Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Chapter I

Food Safety and Inspection Service

9 CFR Chapter III

[Docket No. APHIS–2020–0079]

RIN 0579–AE60

Regulation of the Movement of Animals Modified or Developed by Genetic Engineering

AGENCY: Animal and Plant Health Inspection Service, Department of Agriculture (USDA); Food Safety and Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking and request for comments.

SUMMARY: We are soliciting public comment on establishing regulations for the movement of certain animals modified or developed by genetic engineering. Under the regulatory framework being contemplated, the United States Department of Agriculture would promulgate regulations using the authorities granted to the Department through the Animal Health Protection Act, the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA). Pursuant to these authorities, the Animal and Plant Health Inspection Service would conduct a safety assessment of animals subject to the FMIA or PPIA that have been modified or developed using genetic engineering that may increase the animal's susceptibility to pests or diseases of livestock, including zoonotic diseases, or ability to transmit the same. The Food Safety and Inspection Service would conduct a pre-slaughter food safety assessment to ensure that the slaughter and processing of certain animals modified or developed using genetic engineering would not result in a product that is adulterated or misbranded.

DATES: We will consider all comments that we receive on or before February 26, 2021.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0079.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0079, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0079* or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Alan Pearson, Assistant Deputy Administrator, Biotechnology Regulatory Services; APHIS, 4700 River Road, Unit 98, Riverdale, MD 20737–1238; (301) 851–3944; *Alan.Pearson@usda.gov.* Dr. Kis Robertson Hale, Deputy Assistant Administrator, Office of Public Health Science, USDA Food Safety and Inspection Service, 1400 Independence Avenue SW, Room 341–E. Whitten Building; (202) 720–4819; *Kis.Robertson1@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Statutory Authorities

Under the Animal Health Protection Act (7 U.S.C. 8301, *et seq.*) (AHPA), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) is authorized, among other things, to prohibit or restrict the importation and interstate movement of live animals to prevent the introduction and dissemination of diseases and pests of livestock within the United States. The AHPA broadly defines the terms ''livestock'' as ''all farm-raised animals'' (7 U.S.C. 8302(10)), and ''animal'' as ''any member of the animal kingdom (except a human)'' (7 U.S.C. 8302(1)). Importantly, these definitions do not place any conditions or restrictions on the method by which the animal has been produced, whether it is through conventional breeding or genetic engineering. (We provide illustrative examples of conventional breeding and a working definition of the term *genetic engineering* later in this document, beneath the heading ''Contemplated Regulatory Framework.'') The AHPA also establishes broad definitions of ''import,'' ''interstate commerce,'' and how animals and products ''move'' in commerce. (7 U.S.C. 8302(7), (9), (12)). The statute provides that the term ''disease'' has the meaning given the term by the Secretary of Agriculture (7 U.S.C. 8302(3)), although that term has remained undefined to date, and provides that the Secretary may promulgate such regulations and issue such orders as the Secretary determines necessary to carry out the responsibilities under the AHPA. (7 U.S.C. 8315). Collectively, these provisions provide ample authority for the Secretary of Agriculture to promulgate regulations for the pre-market review and oversight of animals modified or developed using genetic engineering and intended for importation, interstate movement, or environmental release if there is reason to believe that such movement may present a pest or disease risk to livestock.

USDA's Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA, 21 U.S.C. 601, *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*). Specifically, FSIS protects the public by verifying that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged. FSIS verification programs include ante-mortem and post-mortem inspection of livestock and poultry intended for use as human food, as well as the inspection of meat and poultry products for processing. Livestock subject to FSIS jurisdiction under the FMIA (defined as ''amenable species'' at 21 U.S.C. 601(w)) are cattle, sheep, swine, goats, horses, mules, or other equines, and fish of the order Siluriformes. Poultry subject to FSIS jurisdiction under the PPIA (defined as ''any domesticated bird,

whether live or dead'' at 21 U.S.C. 453(3)) are chickens, turkeys, ducks, geese, guineas, ratites, and squabs, as listed in the regulations at 9 CFR 381.1. Under both statutes, FSIS prevents adulterated or misbranded meat and poultry products from entering commerce, working with the Food and Drug Administration (FDA), which determines the safety of food additives and animal drug residues. ''Adulterated'' is defined in the FMIA and PPIA (21 U.S.C. 601(m) and 453(g), respectively) as a number of conditions that may render meat or poultry to be injurious to human health, otherwise cause meat or poultry to be unfit for human food, or make a meat or poultry product appear better or of greater value than it is. ''Misbranded'' is defined in the FMIA and PPIA (21 U.S.C. 601(n) and 453(h), respectively) as several types of product labeling or representation of a meat or poultry product that are false or misleading.

USDA acknowledges that the number of species subject to APHIS' purview under the AHPA is significantly greater than the number of species subject to FSIS' purview under the FMIA and PPIA. For purposes of this document and the contemplated regulatory framework discussed in it, USDA limits its discussion to species subject to both APHIS and FSIS purview.[1] This is not intended to infer any limitations or restrictions regarding APHIS' statutory authority in this matter.

Coordinated Framework for the Regulation of Biotechnology

Along with the Environmental Protection Agency (EPA) and FDA, USDA (APHIS and FSIS) is responsible for the oversight and review of organisms modified or developed using genetic engineering and the foods derived from them. In 1986, the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework)[2] was published by the Office of Science and Technology Policy (OSTP). The Coordinated Framework explains the regulatory roles for USDA (APHIS and FSIS), EPA, and the FDA, and how Federal agencies use existing Federal statutes to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework was subsequently updated in 1992 (*see* 57 FR 6753). A 2016 document issued by OSTP, discussed immediately below, led to a third update to the Coordinated Framework in 2017.

In 2016, OSTP issued the National Strategy for Modernizing the Regulatory System for Biotechnology Products (National Strategy).[3] Recognizing that rapid scientific advances would result in novel types of products, the National Strategy stated that EPA, FDA, and USDA should continue to examine their regulatory structures with the goal of clarifying how the Federal Government will regulate genetically engineered insects and noted that the agencies are working to better align their responsibilities over genetically engineered insects with their traditional oversight roles. (For example, the 2016 National Strategy highlighted the agencies' work to consider mechanisms that would enable EPA to regulate mosquitoes under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136, *et seq.*) as a pesticide, when the developer claims the mosquitoes are intended for population control, FDA to regulate them when a developer makes a disease claim,[4] and USDA to regulate them using its authorities[5] to control of certain plant or animal pest insects.

As a result of the National Strategy, the Coordinated Framework was then updated in 2017,[6] taking into account advances that had occurred in the field of biotechnology. The 2017 update pointed out that the complexities of the regulatory systems make it difficult for the public to understand how the safety of biotechnology products is evaluated and create challenges for small and mid-sized businesses navigating the regulatory process for the products.

Further, on June 11, 2019, the President signed an Executive Order on Modernizing the Regulatory Framework for Agriculture Biotechnology products in order to conduct improved Federal oversight of agricultural biotechnology products that is science-based, timely, efficient, and transparent. 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.

Current Federal Regulatory Approach for Animals Modified or Developed Through Genetic Engineering

Currently, FDA regulates intentional genomic alterations in animals as animal drugs under the FD&C Act; *Institute for Fisheries Resources* v. *Hahn,* 424 F. Supp. 3d 740, 751 (N.D. Cal. 2019), except for mosquito products as described in the 2017 FDA Guidance for Industry #236 entitled ''Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products,''[7] and genetically engineered plant pests, which are subject to APHIS regulation under the Plant Protection Act (7 U.S.C. 7701, *et seq.*).[8] FDA's oversight of intentional genomic alterations in animals includes an evaluation of food safety, safety to the animal, and effectiveness. Although sponsors are generally required to have an approved new animal drug application for intentional genomic alterations in animals prior to marketing, FDA has exercised enforcement discretion for certain low-risk alterations, such as intentional genomic alterations in aquarium fish intended to cause the fish to fluoresce or intentional genomic alterations in animals of food-producing species intended for use as models of disease.

Contemplated Regulatory Framework

In consultation with FDA, USDA is contemplating regulations that would establish a flexible, risk- and science-based regulatory framework for the regulation of certain animals modified or developed using genetic engineering that are intended for agricultural purposes. (For purposes of our contemplated regulatory framework, we envision *genetic engineering* to mean ''techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome'' (*see* 7 CFR 340.3). Thus, it would not include conventional breeding methods such as directed breeding, artificial insemination, embryo transfer, selective breeding, cross breeding, genetic

[1] For example, although APHIS has authority over all farmed aquaculture under the AHPA, the contemplated regulatory framework would pertain only to farmed Siluriformes intended for human food because this is the only aquaculture subject to FSIS authority under the FMIA.

[2] To view the 1986 framework, go to *https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.*

[3] To view, go to *https://www.epa.gov/sites/production/files/2016-12/documents/biotech_national_strategy_final.pdf.*

[4] Under the Federal Food, Drug, and Cosmetic Act (FD&C Act, 21 U.S.C. 301, *et seq.; see* 21 U.S.C. 321(g)).

[5] Plant Protection Act of 2000; (PPA, 7 U.S.C. 7701 *et seq.*) and Animal Health Protection Act (7 U.S.C. 8301, *et seq.*).

[6] To view the 2017 update to the Coordinated Framework, go to: *https://www.aphis.usda.gov/biotechnology/downloads/2017_coordinated_framework_update.pdf.*

[7] To view GFI #236, go to: *https://www.fda.gov/media/102158/download.*

[8] FDA has exercised enforcement discretion over certain intentional genomic alterations in animals of non-food-species that are regulated by other government agencies or entities, such as plant or animal pest insects modified or developed using genetic engineering for plant pest control or animal health protection, which are under APHIS oversight.

backgrounding for purposes of studding, or other practices commonly available to and employed by producers.) Under this contemplated regulatory framework, USDA would in most instances provide end-to-end regulatory oversight from pre-market reviews through post-market food safety monitoring for animals modified or developed using genetic engineering intended for use as human food that are subject to the FMIA or the PPIA (cattle, sheep, goats, swine, horses, mules, or other equines,[9] and fish of the order Siluriformes, domesticated chickens, turkeys, ducks, geese, guineas, ratites, and squabs). Instances where this would not be the case are discussed later in this document. USDA also would provide pre-market animal health regulatory oversight for cattle, sheep, goats, swine, horses, mules, other equines, fish of the order Siluriformes, domesticated chickens, turkeys, ducks, geese, guineas, ratites, and squabs modified or developed using genetic engineering intended for agricultural purposes other than human or animal food (*e.g.,* fiber or labor). For ease of reading, we refer to the animals listed in this paragraph that are modified or developed using genetic engineering and intended for agricultural purposes as ''amenable species modified or developed using genetic engineering.'' As discussed above, ''amenable species'' is a statutorily defined phrase under the FMIA and used generally by FSIS to refer to livestock and poultry species subject to the FMIA or PPIA. Since the contemplated regulatory framework would apply to certain foods only from those species, we use this phrase for the rest of the document, except where context dictates otherwise (*e.g.,* when the use of the phrase could be misconstrued to suggest that a USDA determination that would apply only to a particular animal would instead apply to the entire species). USDA's safety reviews would focus on risks to animal health and human health, by:

- Ensuring that the animal of the amenable species that has been modified or developed using genetic engineering and that is subject to the review is not more susceptible to pests or disease of livestock (infectious and non-infectious), or more likely to spread pests or infectious diseases of livestock, including zoonotic diseases, than animals from the same species that were not modified or developed using genetic engineering.
- Regulating the importation, interstate movement, and environmental release of the animal of the amenable species that has been modified or developed using genetic engineering accordingly.
- Ensuring that animals of the amenable species modified or developed using genetic engineering that are intended to enter the food supply are safe for human consumption by ensuring such animals would not result in a meat or poultry product that is adulterated or misbranded, using the same statutory criteria used for meat and poultry products made from animals produced without genetic engineering.
- Providing permits for the import, interstate movement, or environmental release (*i.e.,* controlled field trials to evaluate the animals) of amenable species modified or developed using genetic engineering.
- Having clear mechanisms for APHIS deregulation when the animal under review is found to pose no greater risk to animal health than the animal from which it was derived.

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.

As described, under the contemplated regulatory framework, USDA would in most instances serve as a single point of entry for amenable species modified or developed using genetic engineering that are intended for agricultural purposes and would provide coordinated end-to-end regulatory oversight from pre-market animal pest and disease risk and human food safety reviews through post-market human food safety reviews for amenable species modified or developed using genetic engineering intended for use as human food. USDA also would provide pre-market animal health regulatory oversight of amenable species modified or developed using genetic engineering intended for agricultural purposes other than human food (*e.g.,* fiber or labor). Under the contemplated regulatory framework, USDA would not regulate amenable species modified or developed using genetic engineering intended for non-agricultural purposes, including medical and pharmaceutical purposes (other than veterinary biologics), and gene therapies. FDA would continue its review of intentional genomic alterations in these amenable species as well as the regulation of dairy products, table and shell eggs, and animal food (feed) that are derived from amenable species. In addition, FDA would continue its review of intentional genomic alterations in animals and the animal food products derived from them that are not subject to the FMIA or PPIA and not previously determined by FDA to be low risk.

The regulatory framework that USDA is considering would be conceptually similar to the recently updated USDA regulations for the movement of organisms, notably plants, modified or developed using genetic engineering, which are found in 7 CFR part 340. However, due to the differences in experience, biology, and breeding practices of animals as compared to plants, there would be some differences between these regulatory frameworks. For example, although 7 CFR part 340 includes up-front exemptions from the regulations for certain types of modifications, we envision that all amenable species modified or developed using genetic engineering and intended for agricultural purposes would be subject to permitting requirements for their import, interstate movement, or environmental release until they have undergone an expedited safety review or an animal health risk assessment and been determined not to pose an increased risk to animal health. We do seek comment on this issue.

Under the contemplated regulatory framework, developers could request that USDA conduct a risk-based and science-based safety review focused on animal health; if the animal of an amenable species has been modified or developed using genetic engineering and is intended for use as human food, then the risk-based and science-based safety review would also be focused on food safety. Depending on the conclusions of the review, the animal subject to the safety review could be determined to not require a permit for import, interstate movement, or environmental release under regulations issued pursuant to this framework, and, if such animal is intended for use as human food, it could be eligible for inspection and to be marked ''Inspected

[9] Horses, mules, and other equines are subject to FSIS jurisdiction under the FMIA, but there are no USDA-inspected horse slaughter establishments in the United States, and USDA is currently prohibited from spending funds to perform ante-mortem inspection of horses for human consumption.

and Passed,'' as free from adulteration, at any USDA-inspected meat packing facility.

We envision a two-tiered system for such reviews. First, USDA is considering an expedited safety review for any genetic modification made that is already known to occur in the gene pool of the species, except in cases where an animal health claim is made for the animal or the modification is known to adversely affect animal health.[10] The purpose of the review would be to verify, through a molecular characterization of the modification and an understanding of the process by which it was introduced, that the intended change was made and that there were no unintended disruptions of endogenous genes,[11] unintended DNA insertions, or off-target changes if the genome was modified without inserting DNA. The expedited safety review would assess whether the modification made using genetic engineering is equivalent to what can be accomplished through conventional breeding practices to ensure that the animal presents no increased risk relative to the animal from which it was derived, including the verification process described above. If USDA finds that the modification made using genetic engineering is equivalent to what can be accomplished through conventional breeding practices, the animal would not be subject to further regulation under the contemplated regulatory framework, and USDA would issue a notice in the **Federal Register** that the animal of the amenable species modified or developed using genetic engineering poses no increased risk to animal health or human health relative to the animal from which it was derived.

If, as part of the expedited safety review, USDA finds that the animal of the amenable species modified or developed using genetic engineering has one of the aforementioned unintended changes, the submitter will be informed. A permit would be required for import, interstate movement, or environmental release of such animal until USDA completes a full animal health risk assessment, and, if the animal of the amenable species modified or developed using genetic engineering is intended for use as human food, a food safety assessment, as described below. For all other types of modifications that are not eligible for expedited safety review, a permit would likewise be required for the importation, interstate movement, or environmental release of the animal of the amenable species that had been modified or developed using genetic engineering, until USDA conducted an animal health risk assessment of the animal and, if the animal is intended for use as human food, a food safety assessment, and determined that there was no additional animal health risk relative to an appropriate comparator.

Review Under the AHPA

The animal health risk assessment would identify any plausible increased risks to animal health or to human health, relative to the risk posed by animals from the same species that were not modified or developed using genetic engineering. In particular, the risk assessment would examine whether the animal could plausibly exhibit increased susceptibility to pests, non-infectious diseases, or infectious diseases of livestock, including zoonotic diseases, or increased ability to transmit such pests or diseases. If a plausible increased risk is identified, USDA would evaluate the scientific data submitted by the developer to ensure that the animal of the amenable species modified or developed using genetic engineering would not pose an increased risk to animal health as compared with animals from the same species that were not modified or developed using genetic engineering.

If the risk assessment concludes that the animal is unlikely to pose an increased risk to animal health relative to the animal from which it was derived, USDA would make the risk assessment available for public comment through a notice published in the **Federal Register**. If no new information emerges that changes USDA's conclusion, USDA would determine that the animal of the amenable species that had been modified or developed using genetic engineering is not regulated under the contemplated regulatory framework. If the risk assessment is unable to reach such conclusion, the animals of the amenable species that had been modified or developed using genetic engineering would remain regulated, and a permit would be needed for importation, interstate movement, or environmental release. APHIS and FSIS would coordinate in these situations to determine whether such animals would be eligible for slaughter. A developer could request a re-review at any time and would be able to provide additional information. USDA would keep the developer apprised of the review's progress.

Additionally, when USDA is unable to reach a conclusion that the animal is unlikely to pose an increased risk to animal health relative to the animal from which it was derived, the developer could request that USDA seek public comment on its risk assessment. Where appropriate when conducting this review, USDA would consult with FDA as described in a MOU.

At a minimum, the animal health risk assessment would include an evaluation of the following issues:

- *Molecular Characterization:* What is the genetic modification(s) in the animal, how was the genetic modification(s) introduced, and how does the genetic modification(s) alter protein or ribonucleic acid (RNA expression)?
- *Animal Health:* Is there scientific evidence that the modified animal could plausibly, either directly or indirectly, increase susceptibility of livestock, including of the animal itself, to pests, non-infectious diseases, or infectious diseases of livestock, including zoonotic diseases? Is there scientific evidence that the modified animal could plausibly increase the spread of pests or infectious diseases of livestock, including zoonotic diseases? When a plausible pathway to such an increased risk is identified, further analysis would be conducted to evaluate the pathway. When an animal health claim is made or a modification is known to adversely affect animal health, the review would assess the animal health claim.
- *Environmental Factors:* Is there scientific evidence that introduction of the modified animal into the environment may result in environmental impacts that would warrant review pursuant to the National Environmental Policy Act (NEPA) or other statutes?

Review Under the FMIA and PPIA

Under the contemplated regulatory framework, FSIS would require food safety assessments of animals of amenable species modified or developed using genetic engineering pursuant to its authorities under the FMIA and PPIA, primarily using its authority to conduct ante-mortem inspections of livestock and poultry presented for slaughter. A discussion of these authorities and how they might be applied within the contemplated regulatory framework for amenable species modified or developed using genetic engineering follows.

[10] When an animal health claim is made or a modification is known to adversely affect animal health and the animal otherwise qualifies for an expedited safety review, USDA would undertake additional review that focuses on the animal health modification, including validation of any animal health claim.

[11] Endogenous genes are pre-existing genes in the genome of the animal being modified or developed using genetic engineering.

As discussed above, under FMIA, FSIS has authority to prevent adulterated meat and meat food products derived from amenable livestock and intended for human consumption from entering commerce. Currently, the amenable livestock eligible for inspection include cattle, sheep, swine, goats, horses, mules, and other equines, and fish of the order Siluriformes. The statute defines ''meat food product'' as ''any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products'' (21 U.S.C. 601(j)). The statute provides that ''this term as applied to food products of equines shall have a meaning comparable to that provided . . . with respect to cattle, sheep, swine, and goats.'' *Id.*

The FMIA requires that, ''for the purpose of preventing the use in commerce of meat or meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species *before* they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce . . . '' (21 U.S.C. 603(a)) (emphasis added). The FMIA also provides for the post-mortem inspection of meat and meat food products. Specifically, the statute provides that ''[t]he Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and for the purposes of any examination and inspection and inspectors shall have access at all times, by day or night, whether the establishment be operated or not, to every part of said establishment; and said inspectors shall mark, stamp, tag, or label as 'Inspected and passed' all such products found *to be not adulterated;* and said inspectors shall label, mark, stamp, or tag as 'Inspected and condemned' all such products found adulterated; and all such condemned meat food products shall be destroyed for food purposes, as hereinbefore provided and the Secretary may remove inspectors from any establishment which fails to so destroy such condemned meat food products'' (21 U.S.C. 606) (emphasis added).

Similarly, the PPIA provides FSIS with authority to prevent adulterated poultry and poultry products for human consumption from entering commerce (21 U.S.C. 451, *et seq.*). The statute defines ''poultry'' as ''any domesticated bird, whether live or dead'' (21 U.S.C. 451(e)). Regulations promulgated under the Act define the domesticated poultry species to include chickens, turkeys, ducks, geese, guineas, ratites and squabs (9 CFR 381.1(b)). The statute defines ''poultry product'' as ''any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting products which contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry, and which are exempted by the Secretary from definition as a poultry product under such conditions as the Secretary may prescribe to assure that the poultry ingredients in such products are not adulterated and that such products are not represented as poultry products'' (21 U.S.C. 451(f)).

The PPIA permits the Secretary to conduct an ante-mortem inspection of every live animal before slaughter. Specifically, the statute provides: ''For the purpose of preventing the entry into or flow or movement in commerce of, or the burdening of commerce by, any poultry product which is capable of use as human food *and is adulterated,* the Secretary shall, where and to the extent considered by him necessary, cause to be made by inspectors ante-mortem inspection of poultry . . .'' (21 U.S.C. 455(a)) (emphasis added). Like the FMIA, the PPIA contemplates an inspection of live animals in order to exclude animals from the slaughter process that could result in the production of adulterated product. The PPIA also requires the Secretary to conduct a post-mortem inspection of every carcass and to inspect processed products as the Secretary deems necessary (21 U.S.C. 455(b)): ''The Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors post-mortem inspection of the carcass of each bird processed, and at any time such quarantine, segregation and reinspection as he deems necessary of poultry and poultry products capable of use as human food in each official establishment processing such poultry or poultry products for commerce or otherwise subject to inspection under this Act'' (21 U.S.C. 455(b)). Further, ''[a]ll poultry carcasses and parts thereof and other poultry products *found to be adulterated* shall be condemned and shall, if no appeal be taken from such determination of condemnation, be destroyed for human food purposes under the supervision of an inspector; *Provided,* That carcasses, parts, and products, which may by reprocessing be made not adulterated, need not be so condemned and destroyed if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated'' (21 U.S.C. 455(c)) (emphasis added).

Both the FMIA and PPIA contain definitions of the term ''adulterated'' (21 U.S.C. 601(m) and 453(g), respectively) that describe a number of conditions that may render meat or poultry to be injurious to human health, otherwise cause meat or poultry to be unfit for human food, or make a meat or poultry product appear better or of greater value than it is. As previously noted, meat, meat food products, poultry, and poultry products cannot be sold or distributed in commerce for use in human food until an inspector makes an affirmative determination that the product is not adulterated. Both statutes also define ''misbranded'' as several types of product labeling or representation of a meat or poultry product that are false or misleading (21 U.S.C. 453(h) and 601(n)). Under the approach contemplated in this document, USDA would conduct a pre-slaughter food safety assessment utilizing the ante-mortem and adulteration provisions of the FMIA and PPIA cited above to ensure that an animal of the amenable species modified or developed using genetic engineering would not result in a product that is adulterated or misbranded.

An issue to be addressed would be the timing of the pre-slaughter food safety assessment for animals modified or developed using genetic engineering. As discussed above, both statutes provide for ante-mortem inspection of live animals in order to prevent adulterated product from being sold or distributed in commerce (21 U.S.C. 455(a), 603(a)). Neither statute specifies how far in advance examinations or reviews relative to this inspection can occur. Thus, on their face, these statutes would appear to authorize USDA to

promulgate a regulation requiring a food safety review of animals of amenable species modified or developed using genetic engineering before arrival at the slaughter facility in order to ensure that the meat or poultry derived from such animals would not be adulterated under the FMIA and PPIA.

Such a conclusion would appear to be consistent with the text of these statutory provisions and the purposes that the statutory text was enacted to further. Providing for review before arrival at the slaughter facility would further the purposes of the provisions of the FMIA and the PPIA that provide for ante-mortem inspection of live animals and, more generally, of the inspection regimes established by the FMIA and the PPIA. Historically, inspectors assigned to work in slaughtering and processing facilities have used a variety of tools, including sensory examination and available laboratory testing, to determine whether meat or poultry products are adulterated within the meaning of the statutes at the time of slaughter or processing. Because certain laboratory tests can take days to finalize, the inspectors require sampled carcasses and products to be held at the establishment until the laboratory tests are completed. For animals of the amenable species modified or developed using genetic engineering, however, a FSIS inspector would likely be unable to make an ''on the spot'' determination about whether the live animal should be segregated, or whether the meat or poultry product is adulterated at the time the animal is presented for inspection at the slaughter facility using currently available testing methodologies and inspection techniques. Live animals of the amenable species modified or developed using genetic engineering and their carcasses typically will not be distinguishable from conventionally produced animals based on their physical appearance. Also, there currently is no generally applicable test that could be administered in the slaughter facility to determine whether the animal was modified or developed using genetic engineering or whether the genetic modification would render the resulting meat or poultry product adulterated within the meaning of the statutes. Therefore, as a practical matter, unless there is a pre-slaughter (or pre-market) safety review, FSIS inspectors would be unable to determine that meat or poultry products derived from animals modified or developed using genetic engineering are not adulterated. By operation of the statutes and regulations, such a product would be precluded from being marked as ''Inspected and Passed,'' and thus could not be sold or distributed in commerce for human food, until a food safety assessment was completed and the meat was determined to not be adulterated.

FSIS Review

For the food safety assessment, FSIS would evaluate the scientific data submitted by the developer to ensure that the animal of amenable species modified or developed using genetic engineering would not result in products that are adulterated as defined under the Acts. FSIS would also examine whether genetic engineering may result in meat and poultry products being misbranded, *i.e.,* labeled in a false or misleading manner, which is prohibited by both the FMIA and PPIA. At a minimum, the FSIS assessment would include an evaluation of the following issues:

- *Evaluation of expressed substances:* Is there scientific evidence that the genetic modification could result, directly or indirectly, in toxins, chemical residues, or other potentially deleterious substances in meat or poultry products?
- *Allergenicity:* Is there scientific evidence that the genetic modification would directly or indirectly alter the allergenic potential of meat or poultry products derived from the animal?
- *Food storage and processing:* Is there scientific evidence that meat or poultry products derived from the modified animal could mislead consumers regarding wholesomeness or the need for appropriate storage (*e.g.,* meat that maintains a red appearance even when spoiled)?
- *Compositional analyses of key components:* Is there scientific evidence that meat or poultry products from the modified animal are compositionally (*e.g.,* nutritionally or functionally) no different than meat from conventional animals, such that it meets any regulatory definition, standard of identity or other labeling requirement, and consumer expectations for the applicable product?

Request for Comments

We are soliciting public comments on all aspects of this document, including the contemplated regulatory framework as described herein, with particular attention on the following questions:

Scope of Regulations and Review

- The contemplated regulatory framework would apply to animals of the ''amenable species'' (cattle, sheep, goats, swine, horses, mules, other equines, fish of the order Siluriformes, chickens, turkeys, ducks, geese, guineas, ratites, and squabs) modified or developed using genetic engineering that are ''intended for agricultural purposes'' such as human or animal food, fiber, and labor. What are the agricultural uses for ''amenable species'' other than use as human or animal food? Should the contemplated regulatory framework define ''agricultural purposes other than food''? If so, how should it be defined?
- Is the safety review process described above (see ''Contemplated Regulatory Framework'') appropriate to protect human health, including for both human consumption and disease transmission? Why or why not?
- Is the safety review process described above (see ''Contemplated Regulatory Framework'') appropriate to protect livestock health of both the target animal and its herd or flock? Why or why not?
- Are there types of modifications that should make an animal of an amenable species modified or developed using genetic engineering eligible or ineligible for the expedited safety review process outlined above?
- How should USDA define ''off-target changes'' for the purposes of expedited review of animals in which modifications already known to occur in the gene pool of the species are made without the insertion of DNA?
- Should USDA exempt certain types of genetic modifications of amenable species intended for agricultural use from regulation? If so, what types of modifications and why?
- Which types of genetic modifications should not be exempted from regulation? Why?
- Should any entities or activities be exempt from regulation? If so, what types of entities and why? If not, why not?
- Are there any statutory or regulatory constraints and/or advantages that need to be considered?

Risk Assessment Process

- How should USDA assess risks to animal health? Which pest or disease risks should be considered? Should any other adverse effects (*e.g.,* specific adverse effects on the biology of the animal modified or developed using genetic engineering) be considered? Please be specific and include examples when possible.
- Under what circumstances would a controlled animal safety study be needed versus general surveillance over the health of the herd?
- What information, beyond that described in the ''Contemplated Regulatory Framework'' section of the

document, would USDA need to consider in order to properly review and assess risks associated with amenable species modified or developed using genetic engineering that are intended for agricultural purposes? Are there limitations to the types of information that could be gathered or technologies that could be used to inform the evaluation of animal health claims? If so, please describe the limitations.

- What is the minimal information would need to consider to evaluate animal disease claims made for the animals of the amenable species modified or developed using genetic engineering? What are the limitations of current technologies that exist to evaluate animal disease claims?
- What other animal health claims, aside from disease resistance, should USDA require developers to validate? Why?
- Under the current proposal, USDA is not performing a post-market evaluation of animal health. Should USDA require developers to submit information in order to monitor risks to animal health post-market? Why?
- Are there any gaps in the contemplated framework with respect to animal and human health, and if so, how might they be addressed?

Regulatory Authority and Framework

- Does the contemplated regulatory framework provide adequate scope and flexibility to regulate current and future advances in agricultural animals developed using genetic engineering?
- What, if any, terms related to the regulation of animals of the amenable species modified or developed using genetic engineering would need to be defined under the contemplated regulatory framework?
- Should animals of the amenable species modified or developed using genetic engineering with multiple uses (such as an amenable species modified or developed using genetic engineering and intended for both biomedical/pharmaceutical purposes and agricultural purposes) receive any different treatment than other amenable species during USDA's review processes? What steps should USDA take to ensure efficient review of these products? What steps should USDA take to account for existing regulatory burden when a product must be reviewed both by USDA and by another agency?
- Do you have any other specific concerns or recommendations for appropriately reducing regulatory burdens involving the regulation of amenable species modified or developed using genetic engineering by USDA as described in this document?

Genetic Engineering and Conventional Breeding

- What are the known current limits of conventional breeding in animals in terms of generating and/or selecting for a specific trait, or multiple traits?
- What problems are entities currently attempting to solve using animals modified or developed using genetic engineering?

FSIS Assessment

- Would the pre-slaughter assessment ever require physical examination or testing by FSIS of amenable species modified or developed using genetic engineering, specifically examination or testing in regard to their genetic modifications, prior to arrival at the slaughter facility? If so, under what circumstances?
- What documentation, if any, should accompany amenable species modified or developed using genetic engineering destined for slaughter, certifying that their modifications have been assessed by USDA (APHIS and FSIS)?

Economic Considerations

- What classes of entities are currently engaged in the modification, production, breeding, distribution, commercialization or any related activities involving animals modified or developed using genetic engineering? How many of these entities fall within or below the threshold for ''small entity'' size standards according to the Small Business Administration?
- What markets are there where animals for agricultural use modified or developed using genetic engineering have been produced and commercialized? What challenges and opportunities (regulatory, economic, or otherwise) have been encountered by the relevant authorities?
- How often does a start-up company or not-for-profit university or research organization modify or develop an animal using genetic engineering?
- Could the contemplated regulatory framework have adverse impacts on international trade (imports or exports)? If so, what?
- Should USDA assess user fees in connection with conducting reviews for animals modified or developed using genetic engineering? If so, how should USDA structure the fees? What factors should USDA consider in assessing fees?

We welcome all comments on the questions outlined above and on all aspects of this document.

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 18th day of December 2020.

Lorren Walker,

Acting Under Secretary for Marketing and Regulatory Programs.

Paul Kiecker,

Administrator, Food Safety and Inspection Service.

[FR Doc. 2020–28534 Filed 12–23–20; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1165; Project Identifier 2019–SW–027–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus Helicopters Model SA341G and SA342J helicopters. This proposed AD was prompted by the determination that a new life limit was necessary for certain tail rotor blades (TRBs). This proposed AD would require replacing certain TRBs, re-identifying certain TRBs, and repairing certain other TRBs, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by February 11, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.