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

Submitted via Regulations.gov

RE: Docket No. APHIS-2020-0079; Regulation of the Movement of Animals Modified or Developed by Genetic Engineering

To Whom It May Concern:

The Animal Welfare Institute (AWI) submits these comments on behalf of our supporters in response to the USDA's Advance Notice of Proposed Rulemaking (ANPRM) on "Regulation of the Movement of Animals Modified or Developed by Genetic Engineering," published in the *Federal Register* on December 28, 2020.

AWI is opposed to the proposed regulatory framework described in the ANPRM for the reasons detailed below.

1. Genetic engineering poses potential negative impacts on animal welfare, which are not addressed by the proposed regulatory framework.

In his "Principle for the Conservation of Welfare," bioethicist Bernard Rollin noted: "Any animals that are genetically engineered for human use should be no worse off, in terms of suffering, after the new traits are introduced into the genome than the parent stock was prior to the insertion of the new genetic material." Unfortunately, the USDA's proposed regulatory framework for genetic engineering of farm animals does not offer that assurance.

Animal agriculture industries have many genetic engineering projects in development. Most have as their primary goal increasing production/efficiency, disease resistance, or the nutritional value of the food product. Promoters of genetically engineered disease-resistant animals occasionally point to benefits such as improved animal welfare or decreased reliance on antimicrobials for secondary bacterial infections; however, their primary concern seems to be the economic losses caused by disorders related to the disease in question. The ultimate effect of genetic engineering on welfare is often up for debate, as they may promote production-enhancing practices that are experienced as negative by animals, even if their bodies can physiologically tolerate them. Moreover, some proposed genetic alterations, such as tolerance for the stress of extreme cold or heat, may have the *potential* to improve animal welfare but whether they would do so in practice would depend on other factors. For example, do animals who are physiologically better able to

tolerate temperature extremes also feel subjectively more comfortable at these temperatures? Will producers invest less in maintaining appropriate environments if they do not suffer economic losses from failing to do so?

Genetic engineering has numerous potentially negative implications for animal welfare, including increased demand for animal research, added suffering due to the invasive nature of procedures associated with egg harvesting and impregnation of female animals, increased risk of unintended and unanticipated consequences of genetic engineering, further entrenchment of intensive animal agriculture, and potential ecological effects due to escape of genetically engineered animals. Given that the technology used to create genetic modifications often leave no trace, it seems foreseeable that issues with labeling and disclosure of the use of genetic engineering will arise. With the potential for unintended consequences of altering the genome, and the fact that not all problems will necessarily be evident within the first few generations, a deregulated approach to non-transgenic animals appears to pose a significant risk to animal welfare.

2. The USDA's proposed regulatory framework exceeds its authority under the FMIA and PPIA.

AWI believes that the ANPRM and proposed regulatory framework would cause the USDA to exceed the scope of its authority under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). An agency must stay within the bounds of its statutory authority. *City of Arlington* v. *F.C.C.*, 133 S. Ct. 1863, 1868 (2013). The language and purpose of these statutes are narrow, and should be interpreted using the plain text of the law. *Id.* As such, it is AWI's position that it would be unlawful and impractical for the USDA to regulate animals modified or developed by genetic engineering under the FMIA and PPIA without a further grant of authority by Congress.

The USDA's authority under the FMIA and PPIA is limited to preventing the entry of adulterated and/or misbranded meat and poultry into interstate commerce through inspection. 21 U.S.C. § 452; § 602. The term "adulterated" bears a technical definition that is not consistent with the authority asserted by the USDA in this ANPRM. "Adulterated" under the FMIA and PPIA is defined (in part) as a product containing a "poisonous or deleterious substance which may render it injurious to health," "consist[ing] in whole or in part of any filthy, putrid, or decomposed substance . . . unsound, unhealthful, unwholesome, or otherwise unfit for human food," prepared in "insanitary conditions" that may cause contamination, or a product that is derived from an animal that has "died otherwise than by slaughter." 21 U.S.C. § 453(g); § 601(m). The ANPRM greatly mischaracterizes the definition, explaining that the definition is so expansive, that the USDA could regulate genetically engineered animals under the FMIA and PPIA as part of its duty to prevent "adulterated" meat and poultry products from entering interstate commerce. However, inspection with the goal of preventing the entry of animals with particular genetic material into interstate commerce concerns none of the definitions listed under "adulterated." As such, the PPIA and FMIA do not permit the USDA to conduct additional inspections or draft further regulations without a further direction from Congress. *City of Arlington*, 133 S. Ct. at 1868–69 ("the question . . . is always whether the agency has gone beyond what Congress has permitted it to do.").

While the USDA's duty to prevent "misbranded" meat and poultry products from entering interstate commerce under the PPIA and FMIA may be more closely related to the authority asserted under the ANPRM, practical considerations bear further consideration. The USDA has consistently interpreted its authority under this provision as essentially limited to post-mortem inspection of carcasses and verification of label content. But ensuring that genetically engineered meat and poultry products are not "misbranded" per the PPIA and FMIA would require far more detailed regulation by the USDA at breeding facilities, on farms, during transport, and at slaughterhouses than could be addressed without further congressional instruction. For instance, it is unclear from the proposed framework whether the issue of segregation of genetically engineered animals from conventional animals is contemplated. Segregation of these animals would be necessary to meet the USDA's duties under the PPIA and FMIA and require oversight from breeding to packaging of derived products—but would conflict with the USDA's longstanding position that it lacks authority to regulate conduct in some of these spaces.

3. The ANPRM also exceeds the scope of the Animal Health Protection Act (AHPA).

In articulating its authority under the ANPRM, the USDA points out that "disease" carries the meaning the Secretary gives it and that the Secretary has not to date given it any. 7 U.S.C. § 8302(3). "Pest," however, is defined and includes, for example, protozoa, bacteria, fungi, prions, and parasites. *Id.* § 8302(13). This definition, and canons of statutory construction, imply that "disease" should carry its ordinary meaning as a condition that impairs normal functioning. Merriam-Webster Dictionary, *available at* https://www.merriam-webster.com/dictionary/disease (last visited Feb. 24, 2021); *F.D.I.C. v. Meyer*, 510 U.S. 471, 476 (1994) (when a statute does not define a term, the dictionary definition controls). Further, the AHPA contains no explicit purpose statement, but its "findings" section provides guidance about Congress' intended grant of authority to the USDA. In this section, Congress lists five findings that guide the subsequent legislation. 7 U.S.C. § 8301. The first, second, and fourth speak to the dangers of diseases and pests of animals to–among others–human and animal health; the third concerns animal health affected by transport; and the fifth establishes constitutionality under the Commerce Clause. *Id.* Nowhere in this statutory grant is there room for the USDA to regulate animals that are distinctive only by their genetic differences, a step which would extend the USDA's authority to an earlier stage, i.e. to an examination of the conditions that *might* lead to disease. This pushing back of the timeline granted by the AHPA oversteps Congress' statutory intent, and is thus not permissible.

4. The proposed regulatory framework is also inconsistent with the USDA's previous interpretation of these laws.

The USDA has a history of extremely limited interpretation of its authority under the FMIA and PPIA. As evidence of this, the Department's Food Safety and Inspection Service has denied a number of rulemaking petitions on the basis that it lacked statutory authority (see FSIS "Petitions" webpage). Some of these petitions were arguably exceedingly more appropriate and relevant to the scope of the FMIA and/or PPIA than what is being proposed for the oversight of genetic engineering under these laws. In addition, the USDA's Animal and Plant Health Inspection Service has neglected to protect animal welfare and the integrity of the nation's food supply through regulating the transport of animals under the AHPA, despite clear scientific evidence that animal welfare and food safety are impacted by the conditions under which farm animals are transported. This suggests that the ANPRM is the result of pressure on the USDA to

remove an impediment to the expansion of animal agricultural products, as opposed to the Department's desire to fulfill its administrative obligations under the FMIA, PPIA, and AHPA.

5. Oversight of genetic engineering of farmed animals should remain under FDA authority.

AWI expressed concerns regarding the regulatory process used by the US Food and Drug Administration (FDA) in its approval of genetically engineered (AquAdvantage) salmon. We felt that issues related to animal welfare, environmental protection, and consumer expectations received inadequate attention. However, we view the FDA processes and protocols to be more stringent and more responsive to these concerns than what has been proposed by the USDA in its ANPRM. The USDA process would be far more vulnerable to corporate interests, given its mission of promoting American agriculture. Moreover, we believe the USDA's mission presents an inherent bias that works to the detriment of animals, the environment, consumers, and independent, small-scale farmers. Regardless of the eventual outcome of this ANPRM, AWI supports creation of a body of independent experts representing various fields of study, including ethics, animal welfare, and environmental and consumer protection, to advise the designated regulatory agency in addressing this extremely complex and consequential issue.

In conclusion, AWI is opposed to the proposed regulatory framework for genetically engineered farmed animals on the basis that the USDA lacks authority under the statutes cited and that the Department's mission prevents it from acting in the best interests of the environment, American consumers, and the animals themselves.

Thank you in advance for your thoughtful consideration of our comments.

Respectfully submitted,

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