



July 13, 2026

Kyle Diamantas, J.D.
Acting Commissioner of Food and Drugs
US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Azodicarbonamide (ADA); Request for Information (Docket No. FDA-2026-N-4126)

Dear Acting Commissioner Diamantas,

The Center for Science in the Public Interest (CSPI) respectfully submits these comments in response to Docket No. FDA-2026-N-4126. As part of the agency's ongoing commitment to reforming the post-market assessment system for evaluating food chemical safety, CSPI is encouraged to see the agency initiate a post-market evaluation of azodicarbonamide (ADA) following its inclusion in the FDA's List of Select Chemicals in the Food Supply Under FDA Review.¹

CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. CSPI has an extensive history of advocating for policies that improve the nutritional quality and safety of foods and beverages in the U.S.

At present, ADA is approved in the US for use as a dough strengthener and flour-treating agent² in a variety of food products and in food contact materials, despite concerns regarding its safe use. These primarily stem from its breakdown products, semicarbazide (SEM) and ethyl carbamate (EC; also known as urethane), that form during the cooking process. The FDA itself recognizes that ADA forms SEM and EC during the baking process and acknowledges that both SEM and EC are associated with cancer in animals.^{3,4}

¹ US Food and Drug Administration. List of Select Chemicals in the Food Supply Under FDA Review. May 27, 2026. Accessed: June 8, 2026. Available: <https://www.fda.gov/food/food-chemical-safety/list-select-chemicals-food-supply-under-fda-review>.

² US Food and Drug Administration. Substances Added to Food (formerly EAFUS): AZODICARBONAMIDE. <https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FoodSubstances&id=AZODICARBONAMIDE>

³ US Food and Drug Administration. Azodicarbonamide (ADA) Frequently Asked Questions. January 4, 2018. Accessed June 8, 2026. Available: <https://www.fda.gov/food/food-additives-petitions/azodicarbonamide-ada-frequently-asked-questions>.

⁴ Canas, BJ et al. Ethyl Carbamate Levels Resulting from Azodicarbonamide Use in Bread. US Food and Drug Administration. *Food Additives and Contaminants*. 1997.14(1); 89-94. Available: <https://pubmed.ncbi.nlm.nih.gov/9059587/>

The FDA states that at high levels, SEM increases the incidence of tumors in female mice.³ SEM caused angiomas, angiosarcomas, and lung tumors in mice⁵, but the International Agency for Research on Cancer (IARC) classified it as Group 3 (“not classifiable as to its carcinogenicity to humans”) in 1987 based on limited evidence of carcinogenicity in animals.⁶

A 1997 FDA study (Canas et al) found that the use of ADA as a dough conditioner increased the EC content in baked breads.⁴ EC is recognized by multiple authorities as a multisite, genotoxic carcinogen, causing cancers including lung adenocarcinoma, hepatic hemangiosarcoma, hepatocellular adenoma, and carcinoma in multiple rodent species as well as in non-human primates.⁷ In 2010, the International Agency for Research on Cancer (IARC) classified EC as “probably carcinogenic to humans (Group 2A)” based on “sufficient evidence in experimental animals”.⁸ A 2021 report by the National Toxicology Program (NTP) classifies EC as “reasonably anticipated to be a human carcinogen” based on sufficient evidence from animal studies.⁹

The Delaney Clause in the Food, Drug, and Cosmetic Act expressly prohibits the approval of food additives shown to cause cancer in humans or animals¹⁰ and does not contain a de minimis exception¹¹. However, FDA has previously declined to extend the anticancer clause to additives that create carcinogens in food. Specifically, in 1988, in its final rule on the use of dimethyl dicarbonate as a food additive, FDA stated:

“The agency now believes that the Delaney or anticancer clause is applicable only when the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer but that contains a carcinogenic constituent, or whose use will lead to the formation of trace amounts of a carcinogenic substance

⁵ International Agency for Research on Cancer (IARC). Some Carbamates, Thiocarbamates and Carbazides. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man, 1976.12: Available: <https://publications.iarc.who.int/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Some-Carbamates-Thiocarbamates-And-Carbazides-1976>

⁶ International Agency for Research on Cancer (IARC). Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1–42 IARC Monographs, Supplement 7. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Suppl 7, 1987. Available: <https://publications.iarc.who.int/Book-And-Report-Series/Iarc-Monographs-Supplements/Overall-Evaluations-Of-Carcinogenicity-An-Updating-Of-Iarc-Monographs-Volumes-1%E2%80%9342-1987>

⁷ WHO. Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Food Additive Series 55. FAO Food and Nutrition Paper 82. 2006. Available: <https://iris.who.int/server/api/core/bitstreams/c077017a-884c-4c28-892a-b99e572c46e0/content>

⁸ International Agency for Research on Cancer (IARC). Alcohol Consumption and Ethyl Carbamate. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, 2010. 96: Available: <https://publications.iarc.who.int/114>.

⁹ US National Toxicology Program. 15th Report on Carcinogens. Urethane. 2021. Available: <https://ntp.niehs.nih.gov/research/assessments/cancer/roc#:~:text=The%20U.S.%20Department%20of%20Health,prepares%20for%20the%20HHS%20Secretary>.

¹⁰ 21 USC 348(c)(3)(A)

¹¹ Public Citizen v. Young, 831 F.2d 1108, 1122 (D.C. Cir. 1987).

in or on food, may be properly evaluated under the general safety clause of the statute.”¹²

We argue that this overly stringent interpretation defies Congressional intent. Congress established a zero-tolerance policy for the addition of carcinogens to food via the Delaney Clause. It stands to reason that banning an unnecessary additive that inherently forms carcinogens in food is within the scope of Congress’ intent. Therefore, we argue that FDA should prohibit the use of ADA in food under the Delaney Clause, even if the agency finds the risk of cancer resulting from its use in food to be minimal.

Notably ADA is banned from being used in the EU as a dough-improver or flour-treatment agent in flour or as a food contact material.¹³ Importantly, FDA acknowledges that ADA “...is not necessary to make bread and there are alternative ingredients approved for use available.”³

We hope the FDA will complete its evaluation quickly and use its existing regulatory authorities to protect consumers from ADA.

Sincerely,



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¹² 53 Fed. Reg. 204. Direct Food Additives; Food Additives Permitted for Direct Addition to Food for Human Consumption; Dimethyl Dicarbonate

¹³ European Food Safety Authority. Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to Semicarbazide in food: Question number EFSA-2003-235. *EFSA Journal*. 2005; 219:1-36. Available: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2005.219>