Animal and Plant Health Inspection Service (APHIS)
Regulatory Analysis and Development, PPD, APHIS
Station 3A-03.8, 4700 River Road, Unit 118
Riverdale, MD 20737-1238

May 7, 2021

Advanced Notice of Proposed Rulemaking (ANPR): Regulation of the Movement of Animals Modified or Developed by Genetic Engineering
Docket No. APHIS-2020-0079

Submitted electronically to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0079*

The Institute for Agriculture and Trade Policy (IATP)[1] appreciates this opportunity to comment on the above-captioned ANPR. As we noted in our previous letter to APHIS on July 30, 2019, the agency did not consult with non-industry stakeholders prior to issuing its proposed rule for a framework to deregulate genetically engineered plant organisms.[2] We request that the agency reverse the previous administration's industry-only consultations in rulemaking and make all consultation documents and comment letters available on the APHIS website. IATP requests that APHIS follow best practices in the Administrative Procedures Act "notice and comment" provision by providing summaries of comments on provisions of proposed rulemaking and summaries of agency responses to those comments in the preliminary section of the proposed rule.

On April 5, IATP and 10 other non-governmental organizations wrote to USDA Secretary Thomas Vilsack concerning the January 13 Memorandum of Understanding (MoU) signed by Secretary Sonny Perdue to transfer much of the Food and Drug Administration's (FDA) regulatory authority over genetically engineered animals to APHIS.[3] We noted that FDA Commissioner Stephen Hahn had refused to sign the MoU and that FDA has not posted the MoU on its website, meaning that the MoU is not legally valid nor operational for FDA. We requested that Secretary Vilsack withdraw the MoU from the APHIS website and that we meet with APHIS biotechnology regulatory services staff to discuss the MoU. The former request has not been granted but some of the signatories of our letter will be meeting with APHIS officials, for which we are grateful.

[1] The Institute for Agriculture and Trade Policy is a 403 c) non-profit organization headquartered in Minneapolis, MN, with offices in Washington, DC, Halliday, ME and Berlin, Germany. It has been submitting regulatory comments to U.S. Department of Agriculture agencies since soon after its founding in 1986.
[2] https://www.iatp.org/sites/default/files/2019-07/IATP%20Letter%20to%20APHIS.pdf
[3] https://www.centerforfoodsafety.org/files/final-group-letter-to-secretary-vilsack-opposing-transfer-of-ge-animals-to-usda-april-5_39488.pdf

The ANPR states:

> The contemplated regulatory framework for amenable species modified or developed using genetic engineering is intended to operate under a Memorandum of Understanding (MOU) with FDA consistent with each agency's authorities and statutory obligations and informed by the comments received in response to this advance notice of proposed rulemaking and request for comments. A MOU would facilitate an orderly transition of the oversight of amenable species modified or developed using genetic engineering for certain intended uses from FDA to USDA once USDA's regulatory program is established. A MOU would set clear roles, responsibilities, and timeframes for the interaction between FDA and USDA.

Many of the questions in the ANPR assume that FDA will agree to an "orderly transition" of FDA regulatory authority over genetically engineered (GE) animals to USDA. This assumption is premature at best. IATP will wait for a new FDA Commissioner to confirm or not FDA's consent to the "orderly transition" proposed by Secretary Sonny Perdue before we provide substantive responses to questions in a revised and reissued ANPR and/or proposed rule. We anticipate, based on the response of FDA Commissioner Hahn and FDA career lawyers to the MoU, that a subsequent renegotiation of the MoU will not result in establishing USDA as a "one-stop shop" providing "end to end oversight" of GE product developer applications to expedite the commercialization of GE animals with the "regulatory certainty" demanded by industry as noted in our April 5 letter. As a result, we anticipate that APHIS will have to modify the proposed "contemplated framework" and the questions about it before issuing a proposed rule.

The legal authority for the ANPR relies far more on a policy document, the "Coordinated Framework for the Regulation of Biotechnology", as "modernized" in 2019 by a Trump administration Executive Order, than on the higher legal status of clear statutory authority. So, for example, the ANPR states, "The Executive Order pointed out that for many national imperatives for food production and rural prosperity to be realized, the Federal biotechnology regulatory system must both foster public confidence in the technology and avoid undue regulatory burdens." IATP urges APHIS to clarify its legal authority for the ANPR according to the provisions of the Animal Health Protection Act, rather than rely on this Executive Order and the non-scientific standards of the Coordinated Framework.

However, if APHIS understands its primary function to be to "foster public confidence in the technology and avoid undue regulatory burdens," the contemplated framework should state explicitly how it plans to carry out this first objective. (The entire contemplated framework removes nearly all "regulatory burdens," i.e., requirements.) A major impediment to fostering public confidence in the USDA deregulation of agriculture and food products derived from techniques of genetic engineering is the nearly universal granting of GE product developer Confidential Business Information (CBI) claims.[4] What

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3589341/

confidence should the public have in agency letters to product developers announcing non-regulated status of the developers' products, when the data and studies used by the agency to determine non-regulated status are classified as CBI and made unavailable to the public? APHIS is, in effect, asking the public to have faith in evidence not seen, even if that evidence is relevant to animal and human health.

Advocates of unconditional granting of CBI received a boost from the Supreme Court in June 2019, in *Food Marketing Institute v. Argus Leader Media*. The case concerned a Freedom of Information Act (FOIA) request to access store level data reporting Supplementary Nutritional Assistance Program (SNAP) benefits.[5] The Court majority overthrew the confidentiality standard of demonstrating "substantial competitive harm" if the SNAP data did not remain confidential. As a result, GE product developers will not have to demonstrate competitive harm for APHIS and other agencies to grant CBI status to animal, plant, human and environmental health data in product developer data and studies used to apply for non-regulated status.

Given this unprecedented restriction on the public's ability to obtain relevant information and data through FOIA requests, how will APHIS "foster public confidence in the technology," which is not a statutory requirement? Since APHIS relies on the Trump Executive Order and the "modernized" Coordinated Framework for the preponderance of the ANPR's legal authority, APHIS should explicitly state its policy and criteria for granting CBI to product developers and for responding to FOIA requests. APHIS should also outline in a proposed rule how it will "foster public confidence in the technology" while denying or heavily redacting access to the information that would foster that public confidence.

Thank you for considering these short remarks on the ANPR.

Steve Suppan, Ph.D.
Senior Policy Analyst

[5] https://www.law.cornell.edu/supremecourt/text/18-481