4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0715]

Draft Guidance for Industry on Acrylamide in Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled "Guidance for Industry: Acrylamide in Foods." The draft guidance is intended to provide information that may help growers, manufacturers, and food service operators reduce acrylamide in certain foods. Acrylamide is a chemical that can form in some foods during certain types of high-temperature cooking. The draft guidance is intended to suggest a range of possible approaches to acrylamide reduction and not to identify specific recommended approaches.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed

adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1639.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance entitled "Guidance for Industry: Acrylamide in Foods." We are issuing this draft guidance as a Level 1 draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on acrylamide in foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The draft guidance is intended to provide information that may help growers, manufacturers, and food service operators reduce acrylamide in certain foods. Acrylamide is a chemical that can form in some foods during certain types of high-temperature cooking, and is a concern because it can cause cancer in laboratory animals at high doses, and is reasonably anticipated to be a human carcinogen. Reducing acrylamide in foods may mitigate potential human health risks from exposure to acrylamide. The draft guidance is intended to suggest a

range of possible approaches to acrylamide reduction and not to identify specific recommended approaches.

In particular, the draft guidance is intended to give information to manufacturers on selecting and handling raw materials, modifying processing practices, and choosing ingredients, so as to reduce acrylamide in potato-based foods (such as fries, sliced potato chips, and fabricated potato chips) and cereal-based foods (such as cookies, crackers, and breads). The draft guidance also discusses acrylamide reduction in coffee. The draft guidance also is intended to give information to manufacturers for placing preparation and cooking instructions on frozen French fry packages. Lastly, the draft guidance is intended to give information for food service operations on preparation of potato-based and cereal-based foods.

II. Paperwork Reduction Act of 1995

This draft guidance contains proposed information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). "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. Federal law at 44 U.S.C. 3506(c)(2)(A) requires Federal Agencies to publish a 60-day notice in the Federal Register for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we will publish a 60-day notice of the proposed collection of information in a future issue of the Federal Register.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance to http://www.regulations.gov or written comments to the Division of Dockets Management (see

ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments 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.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the draft guidance.

Dated: November 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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