TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping	Total hours
Exemptions under § 112.7	3,285	1	3,285	0.5 (30 minutes)	1,643
Training under § 112.30	24,420	1	24,420	7.25	177,045
Testing requirements for agricultural water under §§ 112.44 and 112.45.	48,361	2.990	144,599	0.825 (~50 minutes)	119,294
Records related to agricultural water	160,605	2.242	360,076	2.160	777,765
Testing requirements for sprouts under §§ 112.144, 112.145, and 112.147.	126	245.660	30,953.16	0.825 (~50 minutes)	25,536
Records related to sprouts	126	62.061	7,819.686	1.412 (~85 minutes)	11,041
"Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations".	126	233	29,358	1	29,358
Documentation supporting compliance with § 112.2	4,568	1	4,568	0.079 (~ 5 minutes)	361
Total	241,617		605,079		1,142,043

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers rounded to nearest 1/1,000.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total disclosures	Average burden per disclosure	Total hours
Disclosure under §§ 112.2, 112.6, 112.31, 112.33, and 112.142.	77,165	3.459	266,914	1.422 (~85 minutes)	379,551

[1] There are no capital costs or operating or 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. As respondents to the collection continue to implement the regulatory requirements and compliance schedules continue to be realized, we retain our current burden estimates. At the same time, and as communicated on our website at *https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-agricultural-water,* we expect the burden associated with the testing of certain agricultural water for covered produce other than sprouts to be minimal for the period of time that FDA intends to exercise enforcement discretion with regard to those requirements.

Dated: July 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15425 Filed 7–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1526]

Fluorinated Polyethylene Containers for Food Contact Use; Request for Information

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is opening a docket to obtain data and information on the use of fluorinated polyethylene for food contact applications. Specifically, FDA is seeking scientific data and information on current food contact uses of fluorinated polyethylene, consumer dietary exposure that may result from those uses, and safety of certain per- and polyfluoroalkyl substances that may migrate from fluorinated polyethylene food containers. The purpose of this request is to ensure that we have current information to support our review of the use of fluorinated polyethylene containers used in food contact applications to help ensure that this use continues to be safe. FDA may use information submitted in response to this notice to update dietary exposure estimates and safety assessments for the authorized food contact use of fluorinated polyethylene.

DATES: Either electronic or written comments and scientific data and information must be submitted by October 18, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 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–2022–N–1526 for ''Fluorinated Polyethylene Containers for Food Contact Use; Request for Information.'' 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.'' We will review this copy, including the claimed confidential information, in our 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: Sharon Koh-Fallet, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, Division of Food Contact Substances (HFS–275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301–796–7732; or Joan Rothenberg, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

Fluorinated polyethylene containers manufactured and used in compliance with our regulation at § 177.1615 (21 CFR 177.1615), *Polyethylene, fluorinated,* may be used in certain food contact applications. Fluorination of polyethylene containers allows for improved chemical barrier properties in comparison to polyethylene containers that have not been fluorinated. FDA's regulation, at § 177.1615(a), states that fluorinated polyethylene containers for food contact use be manufactured only by modifying the surface of the molded container using fluorine gas in combination with gaseous nitrogen as an inert diluent. We are aware that some manufacturers of fluorinated polyethylene produce fluorinated containers through alternative manufacturing methods, such as using alternative diluent gases such as oxygen or other gases. These alternative processes for fluorination of polyethylene do not comply with § 177.1615 and are not lawful for use in food contact applications.

Testing performed by the Environmental Protection Agency (EPA) found that certain per- and polyfluoroalkyl substances (PFAS) can form and migrate from some fluorinated high-density polyethylene (HDPE, which is a type of polyethylene) containers into the pesticide within the containers. EPA's testing was conducted on containers that are not FDA-regulated, specifically containers intended to hold mosquito-controlling pesticides. EPA detected perfluoroalkyl carboxylic acids (PFCAs), and analytical studies indicate that PFCAs can result from fluorination processes that do not comply with FDA's regulations (Ref. 1). PFCAs are a subset of PFAS, that include substances such as perfluorooctanoic acid (PFOA), which is known to be biopersistent in animals and humans. Additionally, PFOA is a potential human carcinogen and known to cause immunotoxicity and reproductive and developmental toxicity (Refs. 2 and 3).

On August 5, 2021, FDA made available on its website a letter (*https://www.fda.gov/media/151326/download*) to manufacturers, distributors, and food manufacturers that use fluorinated polyethylene food contact containers reminding them that only fluorinated polyethylene containers that comply with § 177.1615 are authorized for food contact use. However, because alternative fluorination processes exist, there is a possibility that these alternative fluorination processes are used to manufacture fluorinated polyethylene containers used to contain food. As such, we reminded food manufacturers of their responsibility to only use food contact articles in compliance with FDA's regulations.

Although EPA's testing was of containers not intended to contact food, it raises questions about the potential for PFAS to form and migrate from fluorinated polyethylene containers that are intended for food contact use. As such, we are interested in obtaining information on current food uses of fluorinated polyethylene containers as well as information on current manufacturing processes for these containers and any analytical testing information of substances that may migrate from fluorinated polyethylene containers to food. This information will enable us to better understand current food uses, manufacturing practices, and substances migrating from fluorinated polyethylene containers and, as appropriate, we may use information submitted in response

to this notice to update dietary exposure estimates and safety assessments for the authorized food contact use of fluorinated polyethylene. This is consistent with our efforts to increase our understanding of the potential for PFAS exposure from food and to reduce dietary exposure to PFAS that may pose a health risk. Current data and information on these topics will help us advance our public health mission and further support the current Administration's comprehensive approach to addressing PFAS and advancing clean air, water, and food (Ref. 4).

II. Request for Information

We request information on the food contact uses of fluorinated polyethylene food contact articles, including information on the types of food or food ingredients with which the articles used are in contact, any substances migrating from fluorinated polyethylene food contact articles used in food contact applications, consumer exposure data, and unpublished safety information. Specifically, we request data and information concerning:

1. Current food contact uses, including the types of containers and the food types (*e.g.,* acidic, alcoholic) they may contact, including use conditions (*e.g.,* time, temperature of contact);

2. Manufacturing conditions for the fluorination process and any pre- and post-treatment processes, including time, temperature, pressure, atmospheric conditions, treatment gases (*e.g.,* fluorine or other chemical gases), and use levels/ratios of treatment gases used during the manufacturing process;

3. Manufacturing process controls including moisture control measures and quality control variables monitored during the fluorination process;

4. Analyses related to pre- and post-treatment of fluorinated polyethylene containers, including surface chemical analyses, characterization of surface morphology, and identification of surface chemical functionalities;

5. Analyses characterizing the fluorinated surface thickness of the fluorinated layer on the article surface;

6. Analyses characterizing (qualitatively or quantitatively) the fluorinated polyethylene containers including any analyses for quality control (*e.g.,* Fourier-Transform Infrared Spectroscopy or other analyses);

7. Analyses characterizing (qualitatively or quantitatively) migrating substances from the fluorinated polyethylene containers, including fully and partially fluorinated low molecular weight polyethylene oligomers and other migrating substances;

8. Analyses characterizing (qualitatively or quantitatively) substances migrating from fluorinated polyethylene as a function of the degree of fluorination of the surface;

9. Analyses estimating consumer exposure from the use of fluorinated polyethylene containers in food contact, including substances migrating from fluorinated polyethylene;

10. The safety of fluorinated polyethylene, including unpublished safety studies on substances that migrate from fluorinated polyethylene including fully and partially fluorinated low molecular weight polyethylene oligomers; and

11. Analyses characterizing the polyethylene used to produce the containers prior to fluorination, including the molecular weight distribution, the weight-percent units derived from ethylene and other monomers, monomer ratios, and adjuvant substances (*e.g.,* processing aids) used in the manufacture of polyethylene polymers.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov* . References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website address, as of the date this document publishes in the **Federal Register,** but websites are subject to change over time.

1. Rand, A.A. and S.A. Mabury, ''Perfluorinated Carboxylic Acids in Directly Fluorinated High-Density Polyethylene Material,'' *Environmental Science & Technology,* 2011, vol. 45, pp. 8053–8059.

2. *Agency for Toxic Substances and Disease Registry, ''Toxicological Profile for Perfluoroalkyls,'' May 2021.

3. *The International Agency for Research on Cancer, Monogram for Perfluorooactanoic Acid, 2017.

4. *Fact Sheet: Biden-Harris Administration Launches Plan to Combat PFAS Pollution, October 2021. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/10/18/fact-sheet-biden-harris-administration-launches-plan-to-combat-pfas-pollution/.*

Dated: July 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15455 Filed 7–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurodevelopment and Neuropsychological Disorders.

Date: August 8, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Samuel C. Edwards, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 14, 2022.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–15430 Filed 7–19–22; 8:45 am]

BILLING CODE 4140–01–P