UNITED STATES FOOD & DRUG ADMINISTRATION

New Plant Varieties Intended for Food Use

OMB Control No. 0910-0583 – Revision

SUPPORTING STATEMENT – **Part A. Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports recommendations found in Food and Drug Administration ("FDA, the agency, us or we") guidance pertaining to new plant varieties intended for food use. Respondents to the collection of information are developers of new plant varieties intended for food use.

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

The guidance document entitled "*Guidance on Consultation Procedures: Foods Derived From New Plant Varieties,"* (October 1997) available on our website at https://www.fda.gov/FoodGuidances, 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 FDA issued its "*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 22984 at 22985). Respondents may use Form FDA 3665, submitted via the Electronic Submissions Gateway (https://www.fda.gov/industry/electronic-submissions-gateway), to request consultation.

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

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) (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. We believe that any food

safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. The guidance describes the procedures for early food safety evaluation of new proteins produced by new plant varieties, including bioengineered food plants, and the procedures for communicating with us about the safety evaluation.

Interested persons may use Form FDA 3666 for submissions to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition (CFSAN). Form FDA 3666 is entitled "*Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation)"* and may be used in lieu of a cover letter for a New Protein Consultation (NPC). The form may be accessed at FDA's web page for forms (https://www.fda.gov/about-fda/reports-manuals-forms/forms) using the search term "3666." To enable field-fillable functionality of FDA forms, they must be downloaded. Form FDA 3666 prompts a submitter to include certain elements of an NPC in a standard format and helps the respondent organize their submission to focus on the information needed for our safety review. The form, and elements prepared as attachments to the form, may be completed using the CFSAN Online Submission Module (https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm); via the Electronic Submissions Gateway (https://www.fda.gov/industry/electronic-submissions-gateway); in paper format; or as electronic files on physical media with paper signature page.

For efficiency of agency operations we are revising the information collection to include the topic-related guidance documents. We therefore request OMB approval for the information collection applicable to the guidance documents and associated forms (Forms FDA 3665 and FDA 3666) as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of the information collection is to provide consultation to developers, businesses, and not-for-profit businesses and institutions. FDA reviews NPCs to ensure that foods are safe, wholesome, sanitary, and properly labeled, in accordance with statutory requirements. Under the 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 a biotechnology notification file (BNF). Based on our experience, we expect that ordinarily it will be seed 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 through our Center for Food Safety and Applied Nutrition (CFSAN). 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). CFSAN receives the requests for final consultation and shares all 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 CFSAN or CVM may take a leadership role in the consultation. CVM reviews all notifications with animal food uses. CFSAN reviews all notifications with human food uses. Most

notifications have both human and animal food uses. Files are established and records are maintained by CFSAN. After reviewing this submission, we may, as needed, request information to clarify particular points. When we have no further questions about the safety or regulatory status of the new plant variety, we send a letter to that effect to the developer and the consultation is completed.

3. Use of Improved Information Technology and Burden Reduction

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

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 with 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 regulates the introduction of certain "genetically engineered" plants into the environment. A developer must obtain authorization from APHIS to field test such crops and, depending on the nature of the crop, a developer files either a permit application or a notification. In contrast, FDA requests a submission of data and information concerning the food safety of a specific new protein produced in 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 a NPC, the submission is not duplicative.

5. Impact on Small Businesses or Other Small Entities

We estimate five percent (40%) of respondents are small businesses. We believe our NPC minimizes 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. In addition, we provide small business resources on our website at www.fda.gov.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally.

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 the *Federal Register* of November 23, 2020 (85 FR 74734), we published a 60-day notice requesting public comment on information collection associated with the guidance document "*Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use*." No comments were received.

In the *Federal Register* of March 4, 2021 (86 FR 12688), we published a 60-day notice requesting public comment on information collection associated with the guidance document "*Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use*." No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No gifts or payments are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII) or other data of a personal nature, it is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3665, FDA Final Consultation for Food Derived from A New Plant Variety (Biotechnology Final Consultation) is name, work email address, work position, work telephone numbers, and work fax telephone number for the primary contact at a business. We further 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 Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected.

FDA believes that, in most cases, neither the existence of a NPC, nor most or all of its content, would satisfy the criteria for exemption from disclosure. However, information submitted to FDA in a NPC may contain trade secret and commercial confidential information. As a result, all files are maintained in a secured area. Form FDA 3666, its instructions, and related guidance, provide instructions for assisting FDA with protecting confidential information. A submitter may choose to provide a redacted copy of the NPC, identifying that information that the submitter views as trade secret or as confidential commercial or financial information. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

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	20	2	40	4	160
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						
First four data components	3666	6	1	6	4	24
Two other data components	3666	6	1	6	16	96
TOTAL				64		2,080

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

12b. Annualized Cost Burden Estimate

A. Consultation Procedures: Foods Derived From New Plant Varieties

Gathering the information for the NPC and 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 equivalent to a GS-14/Step-1 in the locality pay area of Washington-Baltimore in 2018, approximately $54.91/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $109.82/hour. Thus, the overall estimated cost incurred by the respondents is $13,178 (120 burden hours x $109.82/hour = $13,178.40, rounded to $13,178). In addition, while FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure (PKI) certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 to 3 years. The certificate typically costs from $20-$30.

Table 2 – Burden Costs			
Category	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
First four data components	24	$109.82	$2,635.68
Nurses	96	$109.82	$10,542.72
Total			$13,178.40

B. Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

Gathering the information discussed here and providing it to the agency may be done by a professional employee such as a scientist. We estimate that the average hourly wage for this employee would be equivalent to a GS-14/Step-1 level in the locality pay area of Washington-Baltimore in 2021, approximately $58.71/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $117.42/hour. The overall estimated cost incurred by the respondents is $230,143.20 (1,960 burden hours x $117.42/hr). In addition, while we do not charge for the use of the ESG, we require respondents to obtain a public key infrastructure (PKI) certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 to 3 years. The certificate typically costs from $20-$30.

Table 2.--Annual Cost Burden Estimate

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Initial Consultation	160	$117.42	$18,787.20
Final Consultation	1,800	$117.42	$211,356.00
Total			$230,143.20

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 estimates the annual cost for Consultation Procedures by multiplying this figure by $60.40/hour, the GS-13/Step-10 rate for the Washington- Baltimore locality pay area for the year 2018 (480 hours x $60.40/hour = $28,992. To account for overhead, this cost is increased by 100%, for a total of $57,984. Regarding Early Evaluations we estimate that CFSAN allocates four (4) full time equivalent positions (FTEs) for the review of notification procedure for human foods, and that CVM will allocate two (2) FTEs for the review of notification procedure for animal food. Based on an average cost of $110,000 per fully supported position and six (6) dedicated positions for review (4 for CFSAN, 2 for CVM), the cost of processing consultations would be $660,000 annually. Together this reflects an annual cost of $717,984.

15. Explanation for Program Changes or Adjustments

For efficiency of operations we are consolidating these related information collections. While we retain our estimate of burden associated with the individual collection activities, the consolidation results in an increase in burden to OMB control no. 0910-0583 by 52 responses and 1,960 hours annually. Upon OMB approval of our request, we intend to discontinue control no. 0910-0704.

16. Plans for Tabulation and Publication and Project Time Schedule

Upon the completion of a consultation, 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.fda.gov/Food/IngredientsPackagingLabeling/GEPlants/Submissions/ucm222595.htm.

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

Display of the OMB expiration date is appropriate and provided as required. As the agency moves from paper-based publication formats and makes guidance and other agency resources available on our website at www.FDA.gov, we are considering the most effective way to communicate this information in alternative formats.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.