



August 18, 2021

Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

RE: Docket APHIS-2020-0072: Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Exemptions

The Center for Food Safety (CFS) appreciates the opportunity to comment on USDA's proposed new exemptions from its genetically engineered (GE) plant regulatory scheme.

USDA's SECURE Rule created three broad classes of exemption from its regulations that were not grounded in science, but rather were crafted to comply with a press release issued by former Secretary of Agriculture Sonny Perdue in 2018.¹ The SECURE Rule went still further, incorporating a mechanism by which new exemptions can be created, initiated by USDA or a third party.² The three additional exemptions at issue here were proposed under this provision.

The ostensible regulatory rationale for both the original and the three proposed exemption classes is an unprovable hypothetical – GE plants are exempted if the targeted modification(s) they embody “could be achieved through conventional breeding.”³ Yet as APHIS concedes, “there is no universally acceptable, sharp delineation between what is and what is not possible to achieve with traditional breeding methods.”⁴ Moreover, both older and newer genetic engineering techniques result in unpredictable off-target effects, and “off-target mutations are not considered when determining eligibility for an exemption.”⁵ These admissions underscore the vague, unscientific nature of the exemption mechanism and the three proposed new exemption classes, as does their basis in a press release by former Secretary Perdue.

¹ Secretary Perdue Issues USDA Statement on Plant Breeding Innovation, USDA Press Release No. 0070.18, Mar. 28, 2018, <https://www.usda.gov/media/press-releases/2018/03/28/secretary-25-perdue-issues-usda-statement-plant-breeding-innovation>.

² 7 C.F.R. § 340(b)(4).

³ Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Exemptions, 86 Fed. Reg. at 37,988 (July 19, 2021).

⁴ Movement of Genetically Engineered Organisms; Proposed Rule, 84 Fed. Reg. at 26,519 (June 6, 2019).

⁵ Movement of Certain Genetically Engineered Organisms; Final Rule, 85 Fed. Reg. at 29,793 (May 18, 2020).

By excluding unpredictable off-target effects and mutations from the exemption eligibility test, unique GE plant events that could not have been developed conventionally are exempted, on the grounds that the “targeted” DNA modifications they exhibit are “similar and functionally equivalent to modifications that commonly occur within conventional breeding...”⁶ This begs several questions. Are off-target effects of concern? And does the ability to generate targeted modifications that are “similar” to modifications achieved with conventional methods even relevant to APHIS’s regulatory mission under the Plant Protection Act?

First, there is still very little research into off-target effects in plants developed with gene-editing techniques such as CRISPR-Cas9, especially in comparison to their use in biomedical applications.⁷ As a result, “uncertainty remains regarding unanticipated genome-wide effects that may be missed,” and “the potential for unanticipated downstream effects from off-target mutations is an important regulatory consideration for agricultural applications” of this technology.⁸

Because of similar unpredictable and unintended effects in plants developed with older genetic engineering techniques, the U.S. Food and Drug Administration (FDA) has recognized that GE plants may harbor novel toxins or allergens, contain elevated levels of native plant toxins, or reduced levels of important nutrients.⁹ There is no reason to believe gene-edited plants, including those covered by the proposed exemptions, would not have these or entirely other adverse effects.

Even the intended, on-target modifications in exempted GE plants could trigger changes that are cognizable under the Plant Protection Act. Two of three exemption classes cover gene-edited plants with contiguous DNA deletions *of any size*, and one also exempts GE plants with deletions of any size combined with insertion of DNA in the absence of a repair template.¹⁰ (86 Fed. Reg. at 27,989). This could mean eliminating hundreds or even thousands of genes and their associated protein products, and/or the critical regulatory functions of non-protein-coding DNA, disrupting cellular metabolism in profound and unpredictable ways.

Such impactful modifications could increase the toxicity of an exempted GE plant, render it more weedy, or cause other changes cognizable under the broad authorities granted to USDA under the Plant Protection Act (PPA).

APHIS should devote its energies to regulation of all GE plants to comply with the PPA, rather than engage in making fruitless, irrelevant and hypothetical comparisons of the molecular nuances of the products of genetic engineering versus “conventional” breeding. We would also note that the primary “conventional” comparators in these exercises are plants generated by

⁶ 86 Fed. Reg. at 37,988.

⁷ JD Wolt, K Wang, D Sashital and CJ Lawrence Dill, Achieving Plant CRISPR Targeting that Limits Off-Target Effects, 9 The Plant Genome doi: 10.3835/plantgenome2016.05.0047.

⁸ *Id.*

⁹ FDA, Statement of Policy: Foods Derived From New Plant Varieties; Notice, 57 Fed. Reg. 22,984, 22,986-87 (May 29, 1992).

¹⁰ 86 Fed. Reg. at 37,989.

wholesale mutagenesis of crop genomes via irradiation or chemicals, followed by back-crossing in an attempt to eliminate the majority of deleterious ones.¹¹ These mutagenesis techniques are little-used today, and to the extent they are used, should be regulated as well.

On a practical level, too, the new exemption classes would result in far more GE plants that escape regulation by USDA, which means their outdoor cultivation could take place without the gene confinement measures formerly required for most GE plants. This in turn will inevitably lead to more frequent gene flow from GE plants to commercial crops, and rejection of contaminated supplies by domestic or foreign buyers in GE-sensitive markets.

Because GE plants developers “self-determine” the regulatory status of their products, there is no mechanism by which they are even required to inform USDA or anyone else of the nature of their “self-exempted” products, much less the scope (acreage) or locations of their cultivation. USDA will thus be ill-equipped to respond to market disruptions created by these self-exempted GE plants.

USDA is well aware of these problems. These concerns are not ours alone, but are shared by major grain handlers, exporters and others in food supply chain. The National Grain and Feed Association (NGFA) and the North American Export Grain Association (NAEGA) recently told USDA of their grave concerns regarding the market risks posed by new GE crops exempted under the SECURE Act on precisely these grounds:

“Technology providers soon will be granted the ability to “self-determine” whether their plant is exempt from APHIS regulatory oversight. This regulatory decision comes without any obligation for the technology provider to notify the agency, the marketplace or consumers about the event being commercialized.”¹²

NGFA/NAEGA chided USDA for ignoring the advice of “more than a dozen trade associations representing technology providers, bakers, food companies, processors, grain handlers, millers and consumers” to require pre-market notification to APHIS of a genetically engineered/gene-edited plant that is exempted from its regulations to help “alleviate trade concerns and promote[] consumer trust.”¹³

In response to such concerns, USDA has stuck its head in the sand. First, USDA continues to pretend that the only market risks posed by self-exempted GE crops is to “organic and other non-GE crops.”¹⁴ In fact, many past debacles have involved experimental GE crops contaminating supplies of **approved GE crops** (or of mixed GE and conventional crops), as well as non-GE and organic supplies. USDA knows this fact, of course, but chooses to ignore it in favor of a false framing that pits biotech agriculture as a whole against producers who eschew

¹¹ *Id.*, see references in footnotes 2 to 5.

¹² Comments to USDA regarding BASF Corporation; Petition for a Determination of Nonregulated Status for Plant-Parasitic Nematode-Protected and Herbicide Resistant Soybean, July 27, 2020. <https://www.regulations.gov/search/comment?filter=APHIS-2020-0023-0011>.

¹³ *Id.*

¹⁴ 85 Fed. Reg. at 29,799.

GE crops. There is every reason to believe that exempted GE plants would pose the same market risks as “regulated articles” did under the old Part 340.

USDA also claims that “transparency” is served by its expectation that some developers whose GE products are exempted may voluntarily seek “confirmation letters” from APHIS, and that such letters will be posted on APHIS’s website.¹⁵ APHIS is entirely silent on how transparency is served by those developers who choose *not* to seek confirmation letters, and further says nothing about the increased contamination risk stemming from lack of gene confinement protocols that were formerly required for most GE crops prior to deregulation.

Contrary to USDA, granting exemptions such as these from regulations that purport to regulate genetically engineered crops is the direct opposite of transparency, will generate confusion, and will have severely disruptive consequences in the marketplace. USDA refuses to require that developers notify it of self-determined “exempt” status for their products for no better reason than it “would run counter to the spirit of regulatory relief underly our new regulatory framework.”¹⁶ And this gets at the true rationale for USDA’s new regime. Viewing its own regulatory activities as a “burden,” USDA would rather “relieve” that burden for a few GE plant developers than utilize its broad authorities under the Plant Protection Act to protect American agriculture, the food supply and the environment from the demonstrated harms of many GE plants and crops.

For all of these reasons, Center for Food Safety urges USDA to reject the proposed new exemption classes, and instead devote its energies to reforming the deeply flawed SECURE Rule to require meaningful regulation of all GE plants, whether developed with older or newer techniques.

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¹⁵ *Id.* at 29,799-780.

¹⁶ *Id.* at 29,802.