



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. FDA-2016-F-1153]

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 two specific perfluoroalkyl containing substances as oil and water repellents for paper and paperboard for use in contact with aqueous and fatty foods because these uses have been abandoned. This action is in response to a petition filed by Keller and Heckman LLP on behalf of 3M Corporation.

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

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 as follows:

- 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-2016-F-1153 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: Vanee Komolprasert, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-1217.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the Federal Register of April 29, 2016 (81 FR 25625), we announced that we filed a food additive petition (FAP 6B4814) submitted on behalf of 3M Corporation (Petitioner) by Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. The petition proposed to amend § 176.170 (21 CFR 176.170) to no longer provide for the use of two different perfluoroalkyl containing substances as oil and water repellents for paper and paperboard for use in contact with aqueous and fatty foods because these uses have been intentionally and permanently abandoned. The two substances that are the subjects of the petition are as follows:

- (1) Ammonium bis (N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, containing not more than 15 percent ammonium mono (N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates, where the alkyl group is more than 95 percent C₈ and the salts have a fluorine content of 50.2 percent to 52.8 percent as determined on a solids basis; and
- (2) Perfluoroalkyl acrylate copolymer (CAS Reg. No. 92265-81-1) containing 35 to 40 weight percent fluorine, produced by the copolymerization of ethanaminium, N,N,N-trimethyl-2-[(2-methyl-1-oxo-2-propenyl)-oxy]-, chloride; 2-propenoic acid, 2-methyl-, oxiranylmethyl ester; 2-

propenoic acid, 2-ethoxyethyl ester; and 2-propenoic acid, 2[[heptadecafluoro-octyl)sulfonyl]methyl amino]ethyl ester.

In response to food additive petitions submitted by the Petitioner (33 FR 14544, September 27, 1968; 35 FR 14840, September 24, 1970; 37 FR 9762, May 17, 1972; and 52 FR 3603, February 5, 1987), FDA authorized certain uses of these two substances as food additives under § 176.170.

II. Evaluation of Abandonment

Section 409(i) of the Federal, Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(i)) states that we may by regulation establish the procedure for amending or repealing a food additive regulation, and that this procedure shall conform to the procedure provided in section 409 for the promulgation of such regulations. FDA's regulations specific to the administrative actions for food additives provide that the Commissioner, 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))). The 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 21 CFR 171.1 and 171.100 for submitting petitions (§ 171.130(b)). Under these regulations, a petitioner may propose that we amend a food additive regulation if the petitioner can demonstrate that there are "old uses abandoned" for the relevant food additive. Such abandonment must be complete and permanent for any intended uses in the U.S. market. While section 409 of the FD&C Act and § 171.130 also provide for

amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety of the food additive. Instead, the amendment or revocation is based on the fact that regulatory authorization is no longer necessary because the use of the food additive has been permanently and completely abandoned.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (e.g., if a substance is no longer used in certain product categories) or on the abandonment of all authorized food additive uses of a substance (e.g., if a substance is no longer being manufactured). If a petition seeks to amend the food additive regulations based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The petition submitted on behalf of 3M Corporation includes the following information to support the claim that the uses of the two substances are no longer being introduced into interstate commerce. The Petitioner provides a statement that the Petitioner does not currently manufacture the two substances for food contact use in the United States, and that to the best of the Petitioner's knowledge, the Petitioner was the sole and exclusive domestic and international manufacturer of the two substances for the abandoned uses. In addition, the Petitioner submitted information on its May 2000 voluntary agreement with the U.S. Environmental Protection Agency to phase out production of perfluorooctane sulfonate (PFOS); which is used to produce the two substances (<https://nepis.epa.gov/Exe/ZyPDF.cgi/P100LTG6.PDF?Dockey=P100LTG6.PDF>). According to the petition, the Petitioner completed a voluntary phase-out of PFOS production in 2002. The Petitioner states that it does not intend to manufacture or import, nor does it maintain an

inventory for sale or distribution, of the two substances for use in food-contact applications in the United States in the future.

III. Comments on the Filing Notice

We provided 60 days for comments on the filing notice. We received two comments from an individual and a consumer group. Both comments raised two issues, which are discussed in the paragraphs that follow. For ease of reading, we preface each comment discussion with a numbered "Comment," and each response with "Response."

(Comment 1) One comment asked why we are amending the regulations if the substances are no longer in use.

(Response) FDA is responding to an FAP, as required under section 409 of the FD&C Act. Amending these food additive regulations addresses the FAP under the process set forth in the FD&C Act. In the case of abandonment, regulatory authorization is no longer necessary for these substances because their use as food additives has been permanently and completely abandoned. Our action also gives interested parties better information about what substances are used as food contact substances.

(Comment 2) Another comment asked FDA to remove the approvals of seven effective food contact notifications for long-chain perfluorinated compounds.

(Response) We decline to address food contact substances that are outside the scope of this food additive petition.

IV. Conclusion

We reviewed the data and information in the petition and other available relevant material to determine whether the use of the two perfluoroalkyl containing substances as oil and water repellents for paper and paperboard for use in contact with aqueous and fatty foods has

been permanently and completely abandoned. Based on the available information, we conclude that the use of these substances has been permanently and completely abandoned. Therefore, we are amending 21 CFR 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) (21 CFR 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. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the Federal Register of April 29, 2016, notice of petition for FAP 6B4814. We stated that we had determined, under 21 CFR 25.32(m), 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. 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>.

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 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 "Ammonium bis (N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates" and "Perfluoroalkyl acrylate copolymer."

Dated: November 17, 2016.

Susan Bernard,

Director,

Office of Regulations, Policy and Social Science,

Center for Food Safety and Applied Nutrition.

[FR Doc. 2016-28116 Filed: 11/21/2016 8:45 am; Publication Date: 11/22/2016]