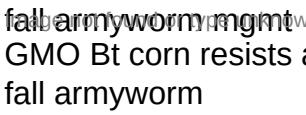
USDA relaxed its GMO, gene-edited crop rules—but not enough to foster biotech innovation

The USDA [recently] published its revision of the rule Movement of Certain Genetically Engineered Organisms, newly dubbed “SECURE,” which deregulates some plants with genetic changes made using new gene editing techniques like CRISPR. Both SECURE’s supporters in industry and its anti-GMO opponents seem to agree that it represents a fundamental shift in regulation, either praising it for encouraging innovation or criticizing it for “letting companies regulate themselves.” But they’re missing the bigger picture.

As an environmentalist and former genetic engineer, I’m thrilled that the USDA has finally deregulated many uses of gene editing. Genetic engineering has already helped reduce the environmental impacts of agriculture — Bt insecticide-producing crops have reduced insecticide use as well as crop loss due to pest damage, and increased insect biodiversity in fields — and gene editing has even greater potential. But in order to maximize this potential, we should break free from the longstanding approach of regulation tied to the method of genetic engineering, which SECURE perpetuates, and embrace an approach based on the actual risks posed by the genetically engineered plant.



GMO Bt corn resists attacks from the fall armyworm

In one sense, SECURE does make a vast departure from the past 30 years of USDA regulation of genetically engineered plants. Historically, the USDA has regulated all genetically engineered (GE) plants for plant pest risk[1], and it made the process of bringing a first-generation GMO plant to market expensive and time-consuming — partially by requiring extensive data from developers to deregulate any GE plant. For crops introduced between 2008 and 2012, the entire process took an average of $136 million and 20 years, with $35 million and 7 years devoted solely to meeting regulatory requirements.

SECURE, by contrast, exempts some GE plants and dramatically streamlines the regulatory process for non-exempt plants. It does this by implementing an initial “Regulatory Status Review” based solely on the plant, trait, and mechanism of action (how the trait is produced on a biochemical level) under review and the relevant scientific literature. If USDA identifies an increased plant pest risk of the GE plant, then a second review may follow. The initial review comes at no cost to the developer, and in most cases the second will not require data from expensive field trials.

More fundamentally, however, SECURE represents the same basic approach to GE regulation in that it is based on the presumption that risk is tied to the process of production, rather than the product itself. The only GE plants that SECURE exempts from regulation are those in which the genetic changes are indistinguishable from changes that “could have been produced using conventional breeding techniques.” [2] The majority of experts prefer product-based regulation — one based on the traits of the particular GE plant — as opposed to process-based regulation tied to the method of genetic engineering. While the USDA claims their new rule is product-based, it has merely shifted regulation from the more distant

process (the technique of genetic engineering, previously regulated via the use of *Agrobacterium*) to the more proximate process (the type of genetic change made), rather than the final product (the plant trait).

The main problem with SECURE's process-based approach is that it is not adaptable to new technologies — a problem that will grow as gene editing technology accelerates.

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Credit: Reuters

In fairness, SECURE's deregulation of some gene editing will increase innovation, thereby improving agriculture and advancing environmental sustainability. Many consider the development of the first-generation of GMOs by only several large companies to be a consequence of the expensive regulatory process; in contrast, SECURE means that more small and mid-size developers will be able to develop GE plants. Argentina was the first country to specify regulatory criteria for gene editing (in 2015) and a four-year study shows that compared to first-generation GMOs, gene edited products move faster to commercialization, are led by smaller developers, and cover more diverse traits and organisms.

That said, SECURE is a significant missed opportunity. The main problem with SECURE's process-based approach is that it is not adaptable to new technologies — a problem that will grow as gene editing technology accelerates. SECURE exempts the "safest" and most familiar uses of gene editing, those that create a product indistinguishable from conventional breeding, which USDA says has "a history of safe use related to plant pest risk." SECURE also deregulates the process of *Agrobacterium*-mediated transformation, a technique for making transgenics that USDA has categorized as a plant pest risk for the last 30 years. But SECURE does not deregulate any categories of transgenic plants — defined as those with DNA from other species or outside their natural breeding pool — which have also been around for 30 years and have a resulting history of safe use. These inconsistencies in categories of exemption are a result of SECURE's focus on process rather than product.

Transgenics are a good example of the blind spots that limit SECURE's potential to encourage innovation. Transgenic plants are a crucial tool for agricultural innovation that have applications for which other breeding techniques are ill-suited, such as making a variety of crops that produce the effective Bt pesticide. However, even though transgenesis as a process is not risky, SECURE has unnecessarily excluded this large category of GE plants.

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Genetically modified soybean plants in a petri dish. Credit: Bayer CropScience.

Popular concern about transgenics similarly focuses on the type of genetic change rather than the resulting plant's characteristics. Transgenesis is widely viewed as making large unnatural changes across species barriers, but the actual applications of transgenesis are varied, including both tobacco plants with a gene from an Arabidopsis plant (deregulated in SECURE) that increases photosynthesis, and the popularly unpopular Roundup-Ready crops. In order to maximize breeding gains and improve US agriculture, biotechnologists need easier access to transgenics in addition to the now deregulated gene editing for mutation and deletion. Since applications of transgenesis vary widely, transgenic plants should not be excluded as a category.

Though transgenesis is not a new technique, CRISPR is a new tool for creating transgenic plants. CRISPR, a new type of gene editing, is often discussed as a powerful tool for making point mutations and deletions, but rarely discussed is CRISPR's improved method for creating transgenics. SECURE draws a poorly justified line between CRISPR gene editing to make transgenics vs. to make mutations and deletions. The result is that SECURE unnecessarily limits the innovative potential of CRISPR gene editing technology.

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SECURE doesn't adapt well to new technologies like CRISPR, and its attempt to remedy this will be inefficient, expensive, and needlessly discouraging to innovation. In an attempt to make SECURE more adaptable, USDA included the ability for outside parties or USDA itself to petition to exempt additional uses of gene editing beyond the three original exemptions. Commenters argued for many new exemptions, indicating there will be numerous petitions — each of which will require USDA resources to

address.

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The better alternative to SECURE is a truly product-based system, which would regulate GE plants based solely on their characteristics — e.g. pesticide production (like Bt crops) or herbicide tolerance (like Roundup-Ready crops). But what exactly would product-based regulation look like? Currently, Canada has one of the most product-based approaches to GE regulation in the world. Canada's system regulates plants with novel traits (PNTs) as defined by the end product, regardless of the technique used to produce them — whether it's genome editing, transgenesis, or conventional breeding.

If the plant has no novel characteristics, then it is exempt from further monitoring. Assessment of a PNT focuses on its molecular characteristics and potential impacts (or risks) in five categories: potential to become invasive, a weed, or a plant pest; potential for gene flow to wild relatives; and impacts on non-target species and biodiversity. Product-based regulation like Canada's more effectively concentrates resources based on risk and can be applied to any new technology that poses new versions of known risks, making it both efficient and adaptable.

Despite SECURE's failure to move beyond process-based regulation, which will become increasingly

problematic as gene editing technologies advance, the rule will exempt many new GE plants from regulation and streamline regulation for non-exempt plants like transgenics. Since SECURE marks the first overhaul of USDA regulation of GE organisms in 30 years (not to mention the revised rules proposed in 2008 and 2017 that were subsequently withdrawn), we should not expect the US to switch to true product-based regulation anytime soon. In the meantime, we can watch Canada's system, compare regulatory outcomes across countries, and learn what to do better next time.

Endnotes

- Plant pest risk is defined as the potential to cause damage to a plant. A GE plant may pose an increased plant pest risk relative to its comparator by exacerbating the impact of a plant pest, for example by causing the pest to develop resistance to a pesticide, or by being a parasitic plant.
- SECURE defines these as one single genetic change of any of three types: changes made without an externally provided repair template (these result from the plant's DNA repair mechanisms), single base pair changes (e.g. changing an A to a T), or addition of a genetic sequence from the plant's gene pool (only from another plant that the plant in question could breed with in the wild).

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