4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-4126]

Azodicarbonamide (ADA); Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting information on the current uses and safety data of azodicarbonamide (ADA) in human food and as a food contact substance. We are requesting this information as part of our systematic process for conducting post-market assessments of chemicals in food. We are conducting a post-market assessment of the safety of ADA in food, considering the latest state of the science. We intend to use the information received and any other available, relevant information to determine if ADA remains safe under its current conditions of use in food and as a food contact substance.

DATES: Either electronic or written comments and scientific data and information on the notice must be submitted by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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-2026-N-4126 for "Azodicarbonamide (ADA); 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: Daniel Hlavaty, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301-796-1481, or Lauren

Kleinman, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting information on the current uses and safety data for azodicarbonamide (ADA) in human food and as a food contact substance as part of a post-market assessment. ADA (CAS No. 123-77-3) is used as a whitening agent in cereal flour and as a dough conditioner in breadmaking and has applications in manufacturing food contact materials.

All uses of ADA in food or as a food contact substance must be authorized for that use through a food additive regulation or an effective food contact notification, or be excluded from regulation as a food additive, for example, because such use is generally recognized as safe (GRAS) or is prior sanctioned (see Sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act). As described below, these uses of ADA in food and as a food contact substance in the U.S. are authorized by FDA's food additive regulations.

ADA is authorized as a direct food additive when used as an aging and bleaching ingredient in cereal flour and as a dough conditioner in bread baking in a total amount not to exceed 0.0045 percent (45 parts per million; 2.05 grams per 100 pounds of flour) (21 CFR 172.806). It is listed as an optional ingredient in the standards of identity for bread, rolls, and buns (21 CFR 136.110); flour (21 CFR 137.105); and whole wheat flour (21 CFR 137.200) when used in accordance with the regulations for ADA in 21 CFR 172.806. ADA is also permitted as an indirect food additive when used in closures with sealing gaskets for food containers (21 CFR 177.1210), rubber articles intended for repeated use (21 CFR 177.2600), and adjuvant substances used in the manufacture of foamed plastics (21 CFR 178.3010). We are not aware of any prior sanctions or conclusions that the use of ADA is GRAS in food or for food contact use.

As part of our systematic review of chemicals in food, FDA is beginning a post-market assessment of the safety of ADA as used in food and as a food contact substance. (see

https://www.fda.gov/food/food-chemical-safety/list-select-chemicals-food-supply-under-fda-review). This assessment supports the Make America Healthy Again Commission's recommendation to implement an evidence-based systematic process for post-market assessment of chemicals in food (see https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf). The objective of our assessment is to determine if ADA is safe under its conditions of use in food or as a food contact substance considering the most recent science. While FDA previously concluded authorized uses to be safe, new information may require reconsideration of the regulatory status or the safe uses of a substance in or on food.

II. Request for Information

FDA is requesting information on uses, use levels, dietary exposure, and safety data on ADA currently used in food and as a food contact substance. This includes decomposition products of ADA, which are the chemicals formed when ADA breaks down, such as during breadmaking. Information from food manufacturers on uses and levels is crucial for food chemical assessments. We encourage food manufacturers to participate in this data call, with options for aggregated submissions through trade groups or other collaborations. We do not need information about individual products and their recipes, but rather data about the levels of use in general product categories. Voluntary submission of data and information on current uses and use levels will help to refine our dietary exposure assessments. We use maximizing assumptions to estimate dietary exposure (see, e.g., "Guidance for Industry: Estimating Dietary Intake of Substances in Food," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-estimating-dietary-intake-substances-food). Without refinements assisted by manufacturer use information, this may lead to overestimation of dietary exposure that could impact authorizations for the chemical's use in food or as a food contact substance.

Specifically, FDA requests the following:

1. General food categories in which ADA is used (for example, cookies, soft drinks, other categories listed in 21 CFR 170.3(n)), USDA's What We Eat in America survey (Ref. 1), or the Codex General Standard for Food Additives (Ref. 2));

2. Typical and maximum use levels of ADA in each applicable general food category;

3. Information on actual or expected residual levels of decomposition products of ADA (including semicarbazide and ethyl carbamate) in foods and food contact materials where ADA is used;

4. Information on the current food contact uses of ADA, including data on migration of ADA or its decomposition products from food contact materials into food;

5. Subpopulations with high dietary exposure to ADA or its decomposition products or particular safety concerns relevant to food and food contact uses of ADA;

6. Other dietary sources of ADA or its decomposition products, such as dietary supplements, natural occurrence in common foods, residues in animal products, or as contaminants in food or drinking water;

7. Market share of foods in each applicable general food category and food contact materials that are formulated with ADA;

8. Biomonitoring data for ADA, its decomposition products, or its metabolites;

9. Updated market disappearance or poundage data for ADA;

10. Information on potential chemically or pharmacologically related substances used in food or as a food contact substance;

11. Safety data relevant to use of ADA in food or as a food contact substance, including data pertaining to its decomposition products, and especially unpublished data;

12. Documentation of GRAS conclusions or prior sanctions for uses of ADA in food or as a food contact substance;

13. Information that may support the conclusion that ADA is no longer used for one or more of its authorized intended uses in food or as a food contact substance.

III. References

The following references 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 are also available electronically at https://www.regulations.gov. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. What We Eat in America Food Categories, available at https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/dmr-food-categories/.

2. Codex General Standard for Food Additives, available at https://www.fao.org/gsfaonline/foods/index.html.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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