness of the plant or a sexually compatible relative, making it more likely to spread outside cultivation and serve as a host for plant pests; and
- failure of plant pest confinement during breeding, movement, or field testing.

National Research Council (NRC) and National Academies of Sciences, Engineering, and Medicine (NASEM) reports have consistently found that genetic engineering does not create new categories of risk.[9] A 2002 NRC report concluded "that there is no evidence of unique hazards inherent in the use of recombinant DNA techniques with respect to plants, and that crops modified by molecular and cellular methods should pose risks no different from those modified by conventional breeding methods for similar traits."[10] Similarly, a 2004 NRC report found that the probability of unintended effects due to genetic engineering falls within the range of unintended effects from various conventional breeding methods.[11] These findings are affirmed in the 2016 NASEM report, "Genetically Engineered Crops: Experiences and Prospects."[12]

Several metanalyses and review papers since the publication of the 2016 NASEM report further support this. For example, Pellegrino et al. (2018) found in a meta-analysis that insect-resistant genetically engineered (GE) maize didn't affect non-target organisms except parasitoids of European corn borer, the target of Lepidoptera active Bt maize.[13] This was further affirmed by a

[8] 7 USC Ch. 104, Subchapter 1, §7702.
[9] NASEM (2016).
[10] National Research Council. (2002). *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*. National Academies Press. https://doi.org/10.17226/10258
[11] National Research Council. (2004). Safety of genetically engineered foods: Approaches to assessing unintended health effects. National Academies Press. https://doi.org/10.17226/10977
[12] NASEM (2016).
[13] Pellegrino, E., Bedini, S., Nuti, M., & Ercoli, L. (2018). Impact of genetically engineered maize on agronomic, environmental and toxicological traits: a meta-analysis of 21 years of field data. *Scientific reports*, *8*(1), 3113. https://www.nature.com/articles/s41598-018-21284-2.pdf

2022 systematic review, which concluded that "The effects of Bt maize on the community of non-target invertebrates inhabiting maize fields were small and mostly neutral."[14] In addition, over 850 risk assessments for cultivation of GE crops, conducted by regulatory agencies in the U.S. and other countries, have concluded that the risks from commercialized GE crops do not differ from those of comparable non-GE crops.[15]

Further, differences in the *degree of risk* associated with different breeding methods do not, by themselves, justify separate regulatory regimes. What matters is whether a method creates a distinct category of plant pest risk that cannot be addressed through existing risk assessments. In many cases, conventional breeding introduces more genetic uncertainty than genetic engineering. As the National Biotechnology Policy Board concluded as early as 1992, "biotechnology processes tend to reduce risks because they are more precise."[16] Conventional breeding causes unintended genetic changes similar to the insertional effects from genetic engineering.[17] In fact, selective breeding, mutagenesis, and wide-cross hybridization are more likely to result in off-target changes than gene editing.[18,19,20] Conventional breeding also often results in plants that are more vulnerable to plant pests and lower-yielding than GE varieties, thus requiring more farmland and thus plausibly expanding the range of agricultural pests.[21] Yet USDA has not treated any conventional breeding methods as requiring separate regulatory regimes. Their long history of safe use supports adopting the same approach for genetic engineering: evaluating whether a particular organism or product presents a plant pest risk, rather than presuming risk based on breeding method.[22]

In addition, the lines between breeding technologies are increasingly blurry. For example, modification of traits like flowering time using spray-induced gene silencing (SIGS) does not fit into the narrow definition of genetic engineering or the dichotomy of genetic changes that could or could not have been made using conventional breeding. SIGS uses designed RNA that is sprayed onto plants to use their natural gene silencing systems to prevent assembly of a target protein. The method does not modify the plant's gene sequence but rather alters gene expression. A range of other modern techniques can edit the epigenome, as well as the transcriptome or genome.[23]

Finally, different breeding methods can result in similar traits and risks that are currently regulated in fundamentally different ways. This directly contravenes the policy of the Federal Government, as described in Executive Order 13874, to "avoid arbitrary or unjustifiable distinctions across like products developed through different technologies."[24] One review found

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[14] Meissle, M., Naranjo, S. E., & Romeis, J. (2022). Does the growing of Bt maize change abundance or ecological function of non-target animals compared to the growing of non-GM maize? A systematic review. *Environmental Evidence*, 11(1), 21. https://doi.org/10.1186/s13750-022-00272-0

[15] Lubieniechi, S. A., Van Eenennaam, A. L., & Smyth, S. J. (2025). Regulation of animal and plant agricultural biotechnology. *Trends in Biotechnology*, *43*(3), 511-521. https://doi.org/10.1016/j.tibtech.2024.11.003

[16] National Biotechnology Policy Board. (1993) 1992 National Biotechnology Policy Board Report. *Biotechnology Law Report*. 12(2) 127–182. https://doi.org/10.1089/blr.1993.12.127

[17] Schnell, J., Steele, M., Bean, J., Neuspiel, M., Girard, C., Dormann, N., ... & Macdonald, P. (2015). A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments. *Transgenic research*, *24*(1), 1-17. https://doi.org/10.1007/s11248-014-9843-7

[18] Graham, N., Patil, G. B., Bubeck, D. M., Dobert, R. C., Glenn, K. C., Gutsche, A. T., ... & Morrell, P. L. (2020). Plant genome editing and the relevance of off-target changes. *Plant Physiology*, *183*(4), 1453-1471. https://doi.org/10.1104/pp.19.01194

[19] Georges, F., & Ray, H. (2017). Genome editing of crops: a renewed opportunity for food security. *GM Crops & Food*, *8*(1), 1-12. https://doi.org/10.1080/21645698.2016.1270489

[20] Singer, S. D., Laurie, J. D., Bilichak, A., Kumar, S., & Singh, J. (2021). Genetic variation and unintended risk in the context of old and new breeding techniques. *Critical Reviews in Plant Sciences*, *40*(1), 68-108. https://doi.org/10.1080/07352689.2021.1883826

[21] Kovak, E., Blaustein-Rejto, D., & Qaim, M. (2022). Genetically modified crops support climate change mitigation. *Trends in Plant Science*, *27*(7), 627-629. https://doi.org/10.1016/j.tplants.2022.01.004

[22] Schouten, H. J., & Jacobsen, E. (2007). Are mutations in genetically modified plants dangerous? *Journal of biomedicine and biotechnology*, *2007*, 82612. https://doi.org/10.1155/2007/82612

[23] Loschin, N., Kuzma, J., Barrangou, R., & Grieger, K. (2025). Environmental assessment and regulatory oversight of genetically engineered crops in the United States. *Environmental Science & Policy*, *173*, 104237. https://doi.org/10.1016/j.envsci.2025.104237

[24] Modernizing the Regulatory Framework for Agricultural Biotechnology Products, Exec. Order No. 13874, 84 Fed. Reg. 27899, 27899 (June 14, 2019). https://www.federalregister.gov/d/2019-12802/p-5

that “conventional breeding has been used to produce a broader range of herbicide-resistant crops than have been genetically engineered for herbicide resistance.”[25] For instance, scientists recently developed a non-GE trait, AXigen, in wheat that provides tolerance to Aggressor AX herbicides.[26] This and other non-GE herbicide-tolerant (HT) crops pose a similar risk as GE HT crops to increase weed herbicide resistance, whether through selective pressure or gene flow. Yet APHIS only requires risk assessment and permits for the GE crops. This difference in treatment lacks scientific justification and has long been criticized.[27]

For these reasons, APHIS should not continue to distinguish genetically engineered organisms from all other organisms in its Plant Protection Act regulations.

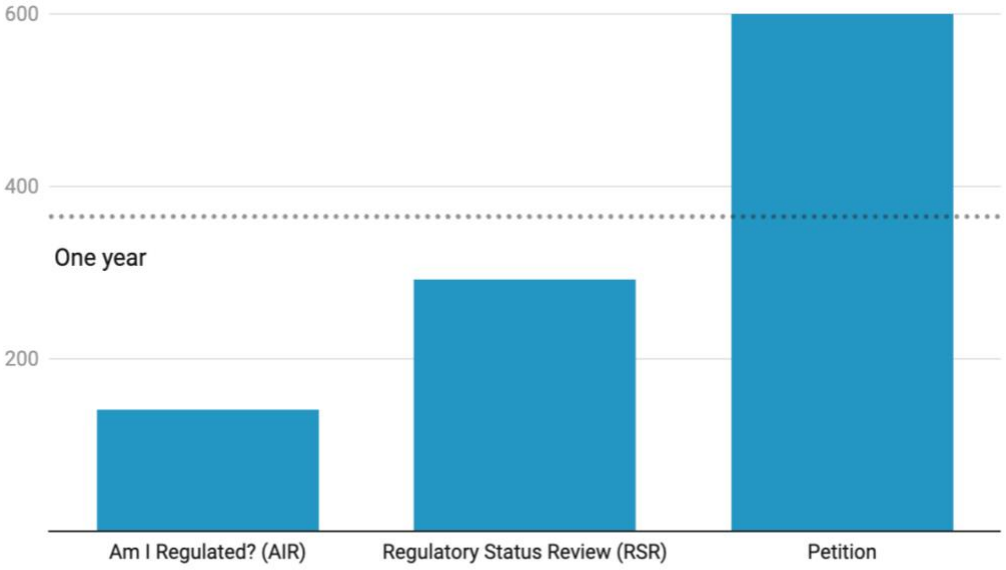
2) Describe your experiences of regulation under the SECURE rule. Were there areas that could have been improved? Were there obstacles to performing field trials? What about obstacles advancing from field trials to commercialization? What were the costs incurred complying with and/or navigating the regulatory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

Before the SECURE rule was vacated, it improved product review by introducing a more flexible system with tiers of review to match different levels of risk. In the initial stage of Regulatory Status Review, the agency looked for plausible pathways by which a genetically engineered organism could pose a plant pest risk. If there were none, then the organism was no longer subject to USDA’s biotech regulations. If there were plausible plant pest risks, then a second stage of review determined the likelihood and degree of that risk. This enabled better allocation of agency resources and sped up reviews of transgenic crops relative to the legacy petition process, as illustrated in the chart below.[28] SECURE also improved the clarity of exemptions compared to the legacy regulations.

[25] Mallory-Smith, C. A., & Sanchez Olguin, E. (2011). Gene flow from herbicide-resistant crops: It’s not just for transgenes. *Journal of Agricultural and Food Chemistry*, *59*(11), 5813-5818. https://doi.org/10.1021/jf103389v
[26] Stubbs, L. R., Zubrod, M., Burke, A. B., & Carter, A. H. (2025). Identifying winter wheat (Triticum aestivum L.) lines with group 1 herbicide tolerance. *Agricultural & Environmental Letters*, *10*(2), e70042. https://doi.org/10.1002/ael2.70042
[27] Mallory-Smith & Sanchez Olguin (2011).
[28] Kovak, E. (2026a). Some Biotechnology Product Reviews Have Gotten Faster, Despite Changing Regulations. *The Breakthrough Institute*. https://thebreakthrough.org/issues/food-agriculture-environment/some-biotechnology-product-reviews-have-gotten-faster-despite-changing-regulations

BRS Reviewed Transgenic Crops Quicker under SECURE's RSRs

Average number of days from application submission to APHIS decision for transgenic products



Average application processing time calculated using data from 2015 to 2025. APHIS completed RSRs from 2022 to 2024; AIRs from 2015 to 2020 and in 2025; and Petitions in every year except 2024. Data accessed January 23, 2026.

However, USDA should not return to the SECURE rule. It used conventional breeding as the benchmark to explain why gene-edited crops should be exempted, despite robust evidence that conventional breeding can increase risk. Its design also would have failed to keep up with the changing technology landscape.[29,30]

SECURE, like the legacy regulations, combined product- and process-based regulations: products were initially selected for review based on the process used to create them (transgenesis or gene editing, not conventional breeding), while the review itself was based on the actual traits of the product. In addition, the exemptions for some gene edited plants were based on whether they had genetic changes that could have been made using conventional breeding (as defined by the size, type, and number of genetic changes), rather than the traits that could actually pose a risk. This initial process-based selection didn't focus on the actual causes of risk, which resulted in an inefficient use of resources from both USDA and developers.

USDA justified the exemptions by arguing that products of conventional breeding have proven safe over the years, and therefore gene edited plants that could have been created using conventional breeding should be presumed safe as well.[31] The agency, in effect, shifted the basis for regulation from the type of technology used to the type of genetic change made. However, USDA itself and several consensus reports by the U.S. National Research Council

[29] Kovak, E. (2020). How Not to Deregulate GMOs. *The Breakthrough Institute.* https://thebreakthrough.org/issues/food-agriculture-environment/how-not-deregulate-gmos
[30] Loschin et al. (2025).
[31] 85 Fed. Reg. at 29791. https://www.federalregister.gov/d/2020-10638/p-33

and other scientific bodies state that conventional breeding can produce both safe and unsafe products, and that genetic engineering processes do not create any new types of risk.[32] The SECURE rule continued to subject many products to extensive regulatory review simply because they had genetic changes that could not have been made using conventional breeding—often because they contained transgenic DNA from other species—which itself is not a source of risk.

SECURE also failed to exempt well-defined categories of low-risk traits from premarket review altogether. For example, USDA continued to regulate domestication traits in some cases under SECURE. Domestication traits make a crop more suitable for agricultural cultivation but less likely to survive in the wild, for example, traits like sterility, dwarfism, seed retention, changes in lignin biosynthesis and flowering time, and altered fruit ripening. However, scientists have concluded for over two decades that domestication traits are particularly low risk and unlikely to increase the invasiveness of wild relatives of crop plants when they spread beyond the agricultural context.[33,34,35] Despite this decades-old case for exempting domestication traits, several plants with domestication traits were reviewed through SECURE's RSR process including a shorter blackberry with less thorns and softer seeds, and a cowpea that stops growing earlier and flowers at a different time.[36,37]

Further, the type of process-based regulation in SECURE does not adapt well to future technologies. For example, modification of traits like flowering time using spray-induced gene silencing does not fit into the narrow definition of genetic engineering or the dichotomy of genetic changes that could or could not have been made using conventional breeding. Therefore, USDA should avoid reinstating a similar process-based regulatory regime in any future rulemaking.

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?

APHIS could effectively address the plant pest risks of modified organisms under 7 CFR Part 330 instead of Part 340, provided that APHIS makes targeted revisions to Part 330 to a) assess and regulate high-risk organisms, and b) create an exemption or deregulation pathway for strains of plant pests modified to no longer pose a risk. This approach would better align APHIS' regulations with the scientific record that genetically engineered organisms do not pose categorically different plant pest risks than organisms developed through selective breeding, mutagenesis, or other methods.[38] Because there is no material difference in the types of risks,

[32] NASEM (2016).
[33] Bradford et al. (2005).
[34] Strauss, S. H. (2003). Regulating biotechnology as though gene function mattered. *BioScience*, *53*(5), 453-454. https://doi.org/10.1641/0006-3568(2003)053[0453:RBATGF]2.0.CO;2
[35] Hancock, J. F. (2003). A framework for assessing the risk of transgenic crops. *BioScience*, *53*(5), 512-519. https://doi.org/10.1641/0006-3568(2003)053[0512:AFFATR]2.0.CO;2
[36] Pairwise Plants Services, Inc. (2024, March 27). *Request for regulatory status review of gene edited blackberry (Document No. 24-087-01rsr)*. Submitted to USDA Animal and Plant Health Inspection Service. https://www.aphis.usda.gov/sites/default/files/24-087-01rsr.pdf
[37] BetterSeeds, Ltd. (2023, October 6). *Request for regulatory status review of gene edited cowpea with altered flowering and a determinate growth habit (Document No. 23-261-01rsr)*. Submitted to USDA Animal and Plant Health Inspection Service https://www.aphis.usda.gov/sites/default/files/23-261-01rsr.pdf
[38] NASEM (2016).

the established regulations and processes within Part 330 are generally suitable to manage risks posed by GE organisms.

§ 330.201 already requires a person to obtain a permit (PPQ 526) before importing, moving interstate, or releasing into the environment a plant pest, an associated article, or an organism of unknown risk to plants that is similar to a plant pest, unless the organism or activity is exempted or otherwise authorized under the regulations.[39] § 330.100 defines an article as "Any material or tangible object, including a living organism, that could harbor living plant pests or noxious weeds. The term includes associated articles such as soil and packaging."[40] This can be interpreted broadly as including plants that could harbor pests. PPQ thus has the authority to require a permit and to specify conditions that prevent a pest's dissemination or establishment.

That makes Part 330 appropriate for managing plant pest risk from modified organisms. If Part 340 were withdrawn, APHIS could still require permits under Part 330 for modified organisms that are plant pests, could harbor plant pests, or are moved or tested in ways that create a plausible risk of introducing or disseminating a plant pest. Field trials involving modified microbes, plant-associated organisms, or plants that involve a regulated plant pest, pathogen, vector, or other covered article could be managed through the same permit framework that APHIS already uses for non-GE plant pests. Where warranted, APHIS could impose permit conditions governing confinement, monitoring, volunteer control, and other measures to reduce plant pest risk.

§ 330.204 provides a flexible mechanism for reducing unnecessary regulatory burden by exempting select plant pests.[41] APHIS has established that certain organisms established throughout their range in the United States or that are commercially produced under regulatory purview of other Federal agencies present no additional plant pest risk and can be moved without restriction. The regulation also allows any person to petition APHIS to add or remove a taxon from the exempt list, including specific cultivars, subspecies, biovars, or other recognized groupings.

However, APHIS would need to revise this exemption process if Part 330 is to serve as the primary framework for modified organisms. Researchers and developers often use attenuated viral vectors, disarmed strains, or other laboratory constructs derived from plant pathogens to modify plants or other organisms. These are intentionally engineered to be nonpathogenic, replication-deficient, host-limited, or otherwise unable to cause plant disease. Yet Part 330 does not clearly provide a pathway to exempt such strains or lines from repeated permitting. In addition, §330.204 limits exemptions to "field populations or lab cultures derived from field populations" of taxa established throughout their range in the continental United States. PPQ could reasonably conclude that attenuated vectors and other novel laboratory constructs are not covered by that language, even when they pose lower risk than the field populations from which they were derived.

[39] 7 CFR § 330.201 (2026).
[40] 7 CFR § 330.100 (defining "Article") (2026).
[41] 7 CFR § 330.204 (2026).

With a revised exemption process and other revisions described in our response to question 5, regulating modified organisms under Part 330 would not reduce federal oversight. Rather, it would align APHIS oversight with the Plant Protection Act risks APHIS is best positioned and authorized to manage, while leaving pesticidal risks to EPA. EPA would continue to regulate plant-incorporated protectants and pesticidal organisms under FIFRA and FFDCA authorities.[42] This allocation of responsibilities is consistent with the Coordinated Framework's core principle that biotechnology oversight should be risk-based and administered by agencies with the appropriate expertise and authority.[43]

4 cont.) What should APHIS consider when determining whether 7 CFR Part 330 could replace regulation of modified organisms under Part 340?

APHIS should consider whether and how it can manage risks posed by GE organisms that are not clearly categorized as plant pest risks and that aren't under the regulatory purview of other Federal agencies. For any such risks, we suggest APHIS issue a separate Request for Information to inform any complementary rulemaking.

One such possible category of risk is plants that synthesize high levels of toxins, allergens or orally active pharmaceuticals. Such plants could harm livestock if consumed or if they out-cross with feed crops; public health if the crops enter the food supply or out-cross with food crops[44]; or the environment if the pharmaceutical or industrial compounds are released in an uncontrolled manner. Under Part 340, regulated articles whose introduced genetic material encodes "products intended for pharmaceutical or industrial use" are ineligible for notification and thus face heightened scrutiny. It may be challenging to regulate these organisms under Part 330 instead; USDA has previously noted that this category of plant-made pharmaceuticals and industrials (PMPIs) does not clearly fall under the PPA's statutory definition of plant pest.[45]

These risks are not necessarily unique, however, to GE organisms and do not always warrant new regulation. Many non-modified crops are grown to produce pharmaceuticals or compounds for industrial use (e.g., yew, pyrethrum-producing chrysanthemum, and flax). USDA generally does not regulate cultivation of these; rather the extracted or processed compounds are regulated based on the risk they pose. Any regulation that USDA considers should be based on the hazard a PMPI poses (e.g., the toxicity and concentration of the compound) and on the likelihood of exposure (e.g., whether the PMPI crop is also grown as a food crop).

Additionally, APHIS should consider the staffing capacity and expertise required to successfully develop and implement a new regulatory framework. A primary challenge will be ensuring the agency has the technical staffing capacity and cross-disciplinary expertise to maintain oversight without creating a bottleneck in the approval pipeline. Making significant changes to Parts 330

[42] 40 CFR § 174.
[43] Executive Office of the President. (2017). Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology. https://usbiotechnologyregulation.mrp.usda.gov/sites/default/files/2017-coordinated-framework-update.pdf
[44] Hundleby, P. A., Sack, M., & Twyman, R. M. (2018). Biosafety, risk assessment, and regulation of molecular farming. *Molecular Pharming: Applications, Challenges, and Emerging Areas*, 327-351. https://doi.org/10.1002/9781118801512.ch13
[45] Importation, interstate movement, and environmental release of certain genetically engineered organisms (Proposed rule). 82 Fed. Reg. 7008, 7012 (2017). https://www.federalregister.gov/d/2017-00858/p-55

or 340 will require more than administrative reorganization; it necessitates a concerted effort to retain the specialized Biotechnology Regulatory Services (BRS) staff who possess deep technical and institutional knowledge.

The historical record demonstrates that even regulatory streamlining efforts require significant upfront investment to be effective. For example, in the President's Budget Request for FY2021, USDA explicitly sought a funding increase of nearly $9 million to support the implementation of the then-new SECURE rule, including resources to manage a unified regulatory website, enhance the IT infrastructure necessary to provide coordinated responses to developers, and dedicate staff to ensuring the regulatory program kept ahead of the pace of innovation.[46] Despite the promise of annual cost savings through modernization, the agency still required consistent discretionary funding to transition systems and manage the existing application workload. Without a similar commitment to adequate staffing and resource allocation, any shift toward a Part 330-centered regulation risks diluting the specialized expertise needed to ensure both scientific integrity and regulatory efficiency in an increasingly complex biotechnological landscape. Therefore, the White House, USDA, and Congress will need to prioritize adequate staffing and resources at APHIS.

5) What would be 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?

One benefit of regulating modified organisms under 7 CFR Part 330 is that it would align with scientific consensus and NASEM recommendations to regulate based on risk, regardless of breeding technology, rather than conducting additional risk analysis only for GE crops.[47,48] It would also better align with APHIS' principle of regulating an organism as a plant pest only when there is "demonstrated evidence or a plausible hypothesis that the organism can cause direct or indirect harm to plants."[49] This should enable APHIS to operate more cost-effectively, reducing costs in the long run while more carefully studying and regulating organisms that pose a high risk. As detailed in our response to question 7 below, it could also reduce unnecessary regulatory costs and delays for developers, which disproportionately impact small developers and specialty crops.

However, if APHIS chooses to regulate modified organisms under Part 330, it should make several changes.

APHIS should establish a tiered system to efficiently assess the plant pest risk of organisms. This system should be restricted only to product types that are most likely to pose a risk based on current scientific understanding, accounting for the organism, trait, mode of action, receiving environment, and use. APHIS could maintain a list of "red flag" product types that require a plant pest risk assessment and that is revised over time based on experience.[50] For instance,

[46] U.S. Department of Agriculture. (2020). *Animal and Plant Health Inspection Service, FY 2021 Explanatory Notes.* https://www.usda.gov/sites/default/files/documents/20aphis2021notes.pdf
[47] Bradford et al. (2005).
[48] NASEM (2016).
[49] USDA APHIS. (2026). BRS Stakeholder Meeting. https://www.aphis.usda.gov/sites/default/files/final-brs-presentation-feb26.pdf
[50] Marchant & Stevens (2015).

herbicide-tolerant crops (both GE and non-GE) can pose a risk of transferring traits to nearby wild relatives or feral populations, increasing their weediness.[51] In such a case, APHIS should exercise continued oversight, setting requirements or restrictions for field trials and cultivation (e.g., minimum separation distances or geographic restrictions), as EPA does for some plants with plant-incorporated-protectants.[52] For any list of criteria that would trigger a plant pest risk assessment, there should be a corresponding process to submit petitions to add or remove criteria from the list and a set timeline for APHIS to respond to petitions. Criteria should be as narrowly defined as is scientifically defensible to ensure the benefit of regulation outweighs the costs. For example, the ability of a modified plant to outcross with wild relatives should not, by itself, trigger review or regulation. It is a well-established biological phenomenon that conventionally bred crops cross-pollinate with wild relatives and transfer traits that could improve their fitness, yet this has generally not been considered to pose an unreasonable risk.[53]

As with SECURE, developers should be able to self-determine whether their organism meets any of the criteria on the "red flag" list or request written confirmation from APHIS that their organism does not. This confirmation process should be available to developers of organisms regardless of how they were developed. The purpose of this voluntary process would be to provide developers with legal certainty needed for investor and commercial assurance, and to provide assurance to trade partners.

APHIS must also revise the plant pest exemption process under § 330.204. APHIS should add a third exemption for modified, attenuated, or disarmed strains of plant-pest taxa that have been shown not to pose a plausible plant pest risk. This could include categorical exemptions for well-characterized laboratory strains and vectors and a petition process for exempting additional strains. Without such changes, withdrawing Part 340 could impose unnecessary, repetitive permitting requirements on routine biotechnology research.

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.

Regardless of whether APHIS regulates plant pest risk from modified organisms under Part 330 or Part 340, there are several elements it should incorporate into its regulatory framework.

APHIS should, to the maximum extent possible under its statutory authority, regulate organisms based on the level of risk they pose (e.g., high, moderate, low, negligible).[54,55] Risk is a function of hazard and exposure, which are determined by the organism, traits (i.e. phenotypes), the

[51] Bauer-Panskus, A., Miyazaki, J., Kawall, K., & Then, C. (2020). Risk assessment of genetically engineered plants that can persist and propagate in the environment. *Environmental Sciences Europe*, *32*(1), 32. https://doi.org/10.1186/s12302-020-00301-0
[52] Bradford et al. (2005).
[53] Herman, R. A., Zhuang, M., Storer, N. P., Cnudde, F., & Delaney, B. (2019). Risk-only assessment of genetically engineered crops is risky. *Trends in Plant Science*, *24*(1), 58-68. https://doi.org/10.1016/j.tplants.2018.10.001
[54] Bradford et al. (2005).
[55] Conko, G., Kershen, D. L., Miller, H., & Parrott, W. A. (2016). A risk-based approach to the regulation of genetically engineered organisms. Nature Biotechnology, 34(5), 493-503. https://doi.org/10.1038/nbt.3568

mechanism of action, use, and the receiving environment.[56] The majority of experts in plant biotechnology polled support this type of product-based approach to regulate genome editing.[57]

A scientifically sound assessment process would avoid determining which organisms to regulate or conduct risk assessments for based on proxies that don't have a strong or consistent association to plant pest risk. This includes whether the donor organism, vector, or vector agent used is a plant pest (e.g., *agrobacterium tumefaciens)* or derived from a plant pest. As APHIS staff have previously written, "the agency has learned that the presence of plant pest sequences or the use of a plant pest vector to modify a plant is unrelated to the properties (and risk) of the plant… many lower-risk plants developed using a plant pest were subject to regulation, while potentially higher-risk plants created without using a plant pest were not."[58] The RFI affirms this in stating that "decades of experience… have not revealed a materially different or distinct set of risks associated with GE plants and microorganisms…"

We believe that establishing a "red flag" system would be an efficient, transparent, and scientifically sound approach to regulating based on risk level.[59] Such a system would start from a presumption of no premarket regulation for most new organisms, regardless of how they were created, and would require field trial permits and premarket risk assessment only if they meet specific criteria. APHIS should develop criteria that have a strong association with both hazard and exposure: an organism that may pose a hazard should not require a full risk assessment if there is no plausible exposure pathway. For example, a new herbicide-tolerance trait in corn may present a hazard because it could introgress into wild or feral populations, but that hazard would not create a meaningful risk where no sexually compatible relatives occur. APHIS should therefore apply these criteria only where a trait or mechanism has a credible pathway to plant pest harm, such as where, as the SECURE rule stated, "the DNA from the donor organism either is capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease."

In practice, developers would assess whether their products meet the regulatory criteria. If they do, they would submit the product to APHIS to confirm it is a regulated product; if so, APHIS would conduct a risk assessment. Developers with products that do not meet the criteria requiring an assessment should be provided the opportunity to go through a voluntary confirmation of exemption process if they need documentation from USDA to show to stakeholders in the supply chain or importers in other countries. To ensure the red flag system still provides sufficient flexibility for USDA, under limited circumstances USDA should have authority to require a field trial permit or premarket assessment for a product that does not meet the regulatory criteria, similar to how PPQ can require action against pests not listed on the Regulated Plant Pest List.

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[56] Smyth, S. J., & Phillips, P. W. (2014). Risk, regulation and biotechnology: the case of GM crops. *GM crops & food*, *5*(3), 170-177. https://doi.org/10.4161/21645698.2014.945880

[57] Lassoued, R., Macall, D. M., Smyth, S. J., Phillips, P. W., & Hesseln, H. (2020). How should we regulate products of new breeding techniques? Opinion of surveyed experts in plant biotechnology. *Biotechnology Reports*, *26*, e00460. https://doi.org/10.1016/j.btre.2020.e00460

[58] Hoffman, N. E. (2021). Revisions to USDA biotechnology regulations: The SECURE rule. *Proceedings of the National Academy of Sciences*, *118*(22), e2004841118. https://doi.org/10.1073/pnas.2004841118

[59] Kovak, E. (2025). SECURE Rule Vacatur Creates Opportunity for USDA to Develop Improved Product- and Risk-Based Agricultural Biotechnology Regulations. *The Breakthrough Institute.* https://thebreakthrough.org/issues/food-agriculture-environment/secure-rule-vacature-creates-opportunity-for-usda-to-develop-improved-product-and-risk-based-agricultural-biotechnology-regulations

As under SECURE, APHIS should exempt organisms highly similar to ones for which the agency previously conducted a risk assessment and determined to be unregulated or otherwise low-risk, requiring that developers only notify the agency. The Extension of Nonregulated Status process under Part 340 enables developers to request a streamlined review for a previously deregulated trait to be extended to a similar crop. However, in one case, review for an additional variety of the same species still took 13 months.[60] APHIS should ensure any similar process it develops can be conducted more quickly.

Red flag criteria should include a) new plant varieties that are herbicide-tolerant and that could plausibly introgress into wild or feral populations, and b) new plant varieties that produce an active pharmaceutical or compounds for industrial use. In addition, APHIS should regulate organisms where, as the SECURE rule stated, "the DNA from the donor organism either is capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease."

7) Did the SECURE rule – and does the current 7 CFR Part 340 – impose disproportionate burdens on smaller entities developing regulated plants or microorganisms?

The current 7 CFR Part 340 imposes disproportionate burdens on smaller entities developing regulated plants or microorganisms, particularly transgenic plants.

Historically, APHIS review of petitions for nonregulated status under Part 340 have been slow and prohibitively expensive. Out of the 30 Petition reviews completed between 2015 and 2025, none were completed on time, the average review time was 600 days, and only 8 were completed within 360 days—double the timeframe set in the regulations. For two insect-resistant and/or herbicide-tolerant corn applications submitted in 2020, USDA did not issue a decision until 2023 and 2025. Slow reviews and extensive requirements for data submission make the Petition process expensive. Based on data from 2017 to 2022 from the four largest biotech companies, the average cost of developing and authorizing a new plant biotech trait (albeit across multiple countries) was $115 million total, with 29% devoted to regulatory science and 9% to registration and regulatory affairs.[61]

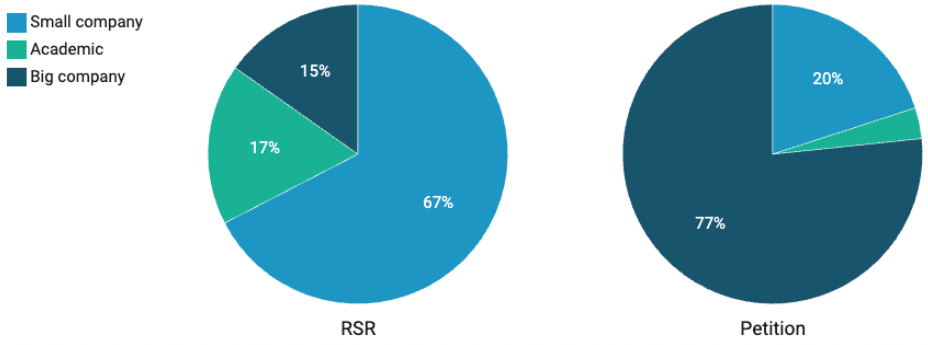
The current Petition process disproportionately burdens smaller entities. The long regulatory process, data submission requirements, and high cost cater to larger companies that are developing multiple products and can afford to wait years for products to be approved and limits participation from small companies and academic developers.

From 2015–2020 and in 2025, about 77% of Petitions were from large companies (defined as for-profit businesses with over 1,000 employees). In contrast, only 15% of RSR submissions

[60] Kovak, E. (2026b). USDA Regulations Stifle Innovation. *The Breakthrough Institute*. https://thebreakthrough.org/issues/food-agriculture-environment/usda-regulations-stifle-innovation
[61] AgbioInvestor. (2022). *Time and cost to develop a new GM trait*. CropLife International. https://agbioinvestor.com/wp-content/uploads/2022/05/AgbioInvestor-Time-and-Cost-to-Develop-a-New-GM-Trait.pdf

under SECURE for transgenic products were large companies; the rest were from small, academic, or non-profit developers.[62]

The Petition process yields fewer submissions for transgenic products from small and academic developers than the RSR process



Includes developers for products that received a response from BRS between 2015 and 2025. Petition data from 2015–2020 and 2025; RSR data from 2021–2024. Data accessed January 23, 2026.

Further, even though larger companies can more easily shoulder the regulatory burden, the high cost incentivizes them to develop genetically modified varieties of mainly staple commodity crops like corn and soy that can be commercialized and grown on many millions of acres or increase sales of complementary herbicides the companies produce to recoup the cost of product development. This is one reason why, despite decades of availability of the technological capacity to produce genetically modified fruits and vegetables, there are only seven kinds of genetically modified produce currently available to U.S. consumers in grocery stores—and most of them are not widely available.[63]

[62] Kovak, E. (2026a).
[63] Kovak, E. (2026b).