

Analysis: Problematic provisions in new USDA rule for GE plants

Over the last three months, the United States Department of Agriculture (USDA) has published materials and conducted webinar presentations to provide additional clarity around how it will implement its regulations for genetically engineered (GE) organisms, with particular emphasis on explaining the [exemptions, self-determination and confirmation provisions](#) in its newly promulgated [SECURE Rule](#).

In my previous analysis of the SECURE rule, I noted significant problems with the four exemptions and the provision allowing developers to self-determine if their products qualify for exemption. In this analysis, I provide several examples of GE products that would be exempt under the SECURE rule, based on the latest USDA information, and discusses potential adverse impacts that could arise if developers take advantage of the self-determination option.

Exemption and self-determination

The SECURE Rule applies to organisms produced through “genetic engineering,” which the rule defines as “techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome.” This broad definition includes GE plants produced using classical GE techniques, in which one or more gene is transferred from one organism to another using recombinant DNA methods (what consumers consider “GMOs”), and newer genome editing techniques (such as CRISPR), which use enzyme systems to more precisely change the DNA of a cell at a specified sequence. However, after establishing an all-encompassing definition for GE plants, the SECURE Rule exempts many GE plants from any substantive oversight.

The first three exemptions, found at 7 CFR 340.1(b), state that a plant that contains a single genetic change is exempt if the change: (1) results from natural cellular repair of a targeted DNA break without any introduced DNA to direct the repair; (2) is a targeted single base pair substitution; or (3) introduces a gene known to occur in the plant’s gene pool, or causes a change in a gene that corresponds to a version of that gene present in the organism’s gene pool. These exemptions were primarily designed to exclude from oversight a single deletion, substitution or addition (if the addition is from the plant’s gene pool) created using CRISPR, TALENS, ZFNs or other genome editing techniques. However, the regulation was not especially clear about how it applies to edited plants with multiple edits. USDA has since clarified that a GE plant with multiple edits qualifies as exempt if each edit arises from individually exempt events that are combined through conventional breeding. GE plants with multiple edits that were achieved at the same time or carried out serially in the same organism do not qualify for an exemption.



Importantly, the regulations do not require developers to submit their products to the USDA to determine if they qualify for the exemption, but they do provide a voluntary procedure (7 CFR 340.1(e)) if developers want the USDA to confirm their self-determination. While it is likely that multinational companies producing products with a potentially large market will seek USDA confirmation, it is less clear whether small and mid-size companies will voluntarily seek confirmation. USDA has stated that those three exemptions and the self-determination/confirmation process replace the voluntary [“Am I Regulated?” process](#) that developers previously used to determine whether their products fall within or outside of USDA regulations. While submitting an “Am I Regulated” request was voluntary, it was the only way a developer avoid USDA oversight, whereas the new regulations provide both exemption categories and self-determination.

The SECURE Rule provides an additional exemption for any new GE plant that contains a plant-trait-mechanism of action (MOA) combination that is the same as a GE plant already evaluated under USDA regulations and determined not to be regulated (7 CFR 340.1(c)). The USDA recently clarified that an MOA is the same if it results in the same biochemical process. According to the SECURE Rule, if a new GE plant is the same plant (e.g. soybean) with the same trait (e.g. herbicide tolerance) achieved with the same MOA as a GE plant already reviewed by USDA and found not to be a plant pest, it is exempt.

Therefore, a glyphosate-tolerant corn developed using the same gene as a previous GE corn approved by USDA or with a new gene that carries out the same biochemical process (e.g., a gene producing a different enzyme but that catalyze the same biochemical reaction), both would be exempt. The USDA has stated that this exemption replaces the [“Extension” process](#) (found at the old 7 CFR 340.6(e)), which allowed for an expedited decision of “non-regulated status” for GE plants “functionally equivalent” to a previously deregulated plant. Developers can use the list — published on the USDA website — of plant-trait-MOA combinations previously granted non-regulated status to determine if their GE plant qualifies for this exemption.

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As I previously discussed, these exemptions are problematic because they are not sufficiently supported by scientific evidence showing that these GE plant categories do not pose risks. They are made more worrisome by the SECURE Rule's allowance for self-determination of exemption status.

GE plants qualifying for exemption

To anticipate the potential impacts of the four exemptions, it is helpful to consider three examples of hypothetical GE products that would qualify for an exemption:

- **Example 1. Non-browning Honeycrisp apple.** [Okanagan Fruits](#) has developed and commercialized GE apples with a modified fruit quality trait that reduces browning introduced through *Agrobacterium*. They previously received non-regulated status for three apple varieties with the same introduced gene. The Golden Delicious and Granny Smith varieties went through the USDA's petition process, while the Fuji variety was granted non-regulated status through the USDA's extension process. Now, if Okanagan Fruits decides to engineer the same modification in Honeycrisp apples using the same gene, they could self-determine that their product met the plant-trait-MOA exemption (7 CFR 340.1(d)) and market it to consumers without USDA oversight.
- **Example 2. Herbicide-tolerant rice.** Years ago, Bayer CropScience developed a GE rice variety with tolerance to the herbicide glufosinate using *Agrobacterium* to add a PAT gene, which carries out a chemical reaction that detoxifies the active ingredient in glufosinate, thereby eliminating the herbicide's ability to kill the plant. The product was never commercially grown, but after undergoing regulatory review, its plant-trait-MOA was placed on the USDA's list of products that do not require regulation. Today, a rice seed developer could engineer a glufosinate-tolerant rice variety by introducing the same PAT gene that Bayer CropScience used, or a different gene with the same MOA, and take advantage of the previous determination of non-regulated status to self-determine their product to be exempt.
- **Example 3. Non-browning mushroom.** Penn State researchers made headlines several years ago for developing a non-browning mushroom using CRISPR to knock out a single gene. They have not commercialized their product. If a seed developer were to develop and market their own non-browning mushroom using CRISPR to knock out that same or a different gene, they could self-

determine the product as exempt from oversight as long as is the new product has just a single deletion that did not involve a DNA repair template. The product could enter commerce without USDA oversight.

Ramifications of self-determined exemptions

The most obvious impact of developers self-determining whether their products are exempt is that there is no process for the USDA to review the accuracy of that decision. For example, the hypothetical glufosinate-tolerant rice developer might introduce a new gene that inactivates L-phosphinothricin and self-determine that it has the same MOA as the PAT gene, while the USDA might have found that the MOA is not the same had they reviewed it. Similarly, the non-browning mushroom developer might believe that they only made one deletion, but an independent USDA review might find additional deletions. Without submitting those self-determinations to the USDA, an intentional or unintentional misapplication of an exemption would be missed, preventing the agency from assessing if the GE plant poses a risk that requires oversight.

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Another impact of developers self-determining an exemption is that the US government and other stakeholders will not know which GE plants have been commercialized, unless voluntarily informed by the developer.^[1] This could prevent the government from carrying out two important functions. First, self-determination that a new GE crop (i.e., one never before commercially grown, such as rice) is exempt would make it difficult (or impossible) for the USDA to provide an accurate annual list of bioengineered foods that require disclosure under the [National Bioengineered Food Disclosure Law](#). This law is intended to provide consumers with transparent information on the bioengineered content of foods to support consumer choice.

If farmers began growing a GE glufosinate-tolerant rice without the government being aware of the product's commercialization, the USDA could not include that variety on its [bioengineered food list](#). An

incomplete list would prevent food manufacturers from asking their suppliers the proper questions to ensure accurate bioengineered disclosures on their products. It could also lead to issues with food exports (both processed and unprocessed products) by making it difficult to ensure compliance with an importing country's GE food labeling laws and biosafety laws. Some countries, including many of our trading partners, might require pre-market biosafety approval for products such as the GE rice, the GE Honeycrisp apple and even the non-browning mushroom. The potential trade problems could be exaggerated for GE plants that have never been grown anywhere in the world.

Additionally, due to the self-exemption option, the US government may not be able to alert other nations to GE plants grown in the US, as required by the [Cartagena Biosafety Protocol](#) (CBP). The US is not a party to the CBP or its parent agreement, the Convention on Biological Diversity, because Congress has never ratified those treaties. However, the US has historically met the CBP's obligation to identify GMOs that have been approved for environmental release. Both the hypothetical GE Honeycrisp apple and the glufosinate-tolerant rice clearly fall under the CBP, and other nations would expect the US to disclose their status in the [Biosafety Clearinghouse](#) (BCH) — the CBP's international disclosure mechanism. If the US is not aware that these GE plants are being grown commercially, their BCH disclosure will be incomplete. This could cause other nations to question the integrity of all US entries in the BCH, as well as the overall adequacy of the US biosafety regulatory system

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Finally, failing to notify the public about new GE plants could have significant impacts on consumer trust. If consumers are unable to find out if the apples in their grocery store are GE, will they become skeptical about those products and their safety? While the presence of GE ingredients does not, to our best understanding, dictate anything related to the safety of a food, consumers who care about this information should be able to find it. The lack of accurate information about GE products in the marketplace would not only affect the accuracy of the required "bioengineered" disclosure but could also impact the National Organic Program, [whose regulations exclude both genetically engineered and genome edited ingredients from products certified "organic."](#) How will organic farmers know to avoid the hypothetical Honeycrisp apples, rice or mushroom varieties if it is not known that some varieties are engineered? Lack of information on GE crops could lead to inaccurate product certifications, hurting the integrity of the organic program and consumer trust in that program. Exposés revealing that foods declared GMO-free actually contain GE ingredients, through no fault of their own, might be damaging to food manufacturers.

The USDA should revisit the problematic provisions I've outlined. Until it does, I call on GE plant developers to commit to requesting the USDA confirm any self-determinations that they make.

[1] Rice, apples, and mushrooms are regulated by FDA under the Federal Food, Drug, and Cosmetic Act. The U.S. government would be aware of these products if the developers submit to the FDA's consultation process for foods derived from new plant varieties. However, the consultation process is voluntary.

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