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SECURE Rule Vacature Creates Opportunity for USDA to Develop Improved Product- and Risk-Based Agricultural Biotechnology Regulations

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Abstract: After a decades-long process to update U.S. agricultural biotechnology regulations, the U.S. Department of Agriculture (USDA) published their revision to regulations regarding the movement of certain genetically engineered organisms at 7 CFR Part 340 in May 2020. The new regulatory framework, called the SECURE rule, was the first comprehensive revision of federal regulations for genetically engineered organisms since 1987. While the SECURE rule streamlined regulatory review processes for non-exempt plants, it perpetuated a process-based approach to regulation. The U.S. Coordinated Framework for the Regulation of Biotechnology, updated by the White House Office of Science and Technology Policy in 1992, affirmed that federal oversight should focus on the characteristics of the product, not the process by which the product is created. In spite of this, the SECURE rule continued to rely upon arbitrary distinctions between genetically engineered and non-genetically engineered organisms to choose products for review, rather than tying regulation to the traits of the end product. The U.S. District Court for the Northern District of California vacated the SECURE rule in 2024. Accordingly, USDA reverted its regulatory review processes to align with the regulatory framework in place prior to the SECURE rule. The current state of U.S. agricultural biotechnology regulation remains overly burdensome and fails to allocate resources based on the actual risks associated with genetically engineered organisms. Given the limitations of the SECURE rule and its repeal, this paper argues that USDA should develop new product- and risk- based regulations for agricultural products of biotechnology.

I. Introduction

In late 2024, a court decision forced the U.S. Department of Agriculture to scrap its newly updated regulations for agricultural biotechnology products, commonly referred to as the SECURE rule. The SECURE rule was finalized in 2020 after an extensive stakeholder engagement process. Shortly after, a group of anti-GMO nonprofits and activists filed a lawsuit against USDA's Animal and Plant Health Inspection Service (APHIS)—*National Family Farm Coalition, et al. v. Vilsack*. A judge for the Northern California District Court sided with the plaintiffs and vacated the entirety of the SECURE rule.

In light of the court decision, USDA has returned to using a decades-old framework for regulating genetically engineered organisms. These legacy regulations unnecessarily limit innovation in agriculture, relying on an outdated understanding of genetic engineering to subject products to years of regulatory review. This in turn delays commercialization of products that make agriculture more productive and resilient while using less land, fertilizer, and pesticides. The Trump administration and USDA now need to decide whether to stick with this decades-old rule or move forward and develop new regulations altogether.

The administration's decision will be consequential given the extent to which biotechnology has positively impacted U.S. agriculture. Genetically engineered crops with resistance to insect pests reduce farmers' spending on pesticides and increase crop yields, increasing farmer income per hectare, while also benefiting the environment. Average net farm income increased by $30–111/hectare in the U.S. from 1996 to 2020 thanks to genetically modified insect resistant maize and cotton, and herbicide tolerant canola and maize. Gene editing can also make microbes that help crops get nitrogen from the air, reducing farmers' reliance on expensive fertilizers.

Biotechnology advances have also enabled farmers to grow more food, feed, and fiber on less land using fewer resources. Genetic improvement—including through biotechnology—accounted for approximately half of the 19–32% yield increase of U.S. corn, soybeans, and wheat from 2000 to 2022. Due to biotechnology's contributions to increasing agricultural productivity, supporting a robust biotechnology industry is critical to keep food prices low, ensure food security without the need for more imports, and to maintain global agricultural competitiveness. In order to compete with countries like Brazil, the U.S. must continue advancing technologically to increase yields and decrease costs of production. From 2015 to 2019, for example, the cost of producing one ton of corn in Brazil was just $90 compared to $155 in the U.S.

Given the potential of agricultural biotechnology to enable an American agricultural system that competes in global markets, brings profits to rural America, and provides affordable food to U.S. consumers, the White House and USDA should take this opportunity to move past decades of overly inhibitory biotechnology regulations. Neither the legacy regulations now back in place nor the SECURE rule is proportionate to the actual risks posed by genetically engineered organisms.

True product- and risk-based regulations—that focus on the risks from a product's traits rather than the types of genetic changes and the technology used to make them—would more efficiently direct government resources toward reviewing the highest-risk products, support innovation by streamlining commercialization of low-risk products, and provide more certainty for all stakeholders as technologies continue to advance.

II. Limitations of the SECURE rule

The final SECURE rule, also known as Movement of Certain Genetically Engineered Organisms or 7 CFR Part 340, was published in May 2020—the first comprehensive revision of USDA's regulations for genetically engineered organisms since they were established in 1987.

In the recent lawsuit, the plaintiffs argued that APHIS violated the Plant Protection Act by failing to explain why it did not incorporate its noxious weed authority into the final rule, and by not adequately justifying exemptions for genetically engineered plants that could have been produced with conventional breeding techniques. The judge agreed with these two claims, which was enough to vacate the rule and send it back to APHIS for further consideration. On several other claims, the judge either sided with the agency or declared the claims moot after vacating the rule. The judge mooted the claims that APHIS violated the Endangered Species Act and the National Environmental Policy Act by failing to assess the impact of biotech crops on other species and the environment, meaning there's no indication of how a judge might treat similar claims if plaintiffs brought them again in the future.

Before the SECURE rule was vacated, it improved product review by introducing a more flexible system with different tiers of review to match different levels of risk, which better allocated agency resources. In the initial stage of Regulatory Status Review, the agency looked for plausible pathways by which the 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, then a second stage of review determined the likelihood and degree of that risk.

SECURE also improved the clarity of exemptions compared to the legacy regulations, though the basis for exempt categories was flawed.

Despite these improvements, the SECURE rule was limited by being partially process-based. Under SECURE, USDA continued to use conventional breeding as the benchmark to explain why gene edited crops should be exempted from existing regulations for genetically engineered organisms. USDA should not return to the SECURE rule because it continued to rely on inaccurate indicators of risk to determine exemptions, failed to keep up with the changing technology landscape, and eliminated a regulatory pathway for genetically engineered microbes.

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 of the product that actually cause 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. The agency has walked a thin line by shifting the basis for regulation from the type of technology used to the type of genetic change made (but not the trait that results from the genetic change). Still, this designation of safe products based on a comparison to conventional breeding was misguided and widely refuted.

USDA itself and many consensus reports by the U.S. National Research Council and other scientific bodies state that conventional breeding can produce both safe and unsafe products, and that the process of genetic engineering does not create any new types of risk. The SECURE rule subjected 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 is not the source of risk. This contradicts the Office of Science and Technology Policy's guidance that products of biotechnology should be regulated the same as products of conventional breeding.

Consider, for example, USDA's review of the drought-tolerant HB4 wheat variety. As a plant genetically modified with a gene from a sunflower—a trait that can't be bred through conventional means—HB4 wheat didn't fall under SECURE's exemptions and thus went through the full Regulatory Status Review process, which took over two years. This delay is hard to justify considering that breeders have been improving drought tolerance in many crop species for decades, and HB4 wheat had already been approved for cultivation in Argentina, Brazil, and Paraguay, as well as for food and feed in many other countries. HB4 has an incredibly beneficial drought tolerance trait, contains one gene from sunflower, and has the same herbicide resistance trait as countless biotech crops USDA has approved over the last 30 years. Under the legacy pre-SECURE regulations, HB4 wheat would likely have gone through the even more time-intensive Determination of Nonregulated Status process, further delaying review and approval.

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 despite the fact that many scientists argue these traits are particularly low risk.

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. Scientists argue that domestication traits have very low risks of increasing the invasiveness of wild relatives of crop plants when they spread beyond the agricultural context. Despite this decades-old case for exempting domestication traits, products reviewed through the RSR process under the SECURE rule in 2024 included a shorter blackberry with less thorns and softer seeds, and a cowpea that stops growing earlier and flowers at a different time. Regulatory review at USDA for these products took 4 months and 8 months, respectively. In addition, under the legacy regulations before SECURE, approval of a non-browning apple took 27 months, and approval of a male sterile canola with a common herbicide resistance trait—similar to a previously-approved version—still took 10 months.

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.

Lastly, SECURE got rid of the existing path to market for genetically engineered microbes which created uncertainty for developers of these products. Under SECURE there were no exemptions for any gene edited microbes like there are for gene edited plants; the Regulatory Status Review process is only for plants, so microbes did not have a path to market. Despite comments from stakeholders on the draft SECURE rule asking for a pathway to market for genetically engineered microbes and on subsequent APHIS requests for information, the agency has still not created one.

III. Returning to USDA's legacy biotechnology regulations is not sustainable

In the weeks following the SECURE rule vacature, USDA swiftly reverted its biotechnology regulatory processes to align with the pre-2020 legacy regulations. USDA's legacy biotechnology regulations do not include an explicit list of exemptions for gene edited crops, they lower regulatory requirements for a wider array of gene edited crops, increase regulatory requirements for genetically modified crops (also known as transgenic crops), and provide a clearer pathway to market for gene edited microbes.

Unlike SECURE, the legacy regulations do not include a list of exemptions for gene edited organisms. The legacy regulations employ the Am I Regulated process, where developers can submit a Regulated Article Letter of Inquiry and get a response from the agency indicating whether their product is subject to USDA's premarket biotech regulations. The Am I Regulated process is less predictable and transparent than the analogous Confirmation of Exemption process under SECURE because there is no list of exemptions; however, a wider array of gene edited organisms have been deemed not regulated under the legacy regulations than were exempted under SECURE. Because there is no clear list of exemptions and because USDA has room for interpreting what is or may be a plant pest, responses to Am I Regulated inquiries may depend on agency leadership. Where possible, regulations should minimize the need for developers to consult with the agency, because this takes more time and resources for developers and requires increased agency capacity to deal with inquiries—especially relevant as the Trump administration oversees a significant downsizing of federal agency staff.

Not only does the return to the legacy regulations mean losing the clearly laid out exemptions for gene edited organisms in the SECURE rule, it also dramatically increases the regulatory requirements, review time, and cost of review for transgenic crops. Under the legacy regulations the agency usually completed an Environmental Assessment under the National Environmental Protection Act, a Plant Pest Risk Assessment, and multiple Federal Register Notices. This increased regulatory burden is unjustified because it applies regulatory oversight based on

characteristics of the organism that do not themselves increase risk—namely DNA from a plant pest—before initial screening for any plausible potential risk. If an organism's genome is like a book, and each gene is a word, then no single word captures the meaning or identity of the entire book. Similarly, an organism is considered a plant pest based on its full set of characteristics—such as its ability to infect a plant or reproduce quickly—not just individual genes. Only some genes have the potential on their own to make an organism a plant pest, like those that code for a toxin that harms plants.

In some cases, process-based regulation leads to particularly irrational outcomes. Bayer developed short-stature corn that is resistant to high-wind events using multiple technologies, all of which U.S. regulations would treat differently. Under both SECURE and the legacy regulations, conventionally-bred short corn is not subject to USDA's premarket biotech regulations at all, and gene edited short corn would likely receive an exemption. Yet transgenic short corn was subject to the RSR process under SECURE and would likely have to go through the Determination of Nonregulated Status under the legacy regulations that are back in place today.

Finally, one improvement of the legacy regulations over the SECURE rule is that they include a path to market for genetically engineered microbes. Under the legacy regulations multiple genetically engineered microbes went through the Am I Regulated process, including Pivot Bio's gene edited nitrogen fixing microbes which USDA determined were not subject to premarket biotech regulations.

IV. Recommendations for a new product- and risk-based regulatory system

Given the limitations of the SECURE rule and legacy regulations alike, USDA should take this opportunity to move past decades of overly restrictive biotechnology regulations. USDA must instead build a biotechnology regulatory system that identifies products for review based on high-risk traits regardless of how they were made.

Such a "red flag" system would start from a presumption of no premarket regulation for most new crop varieties, regardless of how they were created, and only pull products in for review if they have any potentially risky traits from a list of "red flags." Red flag traits could include plants modified to produce an active pharmaceutical or compounds for industrial use that have a "documented likelihood to cause significant harm to humans and the environment." A red flag system for choosing products to review based on known risky traits differs from the Canadian

system for Plants with Novel Traits, which chooses products to review based on novelty, even when the novel trait is clearly low-risk based on existing knowledge.

In practice, developers would assess whether their products have any traits from the red flag list and whether to submit to USDA for regulatory status review. Developers with a product that doesn't have any traits from the red flag list could choose 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 bring a product in for premarket review that is not on the red flag list.

A red flag system is better than a novelty-based system because the latter encourages a precautionary approach. In a novelty-based system, regulators can pull products in for review without providing any evidence to support their decision. In contrast, a red flag system would require regulators to add risky traits to a list in order to review those products based on evidence of their risks, discouraging inefficient regulatory oversight on a precautionary basis and encouraging horizon scanning of new products and technologies.

A red flag system at USDA should be technology agnostic and include oversight of conventionally-bred plants. True product-based regulation would subject all new plant varieties to pre-market review—not just those created using genetic engineering—meaning that some conventionally-bred plants could be newly subject to premarket regulation for plant pest risk that were not previously assessed by USDA before commercialization. With a list of risky traits determining which products go through review, USDA's premarket regulation of plant pest risk would focus on the actual risks of products. Experience with conventionally-bred and genetically engineered crops to date provides enough evidence to exempt whole categories of low-risk traits like domestication traits.

Other U.S. regulations for genetic engineering, plant pests, and noxious weeds provide examples of red flag-like systems to determine which products should go through premarket review. USDA APHIS Plant Protection and Quarantine uses a list of regulated plant pests that they continually update, with the additional provision that under some circumstances they may need to take action against pests that are not currently listed. APHIS' noxious weed regulations at 7 CFR Part 360 apply to organisms on a list of regulated noxious weeds, and anyone can petition to add or remove a taxon from the list. FDA's guidance for gene edited plants lists types of

modifications for which they strongly recommend developers consult them, for example "modifications to endogenous genes that create significant homology to a known allergen."

A red flag system as proposed above would follow existing recommendations from the National Research Council and the National Academies of Sciences, Engineering, and Medicine (NASEM), which have, for decades, recommended regulating risk on a product-by-product basis, rather than based on process.

Further, USDA should not attribute risk to the number of genetic modifications made in a product. A 2016 NASEM report notes that "the size and extent of the genetic transformation has relatively little relevance to the extent of the change in the plant and consequently to the risk that it poses to the environment or to food safety." This is in stark contrast to USDA's new November 2024 exemption categories, which defined low-risk products as products with less than 12 genetic modifications.

V. Additional considerations to ensure success

The first Trump administration was committed to progress on agricultural biotechnology, including setting out an Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products. While the second Trump administration seems once again focused on regulatory streamlining efforts, its attitude toward biotechnology broadly is more uncertain. President Trump recently rescinded Biden's Executive Order on Advancing Biotechnology and Biomanufacturing Innovation, calling these initiatives "radical" and "under the guise of environmental policy."

This administration should double down on its commitment to advancing biotechnology in agriculture by pursuing new product- and risk- based regulations for agricultural products, and weighing the significant downsides of other paths forward.

For example, USDA could make only minimal changes to the SECURE rule to address the specific issues used to vacate the rule, but the agency has no way of knowing whether the judge would have agreed with the two mooted claims, or how to address them in a revised rule. This option would still require going through the resource-intensive rulemaking process, and the revised SECURE rule would still subject products to expensive regulations based on poor indicators of risk and would not easily adapt to new technologies.

USDA could also stick with the legacy regulations that are now back in place and make smaller changes to its regulatory approach using guidance rather than new rulemaking. While this option could expend fewer agency resources in the short term by avoiding new rulemaking, it would not solve the inefficiencies of process-based regulations.

Finally, USDA could opt to get rid of its premarket biotechnology regulations altogether, effectively ceding regulatory oversight of biotechnology to the Environmental Protection Agency and the Food and Drug Administration. While this would end overregulation of low-risk traits at USDA, it would also remove USDA oversight of potentially higher-risk traits, like plants modified to make a product for pharmaceutical or industrial use that are likely to harm humans or the environment. The Trump administration should not rescind USDA's premarket biotechnology regulations altogether as part of its deregulatory agenda.

Ultimately, new product- and risk-based USDA premarket regulation for genetically engineered organisms would incentivize innovation while also minimizing negative impacts on trade, product segregation, and public perception. USDA must take the opportunity presented by the current reversion to the legacy regulations to draft a new rule that improves upon both the legacy regulations and the SECURE rule to better match premarket review with the actual risks of new products.

The short-term use of agency capacity to create a new product- and risk-based rule would efficiently focus resources for premarket reviews and provide more certainty for all stakeholders as technologies continue to advance. Rulemaking is a resource-intensive process that could take several years. It is therefore important for USDA to create product- and risk-based regulations now that will remain relevant for new technologies and not necessitate further rulemaking in the near term.

Agency-wide workforce reductions could jeopardize the administration's ability to implement new regulatory streamlining efforts. Therefore, the White House, USDA, and Congress will need to prioritize adequate staffing and resources at APHIS in order to both keep up with an existing application pipeline and develop new regulations.