Animal Plant and Health Inspection Service (APHIS, the "Agency")
U.S. Department of Agriculture

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

7 CFR Parts 340 and 372 [Docket No. APHIS–2018–0034]
RIN 0579–AE47
Proposed Rule: Movement of Certain Genetically Engineered Organisms[1]

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Radically Abridged Notice and Comment for this Major Proposed Rule

The Institute for Agriculture and Trade Policy (IATP)[2] appreciates the opportunity to comment on this Proposed Rule (PR). We note that the 60-calendar day comment period is very short, relative to the numerous and major changes made to the 2017 Proposed Rule. The Agency did not issue an Advance Notice for Proposed Rulemaking (ANPR), which reduces the opportunity for notice and comment under the Administrative Procedures Act (APA). The stakeholder consultation process for the PR appears to consist largely of private meetings with entities with a direct or indirect (e.g. university research derived "start-up" biotech companies) commercial interest in the rulemaking. The PR outlines the Agency's stakeholder consultation process:

> Following the withdrawal of the January 2017 proposed rule, APHIS conducted extensive outreach to Land Grant and public university researchers, as well as small-scale biotechnology developers, agriculture innovators, and other interested stakeholders. In total, APHIS met with more than 80 organizations, including 17 universities, State Departments of Agriculture, and farmer organizations. Much of the feedback received during this process centered on the need to focus regulatory efforts and oversight upon risk, rather than the method used to develop GE organisms. Stakeholders also expressed a desire for flexible and adaptable regulations so that future innovations do not invalidate the regulations. We also received feedback urging us to keep international trade objectives in mind when proposing new regulations and ensuring that new regulatory requirements are transparent and clearly articulated, (Federal Register (henceforth FR), Vol. 84, No. 109 / Thursday, June 6, 2019, 26516).

IATP is one of the "other interested stakeholders" who must have missed a public consultation opportunity. We cannot find a public announcement or a record of the public

meetings with these 80 organizations. APHIS should publish those public announcements and that record as part of the notice and comment APA requirement. The PR lacks the "Summary of Commenters" that is common to that of PRs from other Agencies, probably because of the lack of an ANPR response. APHIS should remedy that deficiency in the administrative record for this rulemaking by citing in a "Summary of Commenters" for the Interim Final Rule documents received or consulted in the meetings with the 80 organizations with whom it has consulted, so that the public can learn how the Agency considered the views of these stakeholders. Additionally, the Agency should hold at least one public consultation with "other stakeholders" without a direct or indirect commercial interest in the PR. Since APHIS poses just one specific request for comment (FR 26517) in this PR, IATP is left to assume that stakeholder input in the meetings with 80 organizations was invariable and unanimous, so APHIS found no need to pose questions.

IATP, as a nonprofit, non-governmental organization with 31 years of experience in analyzing trade policy and, until very recently, the owner of Peace Coffee, a fair-trade company, appreciates the difficult path that APHIS must walk in USDA's Marketing and Regulatory Program. Yet marketing can only be sustainable where the regulatory function is scientifically robust and independent, not structurally subordinate to Marketing. There is constant industry and political pressure on APHIS to have it assess the risks of a biotechnology product to enable trade, regardless of the risks identified in the methods and process of a GE plant's or organism's development. As a result, APHIS proposes "to regulate GE organisms that are, in and of themselves, plant pests, as well as other GE non-plant organisms that pose plant pest risks," (FR 26516). This regulatory approach isolates the genetically engineered (GE) organism from the environment in which it is used and process by which it is developed, radically impeding science-based risk assessment. As such, the "GE organisms, in and of themselves" are like the Absolute Objects of eighteenth century German philosophical idealism "an und für sich"[3] and not empirical objects whose traits, benefits and risks may be elucidated in risk assessment. APHIS' Biotechnology Regulatory Services (BRS) must be allowed to regulate according to the risks that may be identified in the process of developing biotechnology products. BRS should not be in the business of facilitating trade in products "in and of themselves."

Legal and Scientific Jeopardy: Ignoring the Agency's Obligations Regarding "noxious weeds" in the Plant Protection Act of 2000

On July 30, 2018, IATP wrote to APHIS concerning its Notice of Intent to Prepare an Environmental Impact Statement: Movement and Outdoor Use of Certain Genetically Engineered Organisms ("Notice").[4] In that letter, IATP urged APHIS to regulate GE organisms and novel plants as required by the Plant Protection Act (PPA) of 2000. More specifically, we cited the January 2017 Proposed Rule: Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms (Docket No. APHIS–2015–0057)[5], which APHIS withdrew in November 2017 in response to biotechnology industry objections and to its applause.[6] Citing the withdrawn Proposed Rule, we reiterate here that APHIS must use its authority to make a publicly documented determination of the potential for GE organisms to become "noxious weeds," notwithstanding industry's concerns about the impact of such determinations on its commercial interests:

> If APHIS determines that the GE plant is a noxious weed, it would endeavor to gauge the direct or indirect injury or damage it could cause to crops, livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the

> United States, the public health, or the environment. APHIS would make the results of this evaluation publicly available and share both the evaluation and the information on which it is based with the Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA), as warranted, (Federal Register / Vol. 82, No. 12 / Thursday, January 19, 2017 / Proposed Rules, p. 7011).

The determination of any such "direct or indirect injury or damage" is subsequent to compliance with the PPA requirements, following a determination of the potential for a GE organism to result in a "noxious weed," (7 USC 7702, para 10). APHIS must determine that the data and studies submitted by the commercialization application for a GE organism, plus peer-reviewed studies and the published results of APHIS supervised field trials, demonstrates that the GE organism is unlikely to pose a "noxious weed" risk that could cause "direct or indirect injury or damage." Post-commercialization reporting and monitoring would be required to confirm the validity of the Agency's determination regarding "noxious weed" potential.

By removing "noxious weed" potential as a criterion for determining the regulatory status of a biotechnology product[7], APHIS not only unreasonably restricts its PPA authority but elides the risk assessment needed to determine the potential for biological resistance to develop to an engineered trait (e.g. resistance to a plant pathogen) or to a stacked trait product (e.g. resistance to a product that includes a Plant Incorporated Pesticide and a GE trait to increase the starch content of corn).[8] In the near future, APHIS will receive applications for non-regulated status of CRISPR edited gene drives to control agricultural pests and weeds.[9] "Genes Drives on the Horizon," a 2016 National Academies of Sciences report[10], stated "The potential for gene drives to cause irreversible effects on organisms and ecosystems calls for a robust method to assess risks." How will USDA develop a "robust method to assess risks" for applications to commercialize such unfamiliar products as gene drives, if the Agency continues to abjure using its noxious weed authority to assess risks? How will USDA risk assess such applications, if the "noxious weed" regulatory trigger for undertaking the risk assessment is elided by this PR?[11]

New genetic engineering techniques "bypass natural biological mechanisms governed by evolution, inheritance and gene regulation, and can therefore be much faster than conventional breeding."[12] The GE short-circuiting does not mean that evolution, inheritance and gene regulation cease, but only that biological processes have been delayed long enough to produce a patented product with traits of commercial interest. APHIS, by editing out of the 2017 Proposed Rule its obligation to determine the noxious weed potential of a GE organism, has short circuited the regulatory process and categorically weakened its ability to evaluate the environmental risks of GE organisms. As the PR notes, this regulatory approach reflects the Secretary of Agriculture's statement of March 28, 2019 on how GE organisms are to be regulated to expedite their commercial release (FR 26516). However, the PR does not provide for a comprehensive science-based approach to risk assessment of GE organisms.

The National Academy of Sciences report on "Understanding Risks Related to Future Biotechnology Products" too briefly anticipates the regulatory gap that APHIS has decided to create with many PR features: "There may also be regulatory gaps associated with these types of products. For example, if USDA determines that a product is not regulated by virtue of the mechanism used to insert the genetic modification or the source of the genetic material, and

that product may be a plant pest or weedy species, there would not be oversight when oversight is warranted."[13] In this PR, APHIS has greatly increased the likelihood of eliminating oversight when oversight is warranted.

APHIS invokes the National Academy of Sciences report's discussion of the principle of familiarity to reduce the number of GE plants that APHIS must review to determine its potential for plant pest risks, (FR 26516). According to the explanatory notes for the USDA FY 2020 Budget, "USDA expects the cumulative number of determinations of nonregulated status to increase from 129 in FY 2018, to 135 by the end of FY 2020. In FY 2020, APHIS will continue to devote resources to meet target timelines of 13 to 15 months for petitions that do not require an environmental impact statement."[14] While APHIS plans to use the principle of familiarity to reduce the number of GE plants it reviews to determine plant pest risk potential, it could use that principle to determine the likelihood of noxious weed potential in environmental impact statements. But the agency has chosen not to, regardless of the PPA requirements. Whether the Agency has put itself in legal jeopardy by selectively interpreting and enforcing the Plant Protection Act likely will be a matter for the Courts to decide.

Lowering the Risk Assessment Bar to Expedite Commercialization of Biotechnology Products

Under the Proposed Rule, APHIS lowers the legal bar for determining the regulatory status of a GE organism to a single criterion—whether the GE organism is developed with the aid of a plant pest or could result in a plant pest:

> The approach we are proposing would differ from the current regulatory framework in that regulatory efforts would focus on the properties of the GE organism itself rather than on the method used to produce it. We believe that this new approach, which reflects our current knowledge of the field of biotechnology, would enable us to evaluate GE organisms for plant pest risk with greater precision than the current approach allows. GE organisms that pose a plant pest risk would fall within the scope of the proposed regulations and require permits for movement. As discussed in more detail later in this document, we would define plant pest risk in this proposed rule as ''[t]he possibility of harm resulting from introducing, disseminating, or exacerbating the impact of a plant pest.'' APHIS will continue to regulate GE organisms that are, in and of themselves, plant pests, as well as other GE non-plant organisms that pose plant pest risks. Such organisms would require permits for movement, (Federal Register (henceforth FR) Vol. 84, No. 109 / Thursday, June 6, 2019, 26514).

By lowering the regulatory bar, APHIS would exempt from regulation biotech products from developers using such GE techniques as CRISPR-CAS, TALEN and zinc finger nucleases, on the basis of its "current knowledge" that when the application of those techniques employs a "plant pest" (per APHIS' definition") to produce a GE organism, the resulting product is no longer a plant pest "in and of itself." A recent review of research on techniques to reduce the number, kind and scale of off-target mutations and unwanted traits from CRISP-CAS editing notes, "many plant species are only stably transformable via Agrobacterium-mediated transformation, which is incompatible with the RNP strategy"[15] for reducing the off-target results for editing such plants as wheat and potato. This essential step in the CRISPR-CAS method of editing employs a bacterium with a plant pest risk, but if the agency determines that the bacterium is subsequently edited out, there is nothing to regulate. However,

Professor Jennifer Kuzma, a member of the NAS committee that produced the "Understanding Risks Related to Future Biotechnology Products" report subsequently warned against driving public acceptance of new GE techniques by means of new nomenclature that suggests nothing in the new techniques will enable plant pest risks to emerge:

> Specifically, they [the new terms] hide the facts that 1) rDNA technology is used in laboratory settings to splice, paste, and deliver the genetic machinery for the construction of gene-edited crops; 2) not all kinds of gene edits will be simple mutations that could otherwise be achieved through conventional breeding; and 3) some gene-edited crops will contain foreign, transgenic, or synthetically designed DNA sequences.[16]

In recent applications for commercial authorization to APHIS, the first step of the method to develop the GE organism requires use of a bacterium, *Agrobacterium tumefaciens* or a "gene gun", both of which entail potential plant pest risks, to create the transgene nuclease that is subsequently "edited" by the above-mentioned techniques. According to a Testbiotech review of 22 non-regulated status applications, APHIS approved all the applications following the applicants' assertions (presumably documented by peer-reviewable science) that no trace of the transgene could be detected after "editing" before the product moves from the laboratory to the agricultural environment in which the GE organism is used. Seven of the applicants classified the first step of their product development methods as Confidential Business Information (CBI), and APHIS accepted this classification without question.[17]

Even if IATP did not share the concern of biosafety researchers that the Agency's extensive granting of CBI impedes peer-reviewable risk assessment,[18] we would be alarmed at the alacrity with APHIS proposes in the PR to jettison both its notification procedure for product developers and the petition procedure for non-regulated status, with few exceptions to be noted below, (FR 26533). In lieu of the notification and petition procedures,

> Under our proposed new regulatory framework, a developer would have the option to make a self-determination as to whether his or her GE plant belongs to one of the categories listed under § 340.1(b) or (c) and is therefore exempt from the regulations. A developer who determines that his or her GE plant belongs to an exempted category would have the option under proposed § 340.1(d), to request written confirmation from APHIS that the self-determination is valid. These confirmation letters, which would provide a clear and succinct statement about the regulatory applicability of the GE plant and the nexus to plant health, may be useful to developers wishing to market their products domestically or overseas by allowing them to provide verification to an importing country or other party that APHIS concurs with their self-determinations, (FR 26517).

Given the pressure on APHIS to commercialize domestically and trade internationally food and agriculture products derived from GE techniques, it is very likely that self-determination will be the default option for biotech product developers, particularly start-ups looking to sell or license their patents to transnational companies with the marketing power and the diplomatic clout needed to ensure acceptance in importing countries where the GE organism is not authorized. An APHIS confirmation that the self-determination is valid will be a

formulaic letter, without an accompanying risk assessment, that the GE organism in question does not pose a plant pest risk "in and of itself."

While the PR states that penalties and remedial actions will occur if the Agency does a risk assessment to demonstrate that the self-determination is invalid, the deregulatory barn door will have closed after the GE cows have escaped. Who will have the means and motivation to challenge a self-determination of a GE organisms that has already been commercialized and perhaps even internationally traded? On June 7, APHIS announced that the detection of unauthorized GE wheat in Washington state was "a result of events occurring before USDA strengthened its oversight of regulated GE wheat trials."[19] Under the developer self-determination option, it is not clear how detection of GE plants deriving from invalid self-determinations would occur, nor how the Agency would locate the CBI protected locations of field trials for GE organisms self-determined to meet the Agency plant pest risk criterion.

Non-Regulation of Plants that Produce Plant-Made Industrials and Pharmaceuticals (PMPIs)

The Agency proposes to apply the same simple plant pest risk criterion to PMPIs for determination of non-regulated status. Indeed, the biotech product developer could self-determine that its PMPI product not be regulated. IATP, in our comment on the PMPI regulatory options presented in 2017 Proposed Rule,[20] addressed the risk of horizontal gene transfer (HGT) of PMPI crops to food crop fields. Under the current PR, this HGT risk would remain below regulatory concern. Nevertheless, current GE techniques have not eliminated this risk, so we reiterate this passage from our 2017 letter:

> A Preliminary Opinion of three scientific committees advised the European Commission that as of 2015, there were no reliable bio-containment techniques to prevent horizontal gene transfer.[21] The Preliminary Opinion, as well as the Presidential Commission for the Study of Bioethical Issues in synthetic biology, assume multiple genetic safeguards will be required to solve biosafety risks of horizontal gene transfer from organisms modified by the new GE techniques.[22]

New GE techniques have been advanced to bio-contain HGT. "However," writes a biosafety research group, "with an ever-increasing scale in GMO deployment, the containment and/or killing efficiencies of these systems may not be sufficient to prevent a buildup of GMOs in the environment. Therefore, continuous improvements in system robustness and efficiency are needed to ensure biosafety."[23] Given the low bar the PR has set for non-regulated status, the "buildup of GMOs in the environment," both for food crops and PMPIs, is likely to exceed the capacity of bio-containment systems.

The PR alludes potential PMPI gene outcrossing to contaminate the environment and food crops: "Federal oversight of outdoor plantings of PMPI-producing plants could be necessary to prevent the unlawful introduction into the human or animal food supply of pharmaceutical or industrial PMPI products" (FR 26518). The PR offers two possible options for this oversight after this PR is finalized. One of the options would mentions the available statutory authority for that oversight, the Agency's duty under the PPA to regulate "noxious weeds:"

> Under a second option, a statute would be enacted, or existing statutory authority amended, to grant one or more Federal agencies explicit authority to provide oversight of outdoor plantings of all GE PMPI-producing plants and to evaluate GE PMPI-producing plants for all possible risks, beyond plant pest and noxious weed risks, (FR, 26518).

Given that biotechnology industry opposition removed from this PR regulation of "noxious weeds" under the PPA, the likelihood of enacting such a statute with industry support is extremely politically remote, even if PMPI crops contaminated food crops with severe public health and economic consequences.

Instead of incorporating risk assessment of an applicant's GE product to evaluate its "noxious weed" potential into the PR, APHIS reiterates its simple plant pest risk criterion and its application of the plant-trait-Mechanism of [biochemical] Action review to compare the paperwork for the new GE products to that for past products. In sum:

> Rather, the GE plant would be regulated only if it had a plant-trait-MOA combination that the Agency has not yet evaluated for plant pest risk or if it was evaluated and found to pose a potential plant pest risk. Additionally, APHIS' evaluations of GE plants for plant pest risk would generally not require data from outdoor plantings. Even if the plant represents a new plant-trait-MOA combination not previously reviewed, there is a likelihood that most, if not all, GE PMPI- [Plant Made Pharmaceutical and Industrial chemicals] producing plants that are currently under APHIS permits could be determined to be not regulated under the provisions of the proposed regulations after a regulatory status review because they are unlikely to pose a plant pest risk. Thus, such plants could be grown outdoors without the need for APHIS permits and without APHIS oversight, (FR 26518).

Of this feature of the PR, Professor Jennifer Kuzma has written, "Without explicit safety testing on the exact genetic change in the plant, these risks are likely to go unnoticed. Even though the rule and [President Trump's June 11, 2019] Executive Order [on biotechnology] are purportedly "science-based," forgoing scientific studies or field testing for most GE crops seems anti-science and precarious."[24] To reiterate, Professor Kuzma was a member of the U.S. National Academy of Sciences' Committee on Preparing for Future Biotechnology. When a member of the Committee whose report is invoked in support of this PR calls major features of it anti-scientific, APHIS should seek more and varied input than what it received in private meetings with 80 organizations.

The Advisory Committee on Biotechnology and 21st Century Agriculture was terminated in 2017, apparently because it could not agree on policy recommendations.[25] USDA, rather than eliminating advice that may not support the commercial objectives of the biotechnology product developers, should suspend this rulemaking to obtain critical scientific advice on the limitations of and agronomic consequences of the new GE techniques, particularly CRISP-CAS. There is no shortage of that advice: "Another issue the genome editing crops may suffer would be their open field cultivation particularly for the open pollinated or cross-pollinated plant species. When these plants will be grown in the field, they may revert to wild-type phenotype by crossing with the pollen from unedited plants, (Y. Wang et al., 2014)."[26] Rather than ignore the literature that describes such risks of the genome editing of crops and

promulgate a rule that ignores those risks, APHIS should write a rule that enables it to anticipate and regulate such risks.

Conclusion

The budgetary savings and regulatory efficiency that APHIS claims for the PR do not justify allowing novel GE products to enter into the market based on a plant-trait-MOA comparison of new and older GE products derived from applicant submitted studies and data, much of it classified as CBI. The justification appears logical, particularly as USDA science-based agencies are under budgetary and ideological attack: "By focusing regulatory resources and risk analyses on unfamiliar products, APHIS will be able to avoid conducting repetitive analyses, utilize its staff time more efficiently, and provide better stewardship of taxpayer dollars," (FR 26516). But as GE products stack more traits and produce more unanticipated mutations, the Agency must increase its capacity to understand and anticipate the risks identified with the proliferating unintended mutations and off-target traits of genetic engineering in an agricultural environment driven by climate change.[27] Increasing that capacity does not come cheaply or easily. APHIS should not allow the industry to self-determine the regulatory status of its products, when the Agency, lacking a post-commercialization monitoring program, has little capacity to recall those products of invalid self-determinations.

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[1] https://www.aphis.usda.gov/brs/fedregister/BRS_20190606.pdf

[2] The Institute for Agriculture and Trade Policy (IATP) is a nonprofit, 501(c)(3) nongovernmental organization, headquartered in Minneapolis, Minnesota, with offices in Washington, D.C. and Berlin, Germany.

[3] https://en.wikipedia.org/wiki/Thing-in-itself

[4] https://www.regulations.gov/document?D=APHIS-2018-0034-0001

[5] https://www.aphis.usda.gov/brs/fedregister/BRS_20170119.pdf

[6] "BIO Statement on USDA Withdrawal of 340 Biotech Rules," Biotechnology Innovation Organization. November 7, 2017. https://www.bio.org/press-release/bio-statement-usda-withdrawal-340-biotech-rules

[7] E.g. Ian Heap, "Increase in Unique Resistant Weeds for the USA", Slide 5, in International Survey of Herbicide Resistant Weeds. www.weedscience.org. Accessed June 15, 2017. The international Survey identified 160 unique weed resistant cases in the United States as of June 2017.

[8] E.g. Sandeep Kumar, Wei Chen and Stephen Novak< „Trait stacking in modern agriculture: genome-edited applications," *Emerging Topics in Life Sciences,* Vol. 1:2, 151-169.
DOI: 10.1042/ETLS20170012

[9] Virginie Orgogozo, Baptiste Morizot and Christophe Boete, "Agricultural pest control with CRISP-based gene drive: time for a public debate," *Embo reports*, June 2017.
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[14] https://www.obpa.usda.gov/20aphis2020notes.pdf at 37.
[15] Hahn F, Nekrasov V (2018) CRISPR/Cas precision: do we need to worry about off-targeting in plants? Plant Cell Reports 38:437–441. https://link.springer.com/article/10.1007/s00299-018-2355-9
[16] Jennifer Kuzma, "Regulating Gene-Edited Crops," *Issues in Science and Technology*, Vol. 35, No. 1, Fall 2018. https://issues.org/regulating-gene-edited-crops/
[17] "Am I Regulated?" 13.
[18] Oliver Wright, Guy-Bart Stan and Tom Ellis, "Building-in biosafety for synthetic biology," *Microbiology* 159, July 2013. https://www.ncbi.nlm.nih.gov/pubmed/23519158; Anna J. Simon and Andrew D. Ellington, "Recent advances in synthetic biosafety," *F1000Research,* August 31, 2016. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5007755/
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[21] "Preliminary Opinion [on] Synthetic Biology Risk Assessment Methodologies and Safety Aspects," European Commission, January 2015, at 6. http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_048.pdf.
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[27] E.g. Michael Eckerstorfer, Marianne Miklau and Helmut Gautisch, "New plant breeding Techniques: Risks Associated with their Application," Environment Agency Austria, 2014. http://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0477.pdf; Ricarda Steinbrecher, "Inherent risks and the need to regulate: New Plant Breeding Techniques," Econexus, December 2015 at 6. http://www.econexus.info/sites/econexus/files/NBT%20Briefing%20-%20EcoNexus%20December%202015.pdf; Heidi Ledford, "CRISPR gene-editing produces unwanted DNA deletions," *Nature*, July 16, 2018. https://www.nature.com/articles/d41586-018-05736-3