4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1207]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Plant Varieties Intended for Food Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0583. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Plant Varieties Intended for Food Use

OMB Control Number 0910-0583--Revision

This information collection supports recommendations found in Agency 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.

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

The Agency guidance document entitled "Guidance on Consultation Procedures: Foods Derived From New Plant Varieties," which is 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.

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

Since May 29, 1992, when we issued a policy statement 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 (57 FR 22984). The guidance entitled "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use" (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 to transmit their submission 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 prepared using the CFSAN Online Submission Module (https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm). Once the submission is prepared, it may be submitted in electronic format via the Electronic Submissions Gateway (https://www.fda.gov/industry/electronic-submissions-gateway), paper format, or as electronic files on physical media with paper signature page.

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.

We estimate the burden of the information collection as follows:

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.

For efficiency of Agency operations, we are consolidating these related information collections. We retain our estimate of burden associated with the individual collection activities but have increased burden in OMB control number 0910-0583 by 52 responses and 1,960 hours annually to reflect the reorganization of the information collection. Upon OMB approval of our request, we intend to discontinue OMB control number 0910-0704.

Dated: June 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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