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

**RE: Docket No. APHIS-2023-0022**

*Comments on Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Proposed Exemptions*

Center for Food Safety appreciates the opportunity to comment on the USDA's five proposed exemptions from regulation under the SECURE Rule, on behalf of itself and its 970,000 members and supporters. Center for Food Safety (CFS) is a public interest, nonprofit membership organization with offices in Washington, D.C., San Francisco, California, and Portland, Oregon. CFS's mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. Through groundbreaking legal, scientific, and grassroots action, CFS protects and promotes the public's right to safe food and the environment.

As detailed in pending litigation,[1] the U.S. Dept. of Agriculture's (USDA's) new genetically engineered organism regulations, the SECURE Rule, are unlawful in numerous respects. Nothing expressed in these comments should be construed as contrary to the claims raised in this lawsuit. USDA should withdraw the current regulations and promulgate new ones that protect American agriculture by properly implementing the Plant Protection Act.

USDA has proposed five new categories under which genetically engineered (GE) plants would escape regulation under the SECURE Rule.[2] USDA had originally proposed three new exemption classes,[3] but withdrew them in response to comments, and revised and expanded the exemptions to the five addressed here. CFS comments on the original three exemptions are incorporated by reference.[4]

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[1] *Nat'l Fam. Farm Coal. v. Vilsack*, No. 21-5695 (N.D. Cal.) (filed July 26, 2021).
[2] 88 Fed. Reg. 78285 (November 15, 2023).
[3] Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Exemptions, 86 Fed. Reg. at 37,988 (July 19, 2021).
[4] Center for Food Safety, Comments on Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Exemptions, Docket No. APHIS-2020-0072, August 18, 2021. https://www.centerforfoodsafety.org/files/cfs-part-340-new-exemption-comments--8-18-21_82621.pdf.

Broadly speaking, these proposed new classes broaden the exemptions contained in the SECURE Rule at 7 CFR 340.1(b)(1), (b)(2), (b)(3) and 340.1(e) in two ways. They would extend exempt status to a greater array of polyploid plants, and would increase the number and scope of genetic manipulations permitted in a GE plant that qualifies for exempt status.

The new classes would exempt a greater array of important staple food crops, many of which are polyploid. Autopolyploids are plants that contain more than the usual two copies of each chromosome (diploid, 2n) from the same parental species, and include potato (4n), banana (3n), peanut (4n) and sweet potato (6). Allopolyploid plants also contain more than two copies of each chromosome, but they are derived from different parental species. Important allopolyploid plants include wheat (6n for bread wheat, 4n for durum), cotton, canola, coffee and tobacco.

The proposed classes would also increase the number of genetic manipulations permissible for a GE plant to qualify for exempt status. We give two examples. Single base-pair edits could be made to ***all*** alleles of a genetic locus on the homologous chromosomes of an autopolyploid plant. USDA would also exempt GE plants with up to four modifications that individually qualify for exemption, whether made simultaneously or sequentially. The end effect would be to exempt more staple food crops, with more extensive genetic modifications, from any oversight.

**USDA Cannot Show That Exempted GE Plants Do Not Pose Increased Plant Pest Risks**

In its discussion of these proposed exemptions, however, USDA does not and cannot demonstrate that GE plants thus exempted would not pose increased plant pest or noxious weed risks.[5] This is because of the obvious fact that the proposed exemptions are defined in purely molecular terms, just like the original exemption classes. For simplicity's sake, consider one of the original exemptions, at 340.1(1)(b): "The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template." This exemption thus covers a GE plant with a targeted break in ***any DNA***, regardless of the gene it comprises and the particular function(s) of that gene. Thus, GE plant developers who modify any of the thousands of genes that together determine a plant's many characteristics (as modulated by environmental factors) can escape regulation, as long as the targeted break is accomplished "in the absence of an externally provided repair template." All of the exemptions (original and proposed) are defined in such terms. In other words, USDA has crafted exemption categories that are entirely blind to the traits in GE plants exempted by them, including traits that potentially render the GE plant a plant pest or noxious weed risk.

This can be demonstrated in several ways. First, we survey the types of GE plants that have already escaped regulation under the original exemptions to illustrate the broad range of traits they encompass, and underscore the lack of any correspondence between exempt status and plant traits that might give rise to potential plant pest risk. This is based on the list of GE plant

[5] While USDA decided not to apply its noxious weed authority in the SECURE Rule, CFS maintains this omission is unlawful under the Plant Protection Act, and is challenging the omission in the litigation referenced above. However, for the purposes of these comments we refer mainly to plant pest risks.

developers' exemption requests and APHIS's responses to them.[6] Second, we discuss several traits that are achievable with exemption-eligible genetic alterations in GE plants that would escape USDA regulation even though they pose clear plant pest risks.

Under the existing regime, APHIS has exempted at least 77 GE plants from review.[7] They include GE plants with alterations in seed composition, antinutrient composition, reproductive function, germination, seed morphology and composition, pod composition, fruit characteristics, tuber quality, yield and flavor. One involved disease resistance, while another involved a plant modified for increased susceptibility to herbivores and fungi (discussed further below). The GE trait was hidden as confidential business information in 22 plants. Another nine GE plants were all modified for resistance to herbicides,[8] including one for resistance to the endocrine-disrupting atrazine.[9]

If atrazine-resistant crops are developed, the evident intent of this research, they would lead to substantially increased use of this toxic pesticide, which is already the second most heavily used in the United States, even though banned in over 40 countries.[10] Atrazine is widely detected pesticides in US rivers (Stackpoole et al. 2021), contaminates drinking water wells and the tap water of millions of Americans (CDC ATSCR 2003, Naidenko and Lunder 2017), is associated with adverse birth outcomes such as low birth weight when pregnant women are exposed (Almberg et al. 2018, Chevrier et al. 2011), and also impairs the reproduction of fish and amphibians.[11]

**USDA's Exemption Regime Risks Plant Pest Risks**

Even under USDA's narrow interpretation of plant pest risk,[12] it is clear that its exemption regime violates the Plant Protection Act by permitting the entirely unregulated introduction of GE plants whose cultivation may pose increased plant pest risks.

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[6] This survey provides a conservative sense of the range of GE plants that would be exempted by the five proposed exemption categories, since the latter are mostly extensions of the original ones, as discussed above.

[7] See Confirmation Letters, last updated 1/18/24, at https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/confirmations/responses/cr-table. Note that this group of 77 includes only those GE plants for which a plant developer has formally sought confirmation of exempt status from USDA. It excludes those GE plants a developer has self-determined are exempt without consulting USDA – the number and nature of which neither APHIS nor the public has any way of knowing.

[8] Commercialized GE herbicide-resistant crops and their companion herbicides have a more than quarter-century track record of boosting toxic herbicide use, damaging neighboring crops via rampant drift, and generating epidemics of herbicide-resistant weeds. They urgently require more and better regulation, but thanks to the proposed new loopholes in the Revised GE Rule, would receive ever less.

[9] See https://www.aphis.usda.gov/biotechnology/downloads/confirmation-response/23-265-01cr-request.pdf.

[10] Pesticide Action Network, PAN International Consolidated List of Banned Pesticides, https://pan-international.org/pan-international-consolidated-list-of-banned-pesticides/.

[11] Center for Food Safety, Atrazine, https://www.centerforfoodsafety.org/issues/6459/pesticides/atrazine.

[12] In the lawsuit cited in footnote 1, CFS has shown that USDA needs to adopt a more expansive interpretation of statutory authority to regulate GE plants under the Plant Protection Act.

Herbivore and fungal susceptibility

One clear example is the exempt status of a genetically engineered native tobacco, *Nicotiana attenuata*, modified by use of CRISPR/Cas9 for "herbivore and fungal susceptibility."[13] USDA confirmed the exempt status of this plant under 7 CFR 340.1(b)(1) on June 10, 2021.[14] Scientists at the Max Planck Institute in Germany engineered the plant to reduce its expression of plant compounds associated with defense against herbivory by *Manduca sexta* (tobacco hornworm) and infection by pathogenic plant fungi. The researchers are conducting (or have conducted) field experiments in Utah, and hypothesize that these GE plants "will be more susceptible to the native fungal pathogens and specialist herbivores" by virtue of their compromised plant defenses.[15]

Thus, these GE plants could well function as reservoirs for both fungal pathogens and insect pests, promoting their propagation and spread to neighboring plants or (particularly in the case of fungal pathogens) to soil and plants distant from the field experiments via dispersal of spores. While these field experiments may happen to be small (since conducted for research purposes), there is no limit on their size. Neither are there any requirements to isolate the field trials from neighboring, potentially susceptible plants, which include tomato, potato, pepper and eggplant, which are hosts for tobacco hornworm. Nor are there any prescribed procedures for the disposal of the GE plants or phytosanitary measures to mitigate potential spread of either pathogen or pest. Under the former GE organism regulatory regime, these field experiments would have been subject to such confinement and phytosanitary measures. If the German researchers had self-determined exempt status, which they could have lawfully done, USDA would be unaware these field trials are being conducted at all.

USDA's guidance to GE plant developers for requesting Regulatory Status Reviews (RSRs) confirms that "the production, creation or enhancement of a plant pest or a reservoir for a plant pest" is one important element of assessing plant pest risk.[16] However, USDA did not conduct an RSR of this plant, because RSRs are limited to non-exempt plants. In fact, USDA's exemption confirmation was precisely the same boilerplate response it issues for all such GE plants, focusing entirely on the scientists' representations that the plants were manipulated in such a way as to meet the exemption under 7 CFR 340.1(b)(1), with no reference to plant pest risks.

USDA may argue that these particular field experiments do not pose significant plant pest risks. But whether or not that is true is largely beside the point. What this example illustrates is that

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[13] See the "confirmation request" hyperlink for CR No. 21-025-01cr at https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/confirmations/responses/cr-table. Direct link: https://www.aphis.usda.gov/biotechnology/downloads/confirmation-response/21-025-021cr_a3.pdf.

[14] See the "confirmation response" hyperlink on the website accessed via the first URL in the last footnote.

[15] See https://www.aphis.usda.gov/biotechnology/downloads/confirmation-response/21-025-021cr_a3.pdf.

[16] USDA APHIS (2022). Guide for Requesting a Regulatory Status Review under 7 CFR Part 340, December 20, 2022, p. 8. https://www.aphis.usda.gov/brs/pdf/rsr-guidance.pdf. Namely, one element of USDA's RSR is to determine whether a non-exempted GE plant or a sexually compatible relative might lead to: "The production, creation, or enhancement of a plant pest or [act as] a reservoir for a plant pest" relative to a comparator plant without the genetic modification.

the exemption regime creates huge loopholes for any number of GE plants that may pose plant risks, some perhaps far more serious than any posed by this one.

Plants engineered for low lignin content

There has been a tremendous amount of research invested in genetically engineering trees and other plants to reduce their lignin content (Bryant et al. 2020, Srivastava et al. 2015). Lignin is an ubiquitous component of the secondary walls of plant cells, where it occurs in tight linkage to other cell wall components, such as cellulose and hemicellulose (Frei 2013). It is largely responsible for the strength and stiffness of plant tissues, most notably tree trunks, and forms about 25% of wood (Novaes et al. 2010) and 1-15% of herbaceous crops (Frei 2013). In fact, it represents more of the total organic carbon in the biosphere than any other compound aside from cellulose (Frei 2013).

It is precisely the strength and recalcitrance of lignin that explain efforts to reduce its content. Lignin in forage crops is mostly impervious to microbial degradation in the guts of ruminant animals, reducing feed efficiency. Lignin is also regarded as a hindrance in the processing of wood into pulp and paper, and in the conversion of the lignocellulosic content of trees and other plants to ethanol for bioenergy applications (Bryant et al. 2020, Srivastava et al. 2015).

Yet these same "tough" qualities of lignin underly many of its numerous vital roles in the biology of plant life. Lignin accumulation is important for seed germination; resistance to lodging (bending or breaking of plant stems); tolerance to abiotic stressors such as drought, salt and heavy metals in the soil; and resistance to disease and insect pests (Liu et al. 2018, Frei 2013). Thus, there is widespread concern that efforts to reduce lignin content could compromise plant fitness. One recent review concluded: "…the reduction of lignin biosynthesis can seriously affect plant growth and development, increase the risk of crop lodging, reduce plant resistance to external biotic and abiotic stresses and thus result in a serious threat to crop production" (Liu et al. 2018).

Lignin may also constitute a stable component of soil organic matter by virtue of its recalcitrance to microbial degradation, potentially contributing to soil carbon sequestration and mitigating emissions of carbon dioxide, though there is dispute on this point (Frei 2013). There is more agreement on its role in decelerating the release of nutrients (particularly nitrogen) from crop residues, resulting in a slower and more sustainable supply of nitrogen to crops over the course of a crop season (Ibid. 2013).

Lignin and related phenolic compounds (precursors and byproducts of the lignin biosynthetic pathway) are vital components of a plant's immune system, giving rise to widespread concerns that breeding for low lignin content may compromise a plant's resistance to pathogens (Miedes et al. 2014, Liu et al. 2018, Frei 2013, Polle et al. 2013). There is particularly strong evidence that lignin provides resistance to fungal pathogens – including studies involving manipulation of lignin pathway genes to increase (gain of function) or to decrease (loss of function) its levels in crops including wheat, rice, tobacco, cotton, potato and carrot (Frei 2013). Studies also demonstrate that lignin and related phenolics support pathogen resistance in tomato, melon and tree species such as eucalyptus, elm and Austrian pine – particularly resistance against vascular pathogens such as *Fusarium* sp., *Xanthomonas* sp. and *Verticillium* sp. (Miedes et al. 2014).

Induction of lignin synthesis by pathogens leads to lignification at the site of infection, forming a physical barrier impeding the pathogen's entry into the plant. Thus, wheat in which genes encoding precursors in the lignin biosynthetic pathway are silenced becomes super-susceptible to infection by powdery mildew fungus (Bhuiyan et al. 2009). Leaf lignin content of recombinant inbred lines of wheat was shown to confer resistance to the fungal disease spot blotch, caused by *Bioplaris sorokiniana* (Yusuf 2016). Similarly, lignin accumulation in response to bacterial infection confines the pathogen to the extracellular spaces of plant cells, thus blocking its spread (Lee et al. 2019). Another mechanism of disease resistance involves pathogen induction of lignin pathway-associated compounds, phytoalexins, that fight infection by fungal pathogens (Ninkuu et al. 2023).

Finally, research demonstrates that lignin confers protection against parasitic plants such as dodder, which is an important pest of potato, alfalfa, tomato, coffee, tea and mango (Somssich and Cesarino 2022). For instance, Jhu et al. (2022) only recently elucidated the mechanism of dodder-resistance in tomato cultivars long known to repel parasitism by this plant: the stem cortex of these tomato lines responds to the initial attachment of dodder haustoria with a localized lignification that blocks entry of the parasite into the host plant. Similarly, comparison of rice varieties susceptible or resistant to the devasting parasitic weed Striga showed increased deposition of lignin at the site of infection in the resistant cultivar, together with upregulation of genes in the phenylpropanoid pathway leading to lignification (Mutuku et al. 2019).

Clearly, the genetic engineering of plants for lower lignin levels carries the serious risk of increasing plant pest risks relative to an unmodified comparator, through "enhancement of a plant pest or a reservoir for a plant pest," and USDA acknowledges that "plants with a significant reduction in lignin content" can pose such risks.[17]

Disease susceptibility due to lower lignin levels can even give rise to epidemic plant disease. Brown midrib (BMR) corn varieties harbor mutations that result in lower lignin levels, which increases the digestibility of maize when fed to ruminant livestock. However, these BMR lines were subject to epidemic infections of the fungal pathogen northern leaf blight (NLB) in upstate New York some years ago (Kolkman et al. 2022). In controlled tests, several BMR lines were found to be more susceptible to infection by a range of foliar maize pathogens causing stalk and ear rot as well as foliar disease: not only NLB, but also gray leaf spot, anthracnose leaf blight, Gibberella ear rot, and bacterial Stewart's wilt diseases. Genome-wide association studies associated NLB resistance in BMR lines to a number of genes, including eight lignin-related genes. The authors state: "The susceptibility of these loss-of-function mutants confirms that lignin plays an important role in resistance to pathogens." They also draw the big picture agroecological conclusions that are all too rarely addressed by gene-focused biotechnologists:

> "The increased susceptibility of BMR silage to foliar, stalk, and ear rot diseases has immediate implications for decreased yields and grain or stalk quality and

[17] USDA APHIS (2022), op. cit., p. 8.

> increased stalk lodging. Growing broadly susceptible BMR silage ***across large areas*** may have ***ecological implications resulting in increased inoculum loads for endemic diseases*** (such as NLB in upstate New York) or in ***increasing the agroecological reach of other pathogens, leading to 'new' diseases affecting an area*** (such as the GLS [gray leaf spot] pathogens in upstate New York). If BMR silage is equally susceptible to other fungal and bacterial diseases not tested in this study, such as tar spot and Goss's wilt, ***the general susceptibility of BMR silage can enhance the spread of emerging fungal and bacterial diseases more rapidly across maize growing regions***" (Ibid., emphases added).

The authors identify BMR corn lines as triggering both aspects of increased plant pest risk as defined by USDA in its RSR Guidance: "increased inoculum loads" worsens the adverse plant disease consequences relative to the comparator, while "increasing the agroecological reach of other pathogens, leading to 'new' diseases affecting an area" ticks the "occurrence pattern" box by "exposing a new environment" to the adverse consequences of the modified plant.[18]

And while these BMR mutants were not the products of biotechnology, there is no doubt that powerful gene-editing techniques can equal and exceed their lignin reductions in GE plants engineered in ways that escape regulation via exemptions. To take just a few examples, gene-editing could easily achieve loss-of-function of two genes in the lignin pathway, sharply reducing lignin content, as has been achieved in *Arabadopsis* (Xie et al. 2019). Another example involves poplar.

Biotechnologists have genetically engineered poplar trees to drastically reduce their lignin content by up to 50% or more, with the intent to grow them in plantations for bioenergy applications (Bryant et al. 2020). However, research into the effects this might have on pest and disease resistance are lagging behind, with hardly any studies addressing both issues together (Polle et al. 2013). Despite intensive breeding efforts, most poplar varieties and hybrids in Europe and worldwide are highly susceptible to rust caused by fungal pathogens of the *Melampsora* genus, with annual growth losses of up to 50% (Polle et al. 2013). Monoclonal plantations and *Melampsora*'s ability to rapidly overcome qualitative resistance are major factors (Ibid.).

In controlled tests, colonization of poplar leaves by strains of *Melampsora* upregulated a number of genes in the lignin biosynthetic pathway, probably to generate lignin to strengthen cell walls against (further) infection (Azaiez et al. 2009). This is one of a number of studies demonstrating lignin's role in responding to a variety of fungal pathogens that afflict poplar (Zeng et al. 2023). It is reasonable to assume that poplar and other tree species genetically engineered for low lignin levels are at increased risk of plant disease relative to unmodified comparator trees. Because many poplar species are polyploid, GE trees with genetic alterations for reduced lignin content might well be exempted from regulation under one or more of the proposed new exemptions, escaping any assessment of plant pest risk.

[18] Ibid., p. 8.

Economic efficiency versus plant defense

The majority of research on the lignin pathway in trees and other plants is directed towards sharply reducing their lignin content, driven by efforts to reduce production costs in livestock production and bioenergy applications. However, these efforts come with serious plant pest risks, as detailed above. Unfortunately, such research is often conducted with little regard to these concerns. For instance, in an extensive review of research on transgenic approaches to reducing lignin in poplar, Bryant et al. (2020) devote all of one, throwaway sentence to this topic, which amounts to little more than wishful thinking: "Ideally, an economically viable bioenergy crop will display high biomass yields, drought tolerance, pest resistance and high sugar conversion yield." There is little doubt that economic efficiency and cost arguments will prevail, leading to increasingly pest and disease-susceptible crops, to the detriment of U.S. agriculture.

**Responsible Plant Breeding versus "Regulatory Relief"**

USDA's regulatory regime needs to function as a public interest counterweight to potentially irresponsible applications of new plant technologies, such as gene-editing, and instead use its statutory authority to enact guardrails, and nudge plant breeders towards fuller consideration of the plant pest and noxious weed risk implications of their breeding programs. Instead, just as these powerful new technologies are coming into their own, with the potential for ever more significant and consequential changes to crops and US agriculture as a whole, the Department seems committed to rolling back its regulatory regime, exempting increasingly larger swaths of GE plants from any regulatory scrutiny at all, for no better reasons than "regulatory relief."

We urge the USDA to change course. A first step could be taken by cancelling the five proposed new exemption categories, which only increase the potential for unregulated plant pest risk. Second, we urge USDA to overhaul its regulatory regime to fully comport with the Plant Protection Act.

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