

February 26, 2021

Docket No. APHIS-2020-0079
Regulatory Analysis and Development
PPD
APHIS, Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

RE: Docket APHIS-2020-0079-0001

To Whom It May Concern:

The Campaign for Family Farms and the Environment (CFFE) appreciates the opportunity to comment on APHIS' advanced notice of proposed rulemaking (ANPR) and request for comments on "establishing regulations for the movement of certain animals modified or developed by genetic engineering" (Docket APHIS-2020-0079-0001).

CFFE is a coalition of state and national organizations, including Dakota Rural Action, Iowa Citizens for Community Improvement, Land Stewardship Project, Missouri Rural Crisis Center, Food & Water Watch and Institute for Agriculture and Trade Policy.

Our organizations work together as CFFE to change policies that promote consolidation in animal agriculture at the expense of independent family farms. There is a decades-long trend in U.S. agriculture of consolidation that has driven small operations out of business, with those operations that remain growing larger. This is true in every sector of U.S. agriculture but is particularly severe in food animal production.

Many government policies are explicitly designed for larger operations or promote proprietary technologies that are most likely to be adopted by larger operations that are closely tied to multinational agribusiness firms and serve consolidated supply chains. These policies not only force small operations to compete on an unlevel playing field, but also change the landscape of our food system and rural communities. The trend towards fewer, larger farms has had devastating effects in rural communities across the country, both in the money that flows to local businesses and also in tax revenue to local governments to fund services like schools and roads.

The regulatory framework being proposed by USDA for genetically engineered (GE) animals would unfortunately create yet another federal policy that facilitates the growth of corporate-controlled factory farms at the expense of independent family farms, public health and the environment. The proposed regulatory framework would provide inadequate protection for consumers of foods derived from GE animals and ignores critical questions about the potential

impacts of the adoption of GE animals on the economic structure of the livestock sector and the viability of independent family-scale operations.

It appears that the USDA has failed to learn any lessons from the dramatic impact the widespread adoption of GE crops had on the economics of farming, including the loss of important markets, public health and the environment, and is using the same bad assumptions from that regulatory framework in its approach to GE animals.

And this approach seems premature at best, given the very public debate about whether the Food and Drug Administration (FDA) has actually agreed to this framework for regulating GE animals, which are currently under its jurisdiction. The existing federal coordinated framework for regulation of genetic engineering technologies in the food system is entirely inadequate, including the FDA's current approach of regulating new genetic constructs in food animals as veterinary drugs. But this new proposal to shift responsibility entirely to USDA would not be an improvement over the current flawed system.

Therefore, we urge the USDA to pause this attempt to revise the regulatory regime for GE animals and instead participate in an overall evaluation of the coordinated framework for federal regulation of genetic engineering in the food system, leading to an overhaul of the entire approach. A better framework would emphasize a precautionary approach that evaluates not just the risk for plant and animal pests, but also the economic and environmental impacts of adoption of these technologies, including intellectual property practice impacts on industry structure, environmental impacts of increased use of affiliated herbicides or intensification of confinement production of livestock due to the adoption GE technology. The ANPR does not achieve these goals and we urge the agency to instead embark on a more thorough evaluation of the entire framework.

In addition to these overarching concerns, we have some specific comments related to several sections of the ANPR.

Expedited Safety Review: The review process proposed by APHIS and FSIS fails to provide adequate protection to consumers of food products derived from GE animals. Specifically, the proposal creates opportunities for review to be waived if genetic constructs achieved through GE techniques could also be achieved through conventional breeding. The assumption that the only metric that matters is the resulting genetic modification is inappropriate and is based on a faulty assumption that new techniques like gene editing will never create off-target or unintended changes in the animal's genetic code. The accidental discovery by FDA scientists of non-bovine DNA in a gene edited cow illustrates that the gene editing process may not be as precise as its supporters claim. It is premature to base a regulatory system on the assumption that mistakes cannot happen with new techniques like gene editing, and that simply checking a box that the intended genetic alteration was made is sufficient oversight.

Post-Market Review: The failure to establish a post-market review process to identify possible adverse effects from consuming products derived from GE animals is another major flaw of the

ANPR. Combined with major gaps in traceability and labeling (discussed below), this could eliminate any chance to identify problems once these products are on the market.

Cloning: Another notable absence in the ANPR is any discussion of the regulation of cloned food animals. While the high cost of cloning food animals has supposedly limited the availability of food products derived from cloned animals, the failure of FDA to require tracking or labeling makes this hard to assess. And the adoption of more genetic engineering techniques for food animals could stimulate new demand for cloning of GE animals. Will clones of gene edited or other GE animals require any additional review, tracking or disclosure under this new regulatory framework? Will FDA remain responsible for regulating cloned food animals while USDA regulates GE animals?

Labeling: The ANPR is essentially silent on how other USDA rules for labeling of “bioengineered” food would be enforced under this new regulatory system. While the need to prevent misbranding under FMIA and PPIA is discussed, there is no discussion of the National Bioengineered Food Disclosure Act. While the Act exempts from labeling requirements the meat or milk from animals fed GE crops, it does not exempt all animals that are themselves engineered. In order to ensure that labeling of meat or other foods derived from GE animals can be accurately labeled, these animals will have to be identified and segregated in slaughter and processing facilities. The ANPR should have addressed how APHIS and FSIS will establish regulations and systems to ensure that these products can be accurately tracked and labeled. Additionally, APHIS would have to establish a procedure to ensure that newly deregulated GE animals that trigger labeling requirements are added to the Agricultural Marketing Service’s List of Bioengineered Foods.

Lessons from GE Crops

The ANPR does not seem to incorporate any lessons learned from the widespread adoption of GE crops.

Industry Consolidation: The rapid growth of GE crops, which were primarily designed to be grown with affiliated herbicides or plant incorporated pesticides, had numerous impacts on agriculture, including rising input costs for farms due to licensing fees for genetic traits, lack of choice for producers when specific traits can only be purchased in expensive multi-trait stacked varieties, and increased management costs for herbicide-resistant weeds that were fueled by increased use of GE crop-associated herbicides. These economic consequences of the technology changed the structure of a huge segment of U.S. agriculture, driving consolidation of land into larger operations and consolidation in input suppliers through mergers and intellectual property arrangements.¹ These economic impacts of the adoption of new

¹ American Antitrust Institute, Food & Water Watch, National Farmers Union. Letter to the U.S. Department of Justice regarding the proposed merger of Dow and DuPont. May 31, 2016. https://1yd7z7koz052nb8r33cfxyw5-wpengine.netdna-ssl.com/wp-content/uploads/2016/05/Joint_Dow-Dupont_5.31.16.pdf

technologies need to be assessed and considered before similar technologies are approved. But they are not addressed at all in the proposal for a new regulatory framework for GE animals.

Field Trials: APHIS' system for regulating field trials of GE crops has been shown repeatedly to be totally inadequate.² The ANPR suggests that a similar system will be established for trials and environmental release of GE livestock. Mismanaged trials of GE animals could become an immediate threat to consumers if animals are accidentally allowed into the food supply, potentially damaging markets for all animal producers. APHIS must design a much more rigorous oversight system for field trials than the one that has failed repeatedly for field crops.

Economic Impacts

The list of questions in the ANPR about economic impacts is far too short, and should be expanded to include requests for input about several other ways that this technology could impact the livestock sector:

- What is the possibility of increased vertical integration or more restrictive contracting or marketing arrangements to manage the use of patented or otherwise proprietary GE livestock breeds?
- What is the potential for increased consolidation of slaughter capacity due to the need to segregate GE animals in the supply chain?
- What is the potential impact on producers not raising GE animals or others in the meat industry if consumers become wary of an entire commodity (like beef or pork) if labeling rules do not let them adequately identify which products are derived from GE animals?
- What is the potential impact on producers or others in the meat industry if export markets are unwilling to accept products derived from GE animals, and ban whole classes of commodities if the U.S. does not have an adequate tracking system?

² USDA Office of Inspector General. Audit Report 50601-0001-32. "Controls Over APHIS' Introduction of Genetically Engineered Organisms." September 2015. https://www.aphis.usda.gov/biotechnology/downloads/audits/USDA_OIG_50601-0001-32.pdf; Mateusz Perkowski, "USDA Proposes More Scrutiny for Biotech Wheat Field Trials." Capital Press. December 13, 2018. https://www.capitalpress.com/ag_sectors/research/usda-proposes-more-scrutiny-for-biotech-wheat-field-trials/article_1bbd895c-6e4e-5330-8ef4-285adfc4d93.html

- What impact could the widespread adoption of GE technology in the livestock sector have on the diversity of breeds raised in the U.S.? Does a reduction in genetic diversity increase risk for animal disease outbreaks or have other impacts on the resilience of the sector to disruption?

More Pressing Problems for USDA to Address

Finally, we would like to point out that there are numerous problems in the livestock and protein supply chain, as shown in the recent disruptions in the food system caused by the pandemic. But a lack of genetically engineered animals is not one of those problems. In fact, if the experience with GE crops is any indication, the widespread adoption of this technology in the livestock sector will simply exacerbate existing problems of consolidation, put smaller producers at another disadvantage, increase the intensity of meatpacker-controlled factory farm production, and make the livestock supply chain even less resilient.

Instead of devoting agency resources to facilitating the use of controversial and unproven technologies like genetically engineered animals, the USDA should instead prioritize immediate actions to restore competition and fair practices to agriculture markets while working towards longer-term reforms that shift resources to family farm-based regional food systems instead of corporate-controlled industrialized operations.

Thank you for your consideration of these comments. If you have questions or need more information, please contact Patty Lovera at pattylovera20@gmail.com.

Sincerely,

Campaign for Family Farms and the Environment