



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. FDA-2015-F-0714]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations to no longer provide for the use of three specific perfluoroalkyl ethyl containing food-contact substances (FCSs) as oil and water repellants for paper and paperboard for use in contact with aqueous and fatty foods because new data are available as to the toxicity of substances structurally similar to these compounds that demonstrate there is no longer a reasonable certainty of no harm from the food-contact use of these FCSs. This action is in response to a petition filed by the Natural Resources Defense Council, the Center for Food Safety, the Breast Cancer Fund, the Center for Environmental Health, Clean Water Action, the Center for Science in the Public Interest, Children's Environmental Health Network, Environmental Working Group, and Improving Kids' Environment.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written objections and requests for a hearing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section VIII for further information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows:

### Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on <http://www.regulations.gov>.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### Written/Paper Submissions

Submit written/paper submissions in the following way:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, 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-2015-F-0714 for "Indirect Food Additives: Paper and Paperboard Components." Received objections will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Honigfort, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1206.

SUPPLEMENTARY INFORMATION:

#### I. Background

In a notice published in the Federal Register on March 16, 2015 (80 FR 13508), we announced that we filed a food additive petition (FAP 4B4809) submitted by the Natural Resources Defense Council, 1152 15th St. NW., suite 300, Washington, DC 20005; the Center for Food Safety, 303 Sacramento St., Second Floor, San Francisco, CA 94111; Clean Water Action, 1444 Eye St. NW., suite 400, Washington, DC 20005; the Center for Science in the Public Interest, 1220 L St. NW., suite 300, Washington, DC 20005; Children's Environmental Health Network, 110 Maryland Ave. NE., suite 404, Washington, DC 20002; the Breast Cancer Fund, 1388 Sutter St., suite 400, San Francisco, CA 94109-5400; the Center for Environmental Health, 2201 Broadway, suite 302, Oakland, CA 94612; Environmental Working Group, 1436 U St. NW., suite 100, Washington, DC 20009; and Improving Kids' Environment, 1915 West 18th St., Indianapolis, IN 46202.

The petition proposed to amend § 176.170 (21 CFR 176.170) to no longer provide for the use of three perfluoroalkyl ethyl containing FCSs as oil and water repellants for paper and paperboard for use in contact with aqueous and fatty foods. The three FCSs which are the subjects of this petition are as follows:

1. Diethanolamine salts of mono- and bis (1H,1H,2H,2H perfluoroalkyl) phosphates where the alkyl group is even-numbered in the range C8-C18 and the salts have a fluorine content of 52.4 percent to 54.4 percent as determined on a solids basis;
2. Pentanoic acid, 4,4-bis [(gamma-omega-perfluoro-C8-20-alkyl)thio] derivatives, compounds with diethanolamine (CAS Reg. No. 71608-61-2); and
3. Perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis([gamma], [omega]-perfluoro C4-20 alkylthio) methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide.

## II. Evaluation of Safety

The three subject FCSs are regulated as food additives under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Section 409 of the FD&C Act (21 U.S.C. 348) sets forth the statutory requirements for food additives. Section 201(s) of the FD&C Act (21 U.S.C. 321(s)) includes substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food among the substances defined as food additives, provided the intended use results or may reasonably be expected to result in it becoming a component of food and those uses were not sanctioned prior to 1958 or are not generally recognized as safe among experts qualified by scientific training and experience to evaluate its safety.

Under section 402(a)(2)(c)(1) of the FD&C Act (21 U.S.C. 342(a)(2)(c)(1)), food shall be deemed to be adulterated if it is or if it bears or contains any food additive that is unsafe within the meaning of section 409 of the FD&C Act. A food additive shall be deemed to be unsafe under section 409 of the FD&C Act, in relevant part, unless its use conforms to a food additive regulation or an effective food contact notification. Section 409(i) of the FD&C Act states that the procedure for amending or repealing a regulation shall conform to the procedure for the promulgation of such regulations. FDA's regulations specific to the administrative actions for food additives provide that the Commissioner, either on his own initiative or on the petition of any interested person, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive (§ 171.130(a) (21 CFR 171.130(a)). These regulations further provide that any such petition must include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or appeal. New data must be furnished in the form specified in § 171.1 (21 CFR 171.1) and 21 CFR 171.100 for submitting petitions (see § 171.130(b)). Under these regulations, a petitioner may propose that we amend a food additive regulation if the petitioner can demonstrate that new data are available as to the toxicity of the food additive that may justify amendment of the food additive regulation.

Under section 409(c)(3) of the FD&C Act we will not establish a regulation for the use of a food additive if a fair evaluation of the data fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe. Our regulations, at 21 CFR 170.3(h)(i), define safety as "a reasonable certainty in the minds of

competent scientists that the substance is not harmful under the intended conditions of use." In order for FDA to grant a petition that seeks an amendment to a food additive regulation based upon new data concerning the toxicity of the food additive, such data must be adequate for FDA to conclude that there is no longer a reasonable certainty of no harm for the intended use of the substance.

The petition asserts that publically available information on long-chain perfluorinated compounds as a chemical class, which has become available after the food contact use of the three FCSs was approved, demonstrates that there is no longer a reasonable certainty of no harm from the food contact use of the three FCSs as listed in § 176.170.

All three of the FCSs subject to the petition contain extended alkyl chains where all of the hydrogens are replaced by fluorine (hence the FCSs are "perfluorinated"). The toxicological profile of extended perfluorinated alkyl chains varies with chain length: On a general basis, those with extended perfluorinated alkyl chains greater than or equal to eight carbons in length demonstrate biopersistence in chronic feeding studies, while those with extended perfluorinated alkyl chains less than eight carbons in length do not (Ref. 1). Biopersistence is defined as persistence and accumulation of a material in a biological tissue due to preferential deposition of the material in the tissue combined with resistance of the material to removal from the tissue by natural clearance mechanisms (Ref. 2). As such, compounds containing extended perfluorinated alkyl chains are often classified as long- (i.e.,  $\geq$  eight carbons in length) or short-chain perfluorinated compounds, with implications for toxicology analysis including consideration of biopersistence. All three of the FCSs contain extended perfluorinated alkyl chains  $\geq$  eight carbons in length and as such are long-chain perfluorinated compounds (PFCs).

The petition cites a 2010 FDA comprehensive review memorandum on the available literature for long-chain PFCs (Ref. 3). This memorandum noted that available data on long-chain perfluorocarboxylic acids and fluorotelomer alcohols, both of which are subsets of long-chain PFCs, demonstrate reproductive and developmental toxicity in animal models. The FDA memorandum determined that, based on structural similarity to long-chain perfluorocarboxylic acids and fluorotelomer alcohols, and in the absence of contradictory data, data demonstrating reproductive and developmental toxicity for long-chain perfluorocarboxylic acids and fluorotelomer alcohols was applicable to long-chain PFCs on a general basis. The petition asserts that, as the three subject FCSs are long-chain PFCs, the concern for reproductive and developmental toxicity for long-chain PFCs as determined in FDA's 2010 comprehensive review memorandum is applicable to these three FCSs. The petition also provides the results of an updated comprehensive literature search, which the petition asserts reinforces the concern for reproductive and developmental toxicity for long-chain PFCs. The petition also asserts that the updated literature search did not discover any information which would contradict FDA's 2010 determination that data demonstrating reproductive and developmental toxicity for long-chain perfluorocarboxylic acids and fluorotelomer alcohols was applicable to long-chain PFCs on a general basis.

Upon review of the available information, FDA has confirmed our 2010 determination that data demonstrating reproductive and developmental toxicity for long-chain perfluorocarboxylic acids and fluorotelomer alcohols are applicable to long-chain PFCs on a general basis (Ref. 4). FDA's updated review noted that there are no available toxicological studies conducted with the three FCSs that address the endpoints of reproductive or developmental toxicity. As all three FCSs are long-chain PFCs, and in the absence of data



specific to the three FCSs to address these endpoints, FDA utilized the available data demonstrating reproductive and developmental toxicity for long-chain perfluorocarboxylic acids and fluorotelomer alcohols to assess the safety of the approved food-contact use of the FCSs. FDA's updated review noted deficiencies in the available information used to determine migration of the FCSs into food as a result of their approved food-contact use (Ref. 5). For this reason FDA was unable to calculate consumer exposure to the FCSs in a manner which would allow a quantitative assessment of the safety of that exposure in the context of the available data demonstrating reproductive and developmental toxicity for long-chain perfluorocarboxylic acids and fluorotelomer alcohols. However, FDA's review noted that available data demonstrate that long-chain perfluorocarboxylic acids and fluorotelomer alcohols biopersist in animals and that this biopersistence also occurs in humans (Ref. 4). Although available migration information does not allow a quantitative assessment of the safety of exposure to these FCSs, the reproductive and development toxicity of the three FCSs can be qualitatively assessed in the context of biopersistence and the expectation that chronic dietary exposure to these FCSs would result in a systemic exposure to the FCSs or their metabolic by-products at levels higher than their daily dietary exposure (Ref. 4).

### III. Comments on the Filing Notice

We received very few comments on the petition. These comments stated that the use of the three FCSs as listed in § 176.170 has been abandoned.

The basis for the action requested in the petition is that new data are available as to the toxicity of substances structurally similar to the subject FCSs that justify amending § 176.170. The petition is not based on abandonment of the approved food contact use of these three FCSs. We have made a determination that the information provided in the petition and other publically

available relevant data demonstrates that there is no longer a reasonable certainty of no harm for the food contact use of the three FCS.

#### IV. Conclusion

We reviewed the data and information in the petition and other available relevant material to evaluate whether new data are available as to the toxicity of the subject FCSs that justify amendment of § 176.170. As a result of this review, we concluded that data for subsets of long-chain PFCs (demonstrating biopersistence and reproductive and developmental toxicity) are applicable to long-chain PFCs on a general basis and that this data raises significant questions as to the safety of the authorized uses of the three FCSs subject to the petition (Ref. 4). We also concluded that there is a lack of data specific to the three subject FCSs subject to the petition to address these questions (Ref. 4). For these reasons, in the absence of data specific to the three FCSs to address reproductive and developmental toxicity, adequate migration data to determine dietary exposure to the FCSs from the food-contact use, and sufficient data to account for a consumer's systemic exposure resulting from chronic dietary exposure to these FCSs, we conclude that there is no longer a reasonable certainty of no harm for the food contact use of these FCSs. Therefore, we are amending part 176 as set forth in this document. Upon the effective date (see DATES), these food additive uses are no longer authorized.

#### V. Public Disclosure

In accordance with § 171.1(h), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

## VI. Environmental Impact

We have considered the environmental effects of this rule. As stated in the March 16, 2015, Federal Register notice of petition for FAP 4B4809 (80 FR 13508), we have determined, under 21 CFR 25.15(c), that this action "is of a type that does not individually or cumulatively have a significant effect on the human environment" such that neither an environmental assessment nor an environmental impact statement is required, as set forth in 21 CFR 25.32(m). We have not received any new information or comments that would affect our previous determination.

## VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## VIII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify, with particularity, the provision(s) to which you object and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>. We will publish notice of the objections that we have received or lack thereof in the Federal Register.

#### IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. Rice, P. A. "C6-Perfluorinated Compounds: The New Greaseproofing Agents in Food Packaging," Current Environmental Health Reports, 2:1, pp. 33-40, 2015.
2. International Agency for Research on Cancer,  
<http://monographs.iarc.fr/ENG/Monographs/vol81/mono81-8.pdf>.
3. FDA Memorandum from P. Rice to P. Honigfort, September 30, 2010.
4. FDA Memorandum from P. Rice to P. Honigfort, July 27, 2015.
5. FDA Memorandum from J. Cooper to P. Honigfort, July 23, 2015.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and re-delegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 176 is amended as follows:

PART 176--INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

§ 176.170 [AMENDED]

2. Amend § 176.170 in the table in paragraph (a)(5) by removing the entries for "Diethanolamine salts of mono- and bis," "Pentanoic acid," and "Perfluoroalkyl substituted phosphate ester acids."

Dated: December 29, 2015.

Susan Bernard,

Director,

Office of Regulations, Policy and Social Sciences,

Center for Food Safety and Applied Nutrition.

[FR Doc. 2015-33026 Filed: 12/31/2015 8:45 am; Publication Date: 1/4/2016]