USDA revised regulations of GMO and gene edited plants. Here's what it means.

The long-awaited updates from the United States Department of Agriculture (USDA) to its genetically engineered (GE) organism regulation have been issued. This final rule completed a more than 10-year process started back in 2008 to revise regulations promulgated in 1987. This article discusses these new regulations and some of their potential impacts. Overall, the rule ignores concerns raised by some industry, consumer and environmental groups that the new regulations, including an option for developers to self-determine whether their products are regulated, and could lead to adverse environmental and/or agricultural impacts, potential food safety risks, trade disruptions and a lack of consumer acceptance of new food technologies.

USDA oversight from 1987 to the present

To understand the USDA's new regulation of GE plants, it is important to know how the agency has regulated GE plants since 1987. USDA regulates the import, interstate movement, and environmental release of GE plants under its legal authority to manage "plant pests" under the Plant Protection Act. A "plant pest" is any organism "that can directly or indirectly injure, cause damage to, or cause disease in any plants or plant product." Under USDA regulations, a GE plant has been considered a "potential" plant pest if any of its newly introduced DNA came from an organism on USDA's list of plant pests, or if the method of introducing DNA into the plant's genome involved an organism on USDA's list of plant pests. For example, if a GE plant was developed using the plant pest *Agrobacterium* to introduce new DNA, as many are, it was regulated. However, if the same DNA were introduced using the gene-gun method of transformation, USDA would not regulate the GE plant.

Under those regulations (found at 7 CFR part 340), developers were required to submit their GE plant products to one of three oversight processes before environmental release.

The first process, known as "notification," is used to regulate field trials of low-risk GE plants. The applicant provides the USDA with information detailing its trial and the agency has 30 days to decide whether to permit the trial to proceed. As many as 1,000 field trials are authorized yearly using this procedure.

The second process is "permitting," which requires a more detailed application for any outdoor planting (e.g., field trial) of higher-risk GE plants. After reviewing the application, USDA may issue a permit authorizing the release. The USDA has issued hundreds of permits since 1987.

The third process involves a "petition for non-regulated status," where a developer requests the USDA to determine—based on evidence from field trials—that the GE plant presents no plant pest risk and no longer requires regulation. The petition process is the primary path to commercialization and more than 140 plants have been deregulated.

For each regulatory process, the USDA is ensuring that the GE plant is not going to become a plant pest and cause harm to agricultural interests.

Up until 2011, every GE plant tested outdoors either submitted a notification or received a permit, and all commercialized plants satisfactorily completed the petition process. Then, in 2011, the USDA established a process whereby GE seed developers could ask the agency whether the GE plants they were developing required regulation, or whether they were exempt because they did not involve any plant pest components. The USDA responded to these "Am I regulated?" inquiries stating whether the GE plant was not regulated and could be planted without oversight. By the end of 2019, USDA determined that more than 85 plants did not fall within its regulatory authority and are exempt from oversight. So, over the last eight years, we have seen a decrease in how many GE plants USDA regulates.[1]

Revised regulations in 2020

The new rule (called the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient, (SECURE) Rule), which will be implemented over the next 18 months, applies to organisms produced through "genetic engineering," which is defined to include "techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome." This broad definition includes classical genetic engineering, which add one or more new genes to organism (transgenics, or what consumers consider GMOs), and newer gene editing techniques such as CRISPR, which can make edits within an organism's existing genome.

While the definition captures all GE plants, the USDA exempts many of them from any oversight. First, it exempts products with a single sequence deletion, substitution, or addition (if the addition is from the plant's gene pool). Second, it exempts any GE plant that has the same "plant-trait-mechanism of action" as any GE plant previous regulated by the USDA. This means that if the USDA previously regulated a GE plant, such as an glyphosate-tolerant variety of corn, a new GE glyphosate-tolerant corn is exempt if it employs the same mechanism of action (meaning it biologically operates the same way to provide tolerance). Developers can self-determine whether they qualify for these exemptions; confirmation of their self-determination from the USDA is not required and the agency need not be informed.

If a GE plant is not exempt, the developer can either: (1) apply for a permit if the GE plant has potential plant pest risks; or (2) seek a Regulatory Status Review (RSR). The RSR starts with an initial 180-day process where the USDA determines if the GE plant has any plausible plant pest risks. That initial RSR step is a closer look at the GE plant than the current "am I regulated?" process, but less detailed than the process used for "petitions for non-regulated status." The USDA stated that the initial review does not require any plant-specific "laboratory or field-test data." If the USDA decides there are no plausible risks, it sends a letter to the developer stating the plant is not regulated and publishes the letter on its website. If the USDA cannot conclude that there are no plausible risks, then the developer can either: (1) request that the USDA conduct the second part of the RSR, which is detailed evaluation of potential plant pest risks that can take up to 15 month); or (2) apply for a permit. The more lengthy and detailed RSR evaluation is comparable to the current "petition for non-regulated status" process and ends in the USDA

determining either that the GE plant is not regulated or that it needs a permit. If a developer receives a permit from the USDA, any outdoor planting (e.g. a field trial or a commercial planting) is subject to restrictions to prevent inadvertent release into the environment and any adverse plant pest impacts. These are the same restrictions that virtually all GE plants were subject to prior to 2012 under the notification and permitting processes. Only GE plants that receive permits have any continued USDA oversight.

Worrisome aspects of SECURE

The exemptions are one worrisome aspect of the new SECURE rule. First, they are not supported by scientific evidence showing that these categories of GE plants do not pose risks. Instead, the USDA states that since a single deletion, substitution or addition produces a plant that could be achieved by conventional breeding methods, and because conventionally bred plants have not raised plant pest risks, gene-edited plants that are the same as products that could be achieved through conventional breeding will not pose plant pest risks. The problem with this argument is that a science-based regulatory system should base its oversight on whether the plant possesses traits that make it a potential plant risks, not the plant's method of production. One reason the USDA revised its rules was to focus on the properties of a product, not how it was developed, yet that is the very approach these exemptions enshrine. While many, if not most, plants with a single deletion may not present any plant pest risks, if one does, shouldn't USDA regulate it?

The second concern is that the developer self-determines if its product qualifies for an exemption. This sets up an inherent conflict of interest because developers have financial incentives to determine themselves exempt. While some developers will diligently determine the regulatory status of a GE plant, others may not. In addition, when a developer self-determines its product is exempt, neither the USDA nor the public know that the GE plant is being released into the environment and entering the food supply because there is no requirement to notify the agency of one's self-determination. If the USDA does not know which GE plants are self-determined as exempt, how can it confirm that the determination is correct?

Positive aspects of SECURE

One positive of the new rule is the agency's decision to limit the exemptions to single edits. The USDA reasons that while a single edit mimics a product that can be produced through conventional breeding methods, the same is not true for products with multiple edits. Therefore, if a developer makes two or more edits, the developer must apply for a permit or ask for an RSR. The first gene edited commercial product in the US—Calyxt's high oleic soybean, which the USDA exempted under the "am I regulated?" process—would not be exempt under the new rules because it has two edited genes. If most gene-edited products end up having two or more edits, the exemptions may have limited applicability.

While multi-edited products are not automatically exempt, the USDA is likely to find in the initial step of the RSR process that many do not pose any plausible plant pest risk. So the result may be the same—these products are not regulated. However, at least the initial RSR determination (instead of a developer self-

determination), is made public, so stakeholders will know which multi-edited products are entering the market.

Potential impacts

The USDA states that one goal of its revisions is to provide "regulatory relief," and the final rule clearly achieves that. Many GE plants that historically required containment for field trials through either the notification or permitting process will no longer be subject to any substantive regulation. They either will be exempt or deemed to have no plausible plant pest risks through the initial step of the RSR process. What this means in practice is that GE plant developers (both private developers and academic scientists) can conduct field trials without any confinement conditions that ensure the GE plants do not persist in the environment after the trial is completed. The USDA stated in its proposed rule that it hopes developers voluntarily continue confinement measures, but that may or may not happen. GE plants have escaped from field trials with USDA oversight in the past and the likelihood of that happening will only increase without USDA oversight. That could mean new proteins inadvertently entering our food supply before they are deemed safe for human consumption. Experimental GE plants persisting in the environment after a field trial is concluded could also harm non-target organisms. Finally, if an unregulated GE plant escapes from a field trial and enters the export market, it could result in rejection of the US commodity because the experimental plant has not been approved in the importing country.

The final rule also fails to provide needed transparency on GE plants that will be commercialized. The USDA, food industry and consumers will be at the mercy of developers to make public information about products that they have deemed exempt. How will the food industry know which foods contain GE plants to ensure they are complying with export market legal requirements? How will food manufacturers and retailers answer questions from consumers asking whether their products contain ingredients from GE or gene-edited plants? If consumers are unable to access information about which GE plants are commercialized, will they become skeptical about those products and their safety? The lack of transparency inherent in the rule could result in international trade problems and misinformed consumers.

GE plants have provided benefits to farmers, the environment and consumers and are likely to continue to do so in the future. However, the USDA rule could impact the food industry's acceptance of those products and fuel consumer suspicions about biotech crops and foods.

[1] While the USDA is the primary agency regulating GE plants, the FDA and EPA regulate subsets of GE plants. If a GE plant is used for food or feed, the FDA regulates it under a voluntary consultation process set up under the Federal Food, Drug and Cosmetic Act. If a GE plant produces a pesticide, the EPA regulates it as a plant-incorporated protectant under the Federal Insecticide, Fungicide, and Rodenticide Act.

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