



MEMORANDUM OF UNDERSTANDING

Between the

UNITED STATES DEPARTMENT OF AGRICULTURE

and the

FOOD AND DRUG ADMINISTRATION,

DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. PURPOSE

This agreement reflects the understanding between the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA) (collectively, the "agencies") regarding responsibilities concerning the regulation of "amenable species" ¹ developed using genetic engineering that are intended for agricultural purposes (i.e., human food, fiber, and labor) (hereinafter in this MOU referred to as "agricultural amenable species developed using genetic engineering").

II. BACKGROUND

On June 11, 2019, President Trump signed an Executive Order on "Modernizing the Regulatory Framework for Agricultural Biotechnology Products." This Executive Order calls for, among other things, regulatory streamlining in order to facilitate the innovation of agricultural biotechnology to the market efficiently, consistently, and safely under a predictable, consistent, transparent, and science-based regulatory framework.

Agricultural biotechnology holds tremendous potential to improve animal health, enhance farm productivity, improve nutrition, and even reduce the need for some animal health measures. USDA and FDA are committed to working together to foster safe use of this promising technology and encourage innovation.

III. SUBSTANCE OF AGREEMENT: The agencies mutually agree on the following:

- A. USDA will use its Animal Health Protection Act (AHPA) authority to build a new program through rulemaking for the pre-market evaluation of agriculture amenable species developed using genetic engineering that are moved in interstate commerce.
- B. FDA will immediately implement a streamlined, risk-base approach to oversight of intentional genomic alterations in animals. FDA and USDA will work on a communication plan to explain FDA's involvement with agriculture amenable species developed using genetic engineering.

¹ "Amenable species" include animals subject to the Federal Meat Inspection Act (21 U.S.C. 601, *et seq.*) (cattle, sheep, swine, goats, horses, mules, or other equines, and fish of the order Siluriformes), and animals subject to the Poultry Products Inspection Act (21 U.S.C. 451, *et seq.*) (chickens, turkeys, ducks, geese, guineas, ratites, and squabs).

- C. USDA will use its Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) authorities to establish a new program through rulemaking to conduct pre-market human food safety evaluations and monitoring for agriculture amenable species developed using genetic engineering, and will continue to use its FMIA and PPIA authorities to conduct post-market human food safety monitoring of amenable species.

FDA will continue to use its Federal Food, Drug and Cosmetic Act authority to regulate dairy products, table and shell eggs, certain meat products, and animal food (feed) derived from agriculture amenable species developed using genetic engineering.

- D. FDA will preserve its independent review of intentional genomic alterations intended for any purpose other than agricultural use including but not limited to biopharma (other than veterinary biologics) and non-heritable genomic alteration (e.g., gene therapies). If any such amenable species are intended to enter the human food supply, FDA will consult with USDA on the food safety review to promote consistent food safety reviews and monitoring for all amenable species intended for human food as part of USDA's new program.
- E. USDA will establish a review process, in consultation with FDA, for agriculture amenable species developed using genetic engineering.
 - 1. USDA will use its rulemaking authorities in the AHPA, FMIA, and PPIA, to develop a regulatory framework that covers the pre-market and post-market evaluation and monitoring of agriculture amenable species developed using genetic engineering, consistent with other terms in this MOU.
 - 2. With respect to USDA's rulemaking to establish the USDA framework for reviewing agriculture amenable species developed using genetic engineering, USDA will consult with FDA by providing FDA with advanced copies of such documents for review, as follows: FDA will have 15 calendar days to review and comment on the regulatory documents; USDA will have 7 calendar days to review and respond to FDA's feedback; and, FDA will have 7 calendar days to review USDA's response and provide any further feedback it wishes to offer. Following this preview, FDA will continue to participate in the interagency review process for the rulemaking and may use such process to provide any addition feedback, if necessary.
 - 3. Simultaneously with (though separate from) the development of the rulemaking, USDA and FDA will collaborate and agree upon the areas of concern that USDA and FDA will jointly evaluate as part of USDA's review, should an agriculture amenable species developed using genetic engineering present a concern (1) related to human health, and/or (2) related to an animal health or food safety matter that impacts human health, which is not otherwise covered by USDA's review process. USDA and FDA will then memorialize the areas of concern that USDA and FDA will jointly evaluate, will include such list as an attachment to this MOU, and will review it in accordance with the review frequency for this MOU.
- F. After the completion of the rulemaking process, the new review process will include following:

1. FDA will exercise enforcement discretion over investigational and approval requirements for intentional genomic alterations developed using genetic engineering in agricultural amenable species that are under active USDA review or have been reviewed by USDA except when FDA will review alterations consistent with the terms of this MOU.
 2. USDA will serve as the single point of entry and gateway for agriculture amenable species developed using genetic engineering and will provide end-to-end regulatory oversight, from pre-market reviews, through post-market human food safety monitoring.
 3. Stakeholders will be directed to submit information to USDA.
 4. For agriculture amenable species developed using genetic engineering, USDA will seek FDA's consultation, as necessary, to determine if intentional genomic alterations in such species fall into a category that present a concern, as described in section III (E) of this MOU.
 5. When USDA receives a submission concerning an amenable species developed using genetic engineering that is intended for agriculture purposes for review that presents a concern in one of the agreed upon areas, USDA will request that FDA jointly evaluate the area of concern as part of the USDA review. With respect to the agreed upon areas of concern and as part of USDA's review of the agriculture amenable species developed using genetic engineering, the USDA and FDA joint evaluation will include: (1) evaluation of the FDA area of concern, (2) development of the portion of the risk assessment that relates to the FDA area of concern, and (3) following the publication of information in the *Federal Register* (including, for example, the risk assessment), review and response to public comments related to the FDA concern. USDA will base the regulatory decision on the overall record of scientific evidence and information gathered during USDA's review of the agriculture amenable species developed using genetic engineering, including FDA's joint evaluation when provided.
 6. Any such joint evaluation must occur and be completed within the regulatory timeframes as applicable.
- G. The agencies will maintain collaborative working relationships facilitated by periodic meetings between appropriate USDA and FDA personnel, for purposes such as planning, coordination, evaluation, and review. The agencies agree to abide by agreed upon timeframes and to work in good faith in implementing the terms of this MOU.
- H. The agencies will share information with each other as authorized by law and as appropriate for carrying out the respective responsibilities of the parties.

IV. Limitations

This agreement does not affect or supersede any existing agreements or arrangements between the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements

related to this agreement. This agreement and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which HHS-FDA and USDA operate. Nothing in this MOU shall be construed to limit the statutory authority of USDA or HHS-FDA.

All activities undertaken pursuant to the agreement are subject to the availability of personnel, resources, and funds.

Either agency will immediately notify the other agency if it is unable to carry out any or all of its responsibilities under this MOU.

V. AGENCY LIAISONS

To facilitate the activities carried out under this agreement, each agency will establish a single agency liaison. The initial liaisons will be:

For USDA:

Bernadette Juarez, Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Email : bernadette.r.juarez@usda.gov

For FDA:

VI. EFFECTIVE DATE, TERMINATION, AND MODIFICATION

This agreement will become effective when signed by both parties and made publicly available on the USDA and FDA websites. This agreement may be modified by mutual written consent by the parties at any time and may be terminated by mutual written consent by the parties no sooner than 3 years following the latest date upon which this MOU is signed or anytime thereafter. The agencies agree that they will review this agreement every three years to determine whether it should be modified.

Approved and Accepted for
the U.S. Department of Health and Human Services

Approved and Accepted for
the U.S. Department of Agriculture

Signed by:
ADM Brett Giroir, M.D.
Assistant Secretary for Health
Head of the Public Health Service



Date:
1/13/2021

Signed by:



Date: January 13, 2021