UNITED STATES FOOD & DRUG ADMINISTRATOIN

New Plant Varieties Intended for Food Use

OMB Control No. 0910-0583 - Extension

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of recommendations found in Food and Drug Administration (FDA, agency, or we) guidance pertaining to new plant varieties intended for food use. The information collections involve FDA's procedures for early food safety evaluation and consultations for new plant varieties intended for food use, including biotechnology-derived food plants.

A. *Consultation Procedures: Foods Derived from New Plant Varieties; Form FDA 3665*

The FDA guidance document entitled "Consultation Procedures under FDA's 1992 Statement of Policy: Foods Derived from New Plant Varieties," (October 1997), which is available on our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-consultation-procedures-under-fdas-1992-statement-policy-foods-derived-new-plant, describes our consultation process for the evaluation of information on new plant varieties provided by developers. We believe this consultation process will help ensure that human and animal food safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution. Additionally, such communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development and will help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the standards of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Since 1992, when we issued our "Statement of Policy: Foods Derived from New Plant Varieties" (the 1992 policy) (57 FR 22984; May 29, 1992), we have encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA during the plant development process to discuss possible scientific and regulatory issues that might arise. In the 1992 policy, we explained that under the FD&C Act developers of new foods (in this document "food" refers to both human and animal food) have a responsibility to ensure that the foods they offer to consumers are safe and in compliance with all requirements of the FD&C Act (57 FR at 22985). To initiate a New Plant Variety consultation (also known as a Biotechnology Notification File (BNF)), developers are encouraged to electronically submit their scientific information and data following a step-by-step process to complete Form FDA 3665, assemble their notification, and send fully electronic submissions to FDA via an online submission module (also known as COSM), which may be accessed at https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm. Firms that prefer to submit a paper notification in a format of their choosing or as electronic files on physical media

with a paper signature page, have the option to do so; however, Form FDA 3665 prompts a notifier to input the elements of a BNF in a standard format that we will be able to review efficiently. Form FDA 3665 may be accessed at https://www.fda.gov/about-fda/reports-manuals-forms/forms.

B. *Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Form FDA 3666*

Since we issued the 1992 policy on foods derived from new plant varieties, including those varieties that are developed through biotechnology, we have encouraged developers of new plant varieties to consult with us early in the development process to discuss possible scientific and regulatory issues that might arise. The guidance entitled "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use" (June 2006), which is available on our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-early-food-safety-evaluation-new-non-pesticidal-proteins-produced, continues to foster early communication by encouraging developers to submit to us their evaluation of the food safety of their new proteins. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of the new protein.

To initiate an Early Food Safety Evaluation consultation (also known as a New Protein Consultation (NPC)), developers are encouraged to electronically submit their scientific information and data following a step-by-step process to complete Form FDA 3666, assemble their notification, and send fully electronic submissions to FDA via COSM, which may be accessed at https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm. Firms that prefer to submit a paper NPC in a format of their choosing or as electronic files on physical media with a paper signature page, have the option to do so; however, Form FDA 3666 prompts a notifier to input the elements of an NPC in a standard format that we will be able to review efficiently. Form FDA 3666 may be accessed at https://www.fda.gov/about-fda/reports-manuals-forms/forms.

2. Purpose and Use of the Information Collection

The purpose of the information collection is to provide consultations to developers, businesses, and not-for-profit businesses and institutions. FDA reviews NPCs and BNFs to ensure that foods are safe, wholesome, sanitary, and properly labeled, in accordance with statutory requirements. Under these consultation procedures, any person who is responsible for the development, distribution, importation, or sale of a food derived from a new plant variety may voluntarily consult with us and eventually submit summary safety and nutritional analysis which would form the basis of an NPC or BNF. Based on our experience, we expect that ordinarily it will be plant developers and purveyors who notify the agency about food derived from new plant varieties developed through the use of biotechnology.

Under the consultation procedures, a notifier submits an initial request for consultation to FDA via the Office of Food Chemical Safety, Dietary Supplements and Innovation (OFCSDSI). Subsequently, after a consultation has been initiated, the developer submits a summary of its

safety and nutritional assessment in support of its product (final consultation). OFCSDSI receives the requests for final consultation and shares all NPC and BNF submissions with FDA's Center for Veterinary Medicine (CVM). Thus, we have a single point of contact for industry. Depending on the plant and how it will be used as food for humans or animals, either OFCSDSI or CVM may take a leadership role in the consultation. CVM reviews all submissions with animal food uses, and OFCSDSI reviews all submissions with human food uses. Most submissions have both human and animal food uses. Files are established and records are maintained by OFCSDSI. After reviewing this submission, we may, as needed, request information to clarify particular points in the submission. When we have no further questions about the safety or regulatory status of food from the new plant variety, we send a letter to that effect to the developer and the consultation is complete.

Description of Respondents: Respondents to the collection of information are developers of new plant varieties intended for food (including food for humans and food for animals) use.

3. Use of Improved Information Technology and Burden Reduction

Forms FDA 3665 (for BNF submissions) and FDA 3666 (for NPC submissions), and elements prepared as attachments, may be submitted in electronic format via COSM, or may be submitted in paper format, or as electronic files on physical media with paper signature page. We estimate that all BNFs and NPCs (100%) will be submitted electronically.

We encourage use of COSM as it is a web-based portal that will save submitters time by walking them step-by-step through the information assembly and submission process. Use of COSM will facilitate FDA's review of the submission and will allow the submitter to access real-time status updates.

4. Efforts to Identify Duplication and Use of Similar Information

FDA continues to work with the U.S. Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA) to eliminate areas of duplicate data collection and evaluation. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.), EPA has authority to regulate all pesticides, regardless of how they are made or their mode of action. FDA's NPC applies to non-pesticidal proteins and is not duplicative of EPA responsibilities. Meanwhile, many plants developed using recombinant DNA (rDNA) technology are considered "regulated articles" under regulations of USDA's Animal and Plant Health Inspection Service (APHIS) (7 CFR part 340), which uses its authority over plant pests to regulate the movement and environmental introduction of certain plant varieties. In contrast, FDA requests a submission of data and information concerning the food safety related to a specific new protein or food produced by a new plant variety. Therefore, although a submission to APHIS would include some information, such as the name of the company and the identity of the protein, which would be included in the information requested by FDA in an NPC or a BNF, the submission is not duplicative.

5. Impact on Small Businesses or Other Small Entities

We estimate five percent (5%) of respondents are small businesses. We believe the consultation procedures for BNFs and NPCs minimize the reporting burden on all businesses, including small businesses, by providing that the developer submits a summary of data and information, rather than the data and information itself. We estimate no burden to respondents for developing the data and information that underlie the new protein evaluation regarding this activity as usual and customary to those engaged in the development of these products. At the same time, we assist small businesses in complying with FD&C Act requirements through Regional Small Business Representatives within the agency. Additional assistance is available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally as developers wish to participate in these processes.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of March 12, 2024 (89 FR 17854). Seventeen comments were received. The majority of the comments indicated that the information collected was necessary and had practical utility which allows FDA to make decisions regarding food safety and protection of the public's health. Some of the comments also indicated that the use of automation such as electronic forms made the process of submitting information much quicker and smoother for the respondent. Two comments received were not related to the PRA and will not be addressed here.

9. Explanation of Any Payment or Gift to Respondents

No gifts or payments are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This information collection request (ICR) collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3665 (Final Consultation for Food Derived from a New Plant Variety (Biotechnology Final Consultation)) and Form FDA 3666 (Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation)) is point of contact name, business address, business phone number, business fax number, and business email address. We have determined that although PII

is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This information collection does not ask questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden[1]

Agency Guidance Recommendations; Information Collection	Form FDA No.	No. of Responses	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Consultation Procedures: Foods Derived from New Plant Varieties						
Initial consultation	None	30	2	60	4	240
Final consultation	3665	12	1	12	150	1,800
Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use						
Six data components	3666	6	1	6	20	120
Total				78		2,160

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made minor adjustments to update our burden estimate to reflect recent annual response rates (increased initial consultations under the New Plant Variety consultation procedures) and to clarify the total number of responses under the Early Food Safety Evaluation procedures.

12b. Annualized Cost Burden Estimate

Gathering information for the consultations and then providing it to the agency requires a team of employees, which may include toxicologists, chemists, and lawyers. We assume an average hourly wage for these employees to be equivalent to a GS-14/Step-1 in the locality pay area of Washington-Baltimore in 2024, approximately $66.79/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $133.58/hour. Thus, the overall estimated cost incurred by the respondents is $288,532.80 (2,160 burden hours x $133.58/hour).

Table 2.--Estimated Annual Cost Burden			
Category	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Consultation Procedures: Foods Derived from New Plant Varieties			
Initial Consultation	240	$133.58	$32,059.20
Final Consultation	1,800	$133.58	$240,444.00
Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use			
Six data components	120	$133.58	$16,029.60
Total			$288,532.80

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

We assume staffing burden for review of an NPC to be 80 hours per submission and assume costs for 6 NPCs annually. Using the total of 480 hours, we estimate the annual cost for Consultation Procedures by multiplying this figure by $62.17/hour, the GS-13/Step-4 rate for the Washington-Baltimore locality pay area for the year 2024 (480 hours x $62.17/hour = $29,841.60.) To account for overhead, this cost is increased by 100%, for a total of $59,683.20.

Regarding BNF reviews, we estimate that OFCSDSI allocates four (4) full-time equivalent positions (FTEs) for the review of the submission for human food safety, and that CVM will allocate two (2) FTEs for the review of the submission for animal food safety. Based on an average cost of $129.759 per fully supported position and six (6) dedicated positions for review (4 for OFCSDSI and 2 for CVM), the cost of processing BNF consultations would be $778,554 annually. Together this reflects an annual cost of $838,237.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made minor adjustments to update our burden estimate to reflect recent annual response rates (increased initial consultations under the New Plant Variety consultation procedures by 20 responses, which resulted in an additional 80 burden hours) and to clarify the total number of responses under the Early Food Safety Evaluation procedures.

We have also made minor modifications to the associated forms and their instructions to reflect the change from the Electronic Submission Gateway to the COSM online submission module. Another minor change to the forms and instructions involves the FDA re-organization which will change the Office of Food Additive Safety – Center for Food Safety and Applied Nutrition to OFCSDSI – Human Food Program. Neither of these changes affects the burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

Upon the completion of a BNF consultation, we publish on our website a copy of the agency response to the submitter as well as scientific memoranda. An inventory of completed

consultations can be seen at https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=NewPlantVarietyConsultations. Upon completion of an NPC, we publish a redacted copy of the NPC and an electronic version of the agency response to the submitter on our website at https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=NewProteinConsultations.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with these guidance documents and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance documents' cover page and include a link to https://www.reginfo.gov/public/do/PRAMain to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.