

April 21, 2016
Docket No. APHIS-2014-0054
Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238
<http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0054>

This submission provides comments to Animal and Plant Health Inspection Service (APHIS) Docket No. 2014-0054 concerning APHIS's 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."¹

The 1986 "Coordinated Framework for Regulation of Biotechnology" established "the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products."² In so doing it "sought to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry." It stated further, "This framework is expected to evolve in accord with the experiences of the industry and the agencies, and, thus, modifications may need to be made through administrative or legislative actions."

Bedrock principles laid down as the basis for regulation under the Coordinated Framework are clear, straightforward, and robustly supported by science and experience:

- 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.

By most standards, regulation under the Coordinated Framework has been a conspicuous success. We now have a robust agricultural biotechnology industry that has added over \$150 billion of value to the world economy, improved the livelihood of more than 18 million farmers and billions of consumers worldwide,

while substantially improving the sustainability and reducing the environmental impacts of modern production agriculture.³ All this has been accomplished without a single example of a negative impact on human health or the environment stemming from the biotech derived source of the innovation, an enviable record.

The picture is not, however, one of unblemished success. The biotech improved seeds commercially available today make up but a fraction of those crops that were field tested in the early years of the Coordinated Framework. The common perception is that many innovations have languished in laboratories or the frustrated imaginations of innovators because of the high costs and onerous burden of meeting regulatory requirements for approval of field trials and commercialization.⁴

Over the past three decades we have seen many thousands of field trials around the world of crops improved through biotechnology. As noted above, the Coordinated Framework envisioned that regulations put in place a generation ago would be adapted and updated to incorporate the new knowledge gained from such vast experience; in particular, that regulatory constraints would be decreased where initial worries were allayed by practical experience. In general, this has not happened. Instead, the passage of time has seen an increase in the volume and kinds of information requested by regulators on the innovations developers seek to bring to market. Almost none of the increased information requested involves questions to which different answers would have any conceivable impact on a regulator's decision to approve or disapprove a product in a category with such an unparalleled safety record. It is for this reason, above all, that the White House recently directed regulatory agencies to review their regulations for biotechnology products with an eye to narrowing what was once a gap between the level of hazard and degree of regulatory scrutiny that has since become a chasm.⁵

In the statement of intent addressed by these comments APHIS proposes a new definition of "biotechnology" as:

Laboratory-based techniques to create or modify a genome that result in a viable organism with intended altered phenotypes. Such techniques include, but are not limited to, deleting specific segments of the genome, adding segments to the genome, directed altering of the genome, creating additional genomes, or direct injection and cell fusion beyond the taxonomic family that overcomes natural physiological reproductive or recombination barriers. This definition does not include and is intended not to include traditional breeding, marker assisted breeding, or chemical or radiation-based mutagenesis.

APHIS's proposal then hinges the rest of its proposed regulatory changes on another new definition: "*Product of biotechnology*. An organism developed using biotechnology."

The proposed new definition of biotechnology is both arbitrary and incoherent, departing in significant ways from established usage and understanding. Its focus is undeniably and impermissibly process based, as signaled by the opening “Laboratory-based” constraint. 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 remote connection with any indicators of hazard or risk. Numerous studies by the National Academy of Sciences, the Organization for Economic Cooperation & Development, and authoritative bodies worldwide have confirmed that hazard is a function of the characteristics of a product and is unrelated to the process by which it is produced.⁶ This proposal therefore provides no basis for any improvement in the existing U.S. Department of Agriculture regulatory paradigm.

With this notice APHIS is proposing, in effect, explicitly to abandon the risk-based trigger for oversight codified in the regulations at 7 CFR 340 adopted in 1987 and revised in 1992, and replace it with a trigger that is explicitly (i.e., “laboratory-based techniques...”) process-based. Such a move is explicitly foreclosed under the Coordinated Framework, and would entail abandoning its bedrock virtue of being science based. APHIS does not have the independent authority so profoundly and unilaterally to depart from the ruling policy laid out in the 1986 Coordinated Framework and reaffirmed by the Office of Science and Technology Policy (OSTP) in 2015.

In short, APHIS’s proposed definition of “biotechnology” would do nothing but exacerbate confusion and uncertainty over the scope of its regulatory authority and procedures while making no apparent contribution toward fulfilling the mandate to improve and streamline assigned by OSTP in 2015. These proposals from APHIS ignore or misconstrue the principles laid down under the Coordinated Framework in 1986, which remain the governing authority for U.S. policy. The proposed definitions must be set aside.

APHIS proposes further a series of action alternatives to be examined under the intended EIS. These are discussed below.

First Alternative: Take no action. This approach would make no changes to the status quo. It is inconsistent with the approach envisioned and mandated under the Coordinated Framework, and it does not comply with the instructions from OSTP to update and improve existing regulations.⁷ It must therefore be rejected.

Second Alternative: Revise the current APHIS regulations concerning the introduction of certain GE organisms to provide for a process to review and regulate certain products of biotechnology to protect plant health; analyze potential plant pest and/or noxious weed risks first; and thereafter regulate only when appropriate and necessary.

This alternative demands the implications of the term “certain” be made clear. Which “GE organisms” would be captured for review and regulation, using what trigger(s)? The proposed definition of “biotechnology” and products derived thereby cannot serve for the reasons laid out above. Presumably APHIS would propose some modification to the existing plant-pest trigger, but what those might be and how they might be applied in practice is obscure. Further, what kinds of hazard make regulation “necessary,” what threshold of risk must be crossed in order to trigger regulation and control measures, and what are the objective, empirical, and experiential bases for such determinations?

The unstated but implicit presupposition in this alternative (and, in fact, throughout much of the Notice) seems to involve an assumption that biotechnology products necessarily present a different and elevated hazard/risk profile than the products of conventional breeding, mutagenesis, or other putatively exempt classes, including those produced by natural phenomena in natural populations every day. This unstated and unexamined presupposition is manifest throughout APHIS’s approach in the docket, despite its acknowledgment that “the Coordinated Framework has consistently held and proceeded pursuant to the concept and position that the process of genetic modification has not been shown to be inherently dangerous.”

Until and unless APHIS can provide satisfactory and concrete answers and clarifications to these questions, this alternative cannot be seen as consistent with the Coordinated Framework or compliant with the OSTP mandate.

Third Alternative: Revise the current APHIS regulations concerning the introduction of certain GE organisms to provide for the regulation of “products of biotechnology” as either plant pests or noxious weeds using the existing plant pest “analysis trigger” or a noxious weed “analysis trigger” that might classify plants produced through biotechnology as potential plant pests or noxious weeds. Three decades of experience applying a “plant pest trigger” for regulatory oversight have been conspicuously unproductive in identifying hazardous biotechnology products that must be denied regulatory approval in order to protect U.S. agriculture. Neither experience nor the scientific literature provide any evident support for adding any similar “noxious weed” trigger (although considerable public misunderstanding that would further erode APHIS’s credibility and impair innovation would be unavoidable). Unless APHIS can provide specific, concrete examples of how such revisions would be framed and applied that would deliver demonstrably improved linkage between regulatory oversight and hazards that would be thus managed or mitigated it is impossible to imagine any empirical basis of support for this alternative.

Fourth Alternative: Withdraw the current 7 CFR part 340 regulations completely and implement a voluntary, non-regulatory consultative process for certain products of biotechnology whereby APHIS would document plant pest or

noxious weed risks, if any, of certain products of biotechnology as defined above. This alternative comes closest to defining an approach compatible with the three decades of experience we now have confirming that biotech-improved seeds present neither novel hazards nor elevated risks, though its legitimacy is corroded by its framing as linked to the process-based definition of “biotechnology” we have shown above to be unsound and impermissible.

The plant-pest trigger incorporated in the regulations adopted in 1987 was logical and defensible at the time. Three decades of experience have, however, confirmed the hypothesis that plants grown from biotech-improved seeds carry no unique, technology specific hazards or any elevated risks. As such, there is no empirical justification for regulations that single out such articles for special or heightened scrutiny or specific regulation, as is presently the case. Such regulations do nothing to enhance the safety or health of American agriculture. They have clearly, however, created a substantial disincentive to innovation in an area and at a time when it is urgently needed. Numerous suggestions have been made for ways in which the science- and data-based foundations of U.S. regulatory policy could be more closely reflected in regulations, and the gap between the degree of regulation and the level of hazard/risk might be narrowed.⁸ These remain valid, and superior to anything contemplated in the present docket. APHIS should abandon all the present proposals and revisit the issue taking those suggestions and others rooted in data and experience into account.

Sincerely,



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¹“Environmental Impact Statement; Introduction of the Products of Biotechnology: Extension of the Comment Period,” United States Department of Agriculture, Animal and Plant Health Inspection Service, Federal Register 11738, Vol. 81, No. 44, Monday, March 7, 2016, <https://www.regulations.gov/#!documentDetail;D=APHIS-2014-0054-0023>.

² “Coordinated Framework for Regulation of Biotechnology,” Executive Office of the President, Office of Science and Technology Policy, 51 FR 23302 June 26, 1986, https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.

³ Wilhelm Klümper and Matin Qaim, “A Meta-Analysis of the Impacts of Genetically Modified Crops,” PLoS ONE 9, no. 11 (November 2014). DOI: 10.1371/journal.pone.0111629, <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0111629>; Clive James, International Service for the Acquisition of Agri-Biotech Applications (ISAAA) “Global Status of Commercialized Biotech/GM Crops,” brief 51, 2015, <http://isaaa.org/resources/publications/briefs/51/executivesummary/default.asp>.

⁴ Agne’s E. Ricroch and Marie-Cécile He’nard-Damave, “Next biotech plants: new traits, crops, developers and technologies for addressing global challenges” Crit Rev Biotechnol, Early Online: 1–16; 2015 Informa Healthcare USA, Inc. DOI: 10.3109/07388551.2015.1004521,

<http://www.tandfonline.com/doi/abs/10.3109/07388551.2015.1004521?journalCode=ibry20>; Phillips Mcdougall, “The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait,” A Consultancy Study for Crop Life International, September 2011, at <https://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf>.

⁵ “Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture: Modernizing the Regulatory System for Biotechnology Products,” Executive Office of the President, Office of Science and Technology Policy, July 2, 2015, https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_me_mo_final.pdf; Kalaitzandonakes N, Alston JM, Bradford KJ (2007) Compliance costs for regulatory approval of new biotech crops. Nat Biotechnol 25: 509-511.

⁶ Introduction of Recombinant DNA-Engineered Organisms Into the Environment: Key Issues, U.S. National Academy of Sciences, National Academy Press, 1987; Field Testing Genetically Modified Organisms: Framework for Decisions, U.S. National Academy of Sciences, National Academy Press, 1989; Genetically Modified Pest-Protected Plants: Science and Regulation, U.S. National Academy of Sciences, National Academy Press, 2000; The Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation, U.S. National Academy of Sciences, National Academy Press, 2002; The Safety of Genetically Engineered Foods, U.S. National Academy of Sciences, National Academy Press, 2004; Recombinant DNA Safety Considerations, Organization for Economic Cooperation and Development, Paris, 1986; Agricultural and Environmental Policies: Opportunities for Integration, Organization for Economic Cooperation and Development, Paris, 1989; Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles, 1993.

⁷ “Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture: Modernizing the Regulatory System for Biotechnology Products,” Executive Office of the President, Office of Science and Technology Policy, July 2, 2015, https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_me_mo_final.pdf.

⁸ L.V. Giddings and Bruce Chassy, “Igniting Agricultural Innovation: Biotechnology Policy Prescriptions for a New Administration,” Science Progress, Center for American Progress, 2009, at <http://scienceprogress.org/2009/07/igniting-agricultural-innovation/>; K.J. Bradford, A. Van Deynze , N. Gutterson, W. Parrott, and S.H. Strauss SH, (2005) “Regulating transgenic crops sensibly: lessons from plant breeding, biotechnology and genomics,” Nat Biotechnol 23: 439-444, 2005; H. Miller, K.J. Bradford, “The regulatory bottleneck for biotech specialty crops,” Nat Biotechnol 10: 1012-1014 (2010).