

CDC or CBP may issue additional operational guidance to aircraft operators regarding the collection and transmission of the designated information, including for those who are unable submit data in the manner specified or to meet the deadline of technical compliance.

Any airline that fails to comply with section 1 may be subject to criminal penalties under, *inter alia*, 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571.

2. This section applies to all other aircraft operators not covered in section 1 above. Beginning 11:59 p.m. Eastern Standard Time on March 4, 2021, for each passenger flight transporting passengers destined for the United States from international last points of departure who have been in DRC or Guinea within 21 days prior to the date of entry or attempted entry into the United States, all airlines or aircraft operators shall —

(a) Collect the designated information for all passengers who are departing from, or were otherwise present in, DRC or Guinea within the 21 days prior to their entry or attempted entry into the United States. When collecting the designated information, aircraft operators shall notify passengers that the obligation to provide the information is a United States Government requirement.

(b) Transmit the designated passenger information to CBP or CDC through one of the following means:

(1) Electronic Advance Passenger Information System;⁴ or

(2) Other means meeting minimum standards deemed acceptable to CDC in consultation with CBP.

(c) For all crew members, upon request from the CDC Director, transmit the designated information through encrypted email or other means approved by CDC within 24 hours.

CDC or CBP may issue additional operational guidance to aircraft operators regarding the collection and transmission of the designated information, including for those who are unable submit data in the manner specified or to meet the deadline of technical compliance.

Any entities covered under section 2 that fail to comply with section 2 may be subject to criminal penalties under, *inter alia*, 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571.

3. Requirements for Passengers:

Beginning 11:59 p.m. Eastern Standard Time on March 4, 2021, any

passenger destined for the United States on a flight covered under sections 1 or 2 who is departing from, or was otherwise present in, DRC or Guinea within 21 days prior to entry, or attempted entry, into the United States shall provide the designated information, as instructed by the airline or aircraft operator, insofar as the information exists for the passenger.

Authorized representatives (for example, immediate family member, legal guardian, or travel agent) may provide the designated information on behalf of passengers, including on behalf of minors or other passengers who are unable to do so on their own behalf, but the information must be specific to the individual passenger (*e.g.* agents may not put one number for an entire group of unrelated persons).

Any passenger who fails to comply with the requirements of section 3 may be subject to criminal penalties under, *inter alia*, 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571.

CDC and CBP will maintain the designated information within their respective systems in accordance with Federal law, including the Privacy Act of 1974 (5 U.S.C. 552a). Identifiable information may be used and shared only for lawful purposes, including with authorized personnel of the United States Department of Health and Human Services; the United States Department of Homeland Security; state, local, tribal, and territorial public health departments; and other cooperating authorities, as authorized by law. CDC and CBP will retain, use, delete, or otherwise destroy the designated information in accordance with the Federal Records Act, applicable Privacy Act System of Records Notices, and other applicable law.

CDC may modify this Order by an updated publication in the **Federal Register** or by posting an advisory to follow at www.cdc.gov.

Authority

The CDC Director is issuing this Order pursuant to Sections 361 and 365 of the Public Health Service (PHS) Act, 42 U.S.C. 264 and 268, and implementing regulations at 42 CFR 71.4, 71.20, 71.31, and 71.32.

Dated: March 2, 2021.

Sherri Berger,

Acting Chief of Staff, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0438]

Agency Information Collection Activities; Proposed Collection; Comment Request; Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's procedures for early food safety evaluation of new non-pesticidal proteins produced by new plant varieties intended for food use, including bioengineered food plants.

DATES: Submit either electronic or written comments on the collection of information by May 3, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 3, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 3, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

⁴ <https://www.cbp.gov/travel/travel-industry-personnel/apis/eapis-transmission-system>

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-N-0438 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

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: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical

utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

OMB Control Number 0910-0583—Extension

This information collection supports FDA regulations. 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. We use this information to evaluate the food safety of a specific new protein produced by a new plant variety.

Description of Respondents: The respondents to this collection of information are developers of new plant varieties intended for food use.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

GFI section VI: Format for submission	Form FDA No.	Number of responses	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
First four data components	3666	6	1	6	4	24
Two other data components	3666	6	1	6	16	96
Total						120

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 no adjustments to our burden estimate. The estimated number of annual responses and average burden per response are based on our experience with early food safety evaluations. Completing an early food safety evaluation for a new protein from a new plant variety is a one-time burden (one evaluation per new protein). Many developers of novel plants may choose not to submit an evaluation because the field testing of a plant containing a new protein is conducted in such a way (*e.g.*, on such a small scale, or in such isolated conditions, etc.) that cross-pollination with traditional crops or commingling of plant material is not likely to be an issue. Also, other developers may have previously communicated with us about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop.

We estimate the annual number of NPCs submitted by developers will be six or fewer. The early food safety evaluation for new proteins includes six main data components. Four of these data components, having to do with the identity and source of the protein, are easily and quickly obtainable. We estimate that completing these data components will take about 4 hours per NPC.

Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis that can be performed using publicly available databases. The other

data component involves “wet” lab work to assess the new protein’s stability and the resistance of the protein to enzymatic degradation using appropriate in vitro assays (protein digestibility study). The paperwork burden of these two data components consists of the time it takes the company to assemble the information on these two data components and include it in an NPC. We estimate that completing these data components will take about 16 hours per NPC.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-04448 Filed 3-3-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0025]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency.

Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA regulations requiring the declaration of color additives on animal food labels.

DATES: Submit either electronic or written comments on the collection of information by May 3, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 3, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 3, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

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