



## DEPARTMENT OF AGRICULTURE

### Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

### Animal Plant and Health Inspection Service

*Title:* Unified website for Biotechnology Regulation; Contact Page.

*OMB Control Number:* 0579-NEW.

*Summary:* In 1986, the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) was published by the Office of Science and Technology Policy and explained the regulatory roles for the U.S. Department of Agriculture, the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA), (herein, the Agencies) 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 (57 FR 6753-6762; February 27, 1992) and 2017, taking into account advances that had occurred in the field of biotechnology.

Within the USDA, the Animal and Plant Health Inspection Service's (APHIS') Biotechnology Regulatory Services unit is responsible for ensuring that organisms developed using genetic engineering, such as genetically modified plants, insects, and microbes do not pose a plant pest risk. APHIS derives its authority to promulgate its biotechnology regulations from provisions of the Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) and the Virus-Serum-Toxin Act (VRTA, 21 U.S.C. 151-159). The EPA is charged with protecting human health and the environment through ensuring the safety of pesticides and other chemicals, including those developed using genetic engineering. The EPA derives its regulatory authority from provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, 7 U.S.C. 136 *et seq.*) and the Toxic Substances Control Act (TSCA, 15 U.S.C. 2601 *et seq.*). The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation, which includes oversight of food and feed. FDA derives its regulatory authority from provisions of the Federal Food, Drug and Cosmetic Act (FFDCA, 21 U.S.C. 301-392). Together with the USDA's Food Safety and Inspection Service (FSIS), FDA has oversight of certain chemicals modified using genetic engineering. FSIS

derives its regulatory authority from the Federal Meat Inspection Act (FMIA, 21 U.S.C. 601 *et seq.*) and the Poultry Products Protection Act (PPIA, 21 U.S.C. ch.10, 451 *et seq.*).

On September 12, 2022, Executive Order (E.O.) 14081, *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*, was published and directed the Agencies, among other things, to build on the Unified website for Biotechnology Regulation developed pursuant to E.O. 13874, *Modernizing the Regulatory Framework for Agricultural Biotechnology Products*, June 11, 2019, by including on the website the information developed under subsection (b) of section 8 of E.O. 14081, and by enabling developers of biotechnology products to submit inquiries about a particular product and promptly receive a single, coordinated response that provides, to the extent practicable, information and, when appropriate, informal guidance regarding the process that the developers must follow for Federal regulatory review.

*Need and Use of Information:* The necessity for this information collection arises from E.O. 13874, Section 5, *Unified Biotechnology Web-Based Platform*, and E.O. 14081, Section 8(d).

These provisions seek to ensure that innovators can easily navigate the Federal regulatory system for products of biotechnology by directing USDA, EPA, and FDA to jointly establish a web-based platform that contains and provides links to relevant United States Government regulatory information for biotechnology products. USDA-APHIS, EPA, and FDA will use a web-form on the contact page of the Unified website to enable site visitors to ask questions, make comments, or request a meeting with one or all of the sponsoring agencies. The web-form will collect basic contact information such as the name and email address of contact page respondents, as well as the respondents' questions or comments and their meeting requests. Respondent use of the contact page is voluntary.

*Description of Respondents:* Business

*Number of Respondents:* 30

*Frequency of Responses:* Reporting: On occasion; Annual

*Total Burden Hours: 15*

**Rachelle Ragland-Greene,**  
*Departmental Information Collection Clearance Officer.*

\* Billing Code 3410-34

[FR Doc. 2024-28350 Filed: 12/2/2024 8:45 am; Publication Date: 12/3/2024]