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Animal & Plant Health Inspection Service
Regulatory Analysis & Development, PPD
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Via
https://www.regulations.gov/docket?D=APHIS-2015-0057

This letter provides comments on Docket No. APHIS-2015-0057

USDA Should Set Aside Process-Based Regulatory Proposals

On January 19, 2017, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) proposed changes to the regulations governing "[i]mportation, interstate movement, and environmental release of certain genetically engineered organisms."[1] This was in follow up to an earlier proposal inviting public comment on APHIS' stated intent "to prepare a programmatic environmental impact statement [EIS] in connection with potential changes to the regulations [at 7 CFR 340] regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms."[2]

The purpose of this proposal is clearly stated: "to update the regulations in response to advances in genetic engineering and understanding of the plant pest and noxious weed risk posed by genetically engineered (GE)

[1] "Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms," Animal and Plant Health Inspection Service, *Federal Register 82*, no. 12 (January 19, 2017): pp. 7008-7039, https://www.regulations.gov/document?D=APHIS-2015-0057-0001.
[2] "Environmental Impact Statement; Introduction of the Products of Biotechnology: Extension of the Comment Period" Animal and Plant Health Inspection Service, *Federal Register 81*, no. 44 (March 7, 2016): p. 11738, https://www.regulations.gov/#!documentDetail;D=APHIS-2014- 0054-0023.

organisms, thereby reducing burden for regulated entities whose organisms pose no plant pest or noxious weed risks."[3]

To justify the proposal, APHIS invokes the bedrock principles for regulation under the Coordinated Framework.[4] APHIS also refers to a significant body of experience accrued under the regulations put in place in 1987:

> "APHIS has issued more than 18,000 authorizations for the environmental release of GE organisms in multiple sites, primarily for research and development of improved crop varieties for agriculture. Additionally, APHIS has issued more than 12,000 authorizations for the importation of GE organisms, and nearly 12,000 authorizations for the interstate movement of GE organisms.… APHIS has granted 124 determinations of nonregulated status.…"

This vast body of experience has led APHIS to conclude that "t]he Agency's evaluations to date have provided evidence that most genetic engineering techniques, even those that use a plant pest as a vector, vector agent, or donor, do not result in a GE organism that presents a plant pest risk."

The agency then devotes 30 pages of dense and convoluted prose to outline a new scope for regulating articles they have just explained they have found unlikely to pose any risk and therefore do not need regulating, as well as similar products produced with the latest generation of techniques that are even more precise, manageable, and predictable than anything that has gone before.

The crux of the matter is this:

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[3] "Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms," Animal and Plant Health Inspection Service, *Federal Register 82*, no. 12 (January 19, 2017): pp. 7008-7039, https://www.regulations.gov/document?D=APHIS-2015-0057-0001.

[4] The purpose of regulation is to mitigate or manage the risk of exposure to hazards. The degree of regulation must be proportional to the level of hazard being managed. Hazards that may be associated with biotechnology products are not different in kind from those of other production methods with which we are familiar. Regulation must therefore focus on the qualities of a product that may lead to exposure to a hazard rather than the process used to produce the product, which is irrelevant to hazard. Existing regulatory authorities are generally adequate to capture the hazards of new products in agriculture, biomedicine, and research and development in various spheres; "Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms" (Animal and Plant Health Inspection Service).

> "[T]he proposed regulations would not apply to organisms that are created using techniques that APHIS does not consider to constitute genetic engineering or that fall outside the scope of GE organism.… By genetic engineering, APHIS would mean techniques that use recombinant or synthetic nucleic acids with the intent to create or alter a genome."

APHIS focuses the proposed new regulation squarely on innovations developed with "genetic engineering" as it arbitrarily defines it, leaning heavily on the "intent to create or alter a genome" without regard to the results. With this language, APHIS would unilaterally abandon more than three decades of U.S. policy and move directly, immediately, and explicitly to a process-based regulation. In view of the conspicuous failure of such regulation everywhere it has been tried, this is difficult to understand.

Even if APHIS had the independent authority to take such a move, such a departure from the status quo would need to be justified with a substantial argument showing that such changes are required to safeguard the public good against unreasonable risks, and that they cannot be achieved through less disruptive means. But the agency's own words document the massive data and experience showing the proposed regulations to be incapable of achieving the desired objectives.

Some observers have praised the APHIS proposal because it does exempt some items from this regulatory scrutiny:

> "APHIS would exclude from the definition of *genetic engineering* traditional breeding techniques (including, but not limited to, marker assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion) or chemical or radiation based mutagenesis. APHIS would do so because the Agency has never considered such techniques to constitute genetic engineering.… APHIS would also exclude, from its definition of *GE organism,* certain organisms that are created using techniques that fall within the scope of *genetic engineering,* but that could otherwise have been produced using traditional breeding techniques or chemical or radiation based mutagenesis. Such organisms are essentially identical, despite the method of creation, because while there may be small genetic differences, those differences are not phenotypically observable and these types of changes occur naturally in all organisms."

APHIS states further that:

> "GE plants as a class, which constitute the vast preponderance of GE organisms to date, pose no greater plant pest or noxious weed risk than their counterparts developed through traditional breeding techniques or chemical or radiation based mutagenesis. Moreover, it is both impracticable and unnecessary to regulate plants created through traditional breeding techniques or chemical or radiation based mutagenesis for plant pest or noxious weed risk."

And then APHIS offers the following exculpatory defense for its proposed exclusions, while noting but setting aside the fact that it applies equally to crops improved through biotechnology:

> "Such regulations would also fail to take into consideration the usual purpose of applying traditional breeding techniques or chemical or radiation based mutagenesis to a plant: To introduce desirable phenotypic traits into the organism or remove phenotypically undesirable traits from the organism. Additionally, it would fail to take into adequate consideration that phenotypic traits that could increase the plant pest or noxious weed risk posed by a plant tend to also adversely impact its vitality, uniformity, or commercial viability. For example, a mutation caused by chemical or radiation based mutagenesis could render a plant more susceptible to certain viroids or pathogens and able to transfer this increased susceptibility to sexually compatible relatives, and thus increase the plant pest risk associated with the plant. However, it would also directly adversely affect the plant's vitality."

With these statements APHIS has not even attempted to argue that items not exempted pose greater hazards and higher risks than those exempted, as the law and policy requires. In fact, as APHIS has shown, all data and experience point in the opposite direction.

The proposed new definition of biotechnology is arbitrary and incoherent, departing in significant ways from established usage and scientific understanding, and its focus is overtly and impermissibly process based. And although it exempts a series of techniques and measures clearly understood by the world to be encompassed in the term, the clear meaning of the term captures not only these excluded methods, but numerous processes and phenomena that are ubiquitous among living organisms in the natural world. And it does all this with a definition that lacks even the most tenuous relationship with any indicators of hazard or risk. Numerous studies (incorporated here by reference) by the National Academy of Sciences, the Organization for Economic

Cooperation and Development, and authoritative bodies worldwide confirm that hazard is a function of the characteristics of a product and is unrelated to the process by which it is produced.[5] This proposal from APHIS therefore provides no basis for any improvement in the existing U.S. Department of Agriculture regulatory paradigm and is at odds with the 2015 OSTP mandate as well as the 1986 Coordinated Framework.

Further, if APHIS sincerely intends to rely on the argument that "certain organisms" should be exempted from regulatory scrutiny if they could be produced through other methods or if any differences would be "not phenotypically observable," then APHIS would be on firm ground to establish broad phenotypic categories for exemption from regulatory scrutiny that would include, for example, all herbicide-tolerant and insect or disease-resistant plants, among others. Numerous examples abound in nature of all these phenotypes, and APHIS has not provided a single concrete example of an intentional genetic modification that would impart through these phenotypes any novel threat to agriculture.

If the fatal defects described above are insufficient to compel the administration to set aside the APHIS proposal in its entirety, there are more. APHIS also argues for a significant expansion of its authority to regulate "GE plants" under its existing authority to regulate noxious weeds. In the course of marshaling this argument, APHIS states that:

> "Historically, there has not been a significant need for such a noxious weed evaluation of GE plants. Most of the GE plants that APHIS regulated in the past, such as varieties of corn and soybeans modified with common agronomic traits, do not qualify as 'noxious weeds.' This is because most GE

[5] Organization for Economic Cooperation and Development, "Recombinant DNA Safety Considerations" (Paris: OECD, 1986), ISBN 92-64-12857-3; OECD, "Safety Considerations for Biotechnology" (Paris: OECD, 1992), ISBN 92-64-13641-X; OECD, "Biotechnology, Agriculture and Food" (Paris: OECD, 1992), ISBN 92-64-13725-4; OECD, "Traditional Crop Breeding Practices: An Historical Review to Serve as a Baseline for Assessing the Role of Modern Biotechnology" (Paris: OECD, 1993), ISBN 92-64-14047-6; OECD, "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles" (Paris: OECD, 1993) ISBN 92-64-13859-5; A. Nicolia, et al., "An Overview of the Last 10 Years of Genetically Engineered Crop Safety Research;" Jon Entine and JoAnna Wendel, "With 2000+ Global Studies Affirming Safety, GM Foods Among Most Analyzed Subjects in Science," Genetic Literacy Project, October 8, 2013, https://www.geneticliteracyproject.org/2013/10/08/with-2000-global-studies-confirming-safety-gm-foods-among-most-analyzed-subject-in-science; L. Val Giddings, "U.S. National Academy of Science Reaffirms Safety of GMOs for 11th Time, But Confuses the Story on Yields," *Innovation Files,* June 3, 2016, http://www.innovationfiles.org/u-s-national-academy-of-science-reaffirms-safety-of-gmos-for-11th-time-but-confuses-the-story-on-yields.

> plants to date have been agricultural crops, and most agricultural crops are not biologically weeds prior to modification. Indeed, in order to domesticate a plant for crop production, farmers often had to deliberately eliminate weedy traits, such as seed shattering, thorns, and seed dormancy, from the plant using traditional breeding techniques. Moreover, the phenotypic traits that have historically been introduced into crops through genetic engineering do not confer weediness. Because the plants have not been weeds prior to genetic engineering, and genetic engineering has not introduced weediness, evaluating the plant solely for plant pest risk has not been problematic."

APHIS goes on to argue that some plants now being adapted for agriculture, e.g., switchgrass for use as a biofuel crop, do have some weedy characteristics that could, in principle, be exacerbated by modifications to improve their biofuels utility. But APHIS still fails to articulate (though it asserts otherwise) any hazard that could not be encompassed under their existing plant-pest risk trigger, much less one that poses an unreasonable risk sufficient to justify being regulated. Instead, they claim that "under the [Plant Protection Act's (PPA's)] definition of *plant pest,* a plant must be parasitic in order to be considered a plant pest." But the PPA states that:

> "The term 'plant pest' means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:
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> (A) A protozoan.
> (B) A nonhuman animal.
> (C) A parasitic plant.
> (D) A bacterium.
> (E) A fungus.
> (F) A virus or viroid.
> (G) An infectious agent or other pathogen.
> (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs."[6]

The APHIS argument is plainly without merit. The fundamental challenge APHIS faces in the effort to update its regulations is that with no evidentiary basis they are focused on DNA from certain sources as being potential vehicles for hazards and risks that could threaten U.S. agriculture. But APHIS has correctly

[6] Plant Protection Act of 2000, Pub. L. No. 106-224, 114 Stat. 438 (2000) Sec. 403. Definitions at https://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/PPAText.pdf.

concluded from three decades of experience that this approach has not been fruitful; the energies expended to date in evaluating genetically engineered plants have not identified any novel risks stemming from their modification through genetic engineering, much less unreasonable ones. Furthermore, many of the improvements imparted through genetic engineering are indistinguishable in kind from traits developed through other methods like radiation or chemical mutagenesis, or intrinsic to plants (nearly all plants are tolerant to one or more herbicides, which is why agronomists have developed multiple different herbicides). In other words, no matter how acquired by a plant, a DNA sequence is, at best, an imperfect and unreliable marker of hazard, and of no value as a predictor of risk. It follows logically, then, that DNA sequences provide no basis for rational regulation.

APHIS nevertheless goes on at length in an effort to justify a fundamentally unsound approach. APHIS proposes "a new risk analysis process to determine which organisms would require a permit." Yet, in this second attempt to push these suggestions forward, APHIS still fails to share sufficient information about this "new risk analysis process" to enable one skilled in the art to understand, much less test it. It offers, instead, empty boilerplate:

> "[T]he GE plant would be a regulated organism if it had a plant/trait combination that the Agency has not yet evaluated for plant pest and/or noxious weed risk, if it has received DNA from a taxon that contains plant pests and the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis related that is expected to cause plant disease symptoms, or if it was evaluated and found to represent plant pest or noxious weed risks."

This is not only tautological, but perpetuates dependence on a regulatory trigger that APHIS has already conceded is without value or utility.

APHIS further asserts that:

> "[I]f the developer believes that it possesses sufficient information to demonstrate that the organism presents no plant pest or noxious weed risk, and wished to release it into the environment, it would have to submit this information to APHIS and request that APHIS conduct an evaluation of such risk. The process for submitting such a request, as well as the possibilities for how APHIS would act on that request, is set forth in proposed § 340.4."

This is an assumption of "guilty until proven innocent" based on a presumption of hazard that APHIS has already shown is unfounded. While such approaches may be appropriate under Napoleonic Code-based jurisprudence, they are not permissible under US jurisprudence.

APHIS nowhere provides any concrete example of the questions they would ask to evaluate the regulated article; nor what the answers would have to look like to extract permission from regulators. Nor do they inform as to why APHIS would want to waste time asking these questions and reviewing answers for categories for which no realistic hazard has been identified (e.g., herbicide-tolerant plants). What is the basis for presuming a degree of hazard for genetically engineered or gene-edited plants greater than those known to be associated with conventionally bred plants? Where is there any empirical basis for a presumption of hazard that vast experience and rigorous scientific review to date have failed to document? How is this consistent with the 1986 Coordinated Framework requirement that agencies abjure process-based regulation, and reserve regulation for cases of unreasonable risk? This proposal suggests a lamentable disregard for evidence-based decision-making.

Throughout all of this baroque argumentation, APHIS repeatedly sidles up to the recognition (without ever openly naming and embracing it) that the tool of utility to regulators here would be to identify categories of phenotypes that present hazards leading to risk that would be manageable by regulation. APHIS should set aside the present proposal entirely, and abandon any effort to advance regulatory proposals based on the inheritance or genetics of a regulated article. Instead, APHIS should invite public comment to help them identify classes of hazards of concern (i.e., that would present unreasonable risks), and develop a catalog of the phenotypes of regulated articles that would be vehicles for associated unreasonable risks, regardless of the techniques by which they came to be. APHIS should develop regulations for addressing such risks in a manner that is based on data and experience, and whereby the regulatory burdens are proportionate to the risks thus mitigated or managed. It should be an overarching mandate, as set out in the 1986 Coordinated Framework, that these regulations not discourage or discriminate against innovation without evidence of actual hazards leading to unreasonable risks.

Thank you for the opportunity to provide comments on this proposal.

Sincerely,
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