July 13, 2026

Kyle Diamantas, J.D
Acting FDA Commissioner
Department of Health and Human Services
Food and Drug Administration
Docket No. FDA-2026-N-4126

RE: Environmental Working Group Comments on FDA's request for information on azodicarbonamide (ADA) in human food (Docket No. FDA-2026-N-4126)

The Environmental Working Group (EWG) urges the FDA to take decisive action to end the use of azodicarbonamide (ADA) as a direct food additive and as an indirect food additive. ADA is used as a food additive to improve dough handling and texture, not to enhance nutrition or food safety. Its use has dropped dramatically in the past decade. Toxicological concerns remain regarding semicarbazide, a breakdown product formed during baking, and effective alternatives to ADA are available. Therefore, EWG supports phasing ADA out of the food supply to reduce unnecessary exposure to its potentially hazardous breakdown products.

The availability and widespread commercial use of alternative dough conditioners, such as ascorbic acid, enzyme-based systems or malted barley flour, demonstrate that ADA is not essential for modern commercial baking.

EWG is a nonprofit public health and environmental research and advocacy organization, headquartered in Washington, D.C., with staff also based in Minneapolis and Sacramento. EWG's research focuses on understanding health risks from chemical contamination of food, water, consumer products and the environment, and on supporting a healthy indoor and outdoor environment for all communities.

The FDA first approved ADA as a direct food additive in 1962 for use as a flour treatment agent and dough conditioner in bread and other baked goods.

During dough preparation and baking, ADA breaks down into several compounds, including biurea, semicarbazide (SEM), ammonia and isocyanates. Experimental studies have demonstrated that baking bread made with ADA-treated flour results in the formation of SEM, which has been the focus of toxicological concern because of findings from laboratory and

animal studies suggesting potential concerns of carcinogenicity and genotoxicity (Noonan et al., 2008; Kumari et al., 2026). [1,2]

The formation of SEM during baking and other high-temperature food processing was first characterized in experimental studies of ADA-treated flour and bread (Noonan et al., 2008; Becalski et al., 2004).[1,3] In a 2016 survey of over 250 products, the FDA found levels of SEM can vary widely. The agency found that many products fell into a median range, between 100 and 400 parts per billion (ppb) but maximum outliers reached as high as 767 ppb for biscuits and 1,490 ppb for French and Vienna breads (FDA 2016).[4]

SEM has produced tumors in mice and demonstrated DNA-damaging activity in mechanistic studies. Although in vivo genotoxicity findings are inconsistent, the combination of carcinogenicity and genotoxic potential raises concerns (EFSA 2005; Hirakawa 2003).[5,6]

A rodent study found SEM to have hormone-disrupting properties, altering testosterone regulation male and female rats (Maranghi et al., 2009).[7] SEM has also shown it can harm the reproductive system, affecting sperm maturation in male mice even at low doses (Tian et al., 2014).[8] Animal studies have shown the metabolite may also damage other organs, such as the heart, liver and kidneys (Tian et al., 2014; Olofinnade et al., 2020).[8,9]

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[1] Noonan GO, Begley TH, Diachenko GW. (2008). Semicarbazide Formation in Flour and Bread. Journal of Agricultural and Food Chemistry, 56, 2064–2067. doi: 10.1021/jf073198g

[2] Kumari, D., Janmeda, P., & Singh, D. (2026). From food additive to health hazard? A review of azodicarbonamide, potassium bromate, and monosodium glutamate with in-silico toxicity analysis. Food Chemistry Advances, 10, 101239. https://doi.org/10.1016/j.focha.2026.101239.

[3] Becalski A, Lau BP-Y, Lewis D, Seaman SW. (2004). Semicarbazide Formation in Azodicarbonamide-Treated Flour: A Model Study. *Journal of Agricultural and Food Chemistry*, 52(18), 5730–5734. doi: 10.1021/jf0495385

[4] Food and Drug Administration, 2016. Exposure Estimate for Semicarbazide from the Use of Azodicarbonamide in Bread for the U.S. Population. (Presented at the 251st National Meeting of the American Chemical Society, March 15, 2016). https://www.fda.gov/media/97444/download.

[5] EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food, 2005. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to Semicarbazide in food. *EFSA Journal* 2005; 3(6):219, 141 pp. doi:10.2903/j.efsa.2005.219

[6] Hirakawa K, Midorikawa K, Oikawa S, Kawanishi S. (2003). Carcinogenic semicarbazide induces sequence-specific DNA damage through the generation of reactive oxygen species and the derived organic radicals. *Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis.* 2003;536(1–2):91–101. https://doi.org/10.1016/S1383-5718(03)00030-5

[7] Maranghi, F., Tassinari, R., Marcoccia, D., Altieri, I., Catone, T., De Angelis, G., Testai, E., Mastrangelo, S., Evandri, M. G., Bolle, P., & Lorenzetti, S. (2009). The food contaminant semicarbazide acts as an endocrine disrupter: Evidence from an integrated in vivo/in vitro approach. Chemico-Biological Interactions, 183(1), 40-48. https://doi.org/10.1016/j.cbi.2009.09.016.

[8] Tian, W., Sang, Y., & Wang, X. (2014). Semicarbazide – from state-of-the-art analytical methods and exposure to toxicity: a review. Food Additives & Contaminants Part A, 31(11), 1850–1860. https://doi.org/10.1080/19440049.2014.953012.

[9] Olofinnade, A.T., Onaolapo, A.Y., Onaolapo, O.J., Olowe, O.A., & Adeyeba, O.A. (2020). Food-added azodicarbonamide alters hematological parameters, antioxidant status and

Baking foods with ADA may also contribute to the formation of small amounts of urethane, or ethyl carbamate. This process contaminant forms when ethanol from yeast fermentation reacts with cyanate or carbamoyl-containing compounds, which can be derived from ADA's direct breakdown products like isocyanic acid. Urethane is a Group 2A probable human carcinogen (Abt et al., 2021).[10]

Repeated exposure to ADA led to dose-dependent decreases in weight and food consumption, oxidative stress and lipid peroxidation in rats (Olafinnade et al., 2020).[9] Oxidative stress and lipid peroxidation are associated with cellular and DNA damage and have been implicated in numerous diseases.

Formation of SEM is also a concern for food-contact materials using ADA within the production process, particularly gaskets used in lids for glass baby food jars (Nepalia et al 2017).[11]

The European Union never authorized ADA as a food additive but did allow it as a blowing agent (a substance that helps create foam) in food-contact plastics. In 2004, the EU prohibited the use of ADA in jar seals and gaskets intended for food contact because of concerns about the formation of SEM during heat sterilization.

In the U.S., New York lawmakers introduced a bill in 2017 to ban ADA in foods sold in the state, but it did not pass[12]

Whole Foods Market prohibits ADA in products sold in its stores. Aldi and Walmart have policies restricting ADA in many or all of their private-label food products. Panera and Subway removed ADA from their bread products in 2014.

EWG maintains a searchable food products database, Food Scores,[13] containing thousands of products with product label information provided by LabelINSIGHT®[14]. In a subset of this data consisting of new product labels recorded between 2023 and 2025, EWG identified

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biochemical/histomorphological indices of liver and kidney injury in rats. Journal of Basic and Clinical Physiology and Pharmacology, 32(2), 39-50. https://doi.org/10.1515/jbcpp-2019-0341.

[10] Abt, E., Incorvati, V., Posnick Robin, L. and Redan, B.W., 2021. Occurrence of Ethyl Carbamate in Foods and Beverages: Review of the Formation Mechanisms, Advances in Analytical Methods, and Mitigation Strategies. Journal of Food Protection, 84(12), pp. 2195-2212 https://doi.org/10.4315/JFP-21-219

[11] Nepalia, A., Singh, A., Mathur, N., & Pareek, S. (2017). Baby foods can also have toxic side effects: A review. Asian Journal of Science and Technology, 8(3), 4386-4393. https://www.journalajst.com/baby-foods-can-also-have-toxic-side-effects-review

[12] New York State Assembly. (2017). *A5063 (2017–2018 Regular Session): An act to amend the agriculture and markets law, in relation to prohibiting the manufacture and sale of food products containing azodicarbonamide.* New York State Legislature. Available at:https://www.nysenate.gov/legislation/bills/2017/A5063

[13] EWG's Food Scores. 2026. https://www.ewg.org/foodscores/

[14] NIQ Label Insight. https://nielseniq.com/global/en/landing-page/label-insight/

approximately 172,000 food products. Of these products, 60 contain ADA, demonstrating that ADA is now used in only a small fraction of newly introduced food products.

The top grocery aisles include: deli, bakery and frozen foods (see Figure 1). The leading product categories in this aisles containing ADA include sandwiches and subs; breads and buns; and frozen appetizers and hor d'oeuvres (see Figure 2). In 2014, EWG completed a similar analysis and identified nearly 500 foods sold under 130 different brands listing the use of ADA.[15]

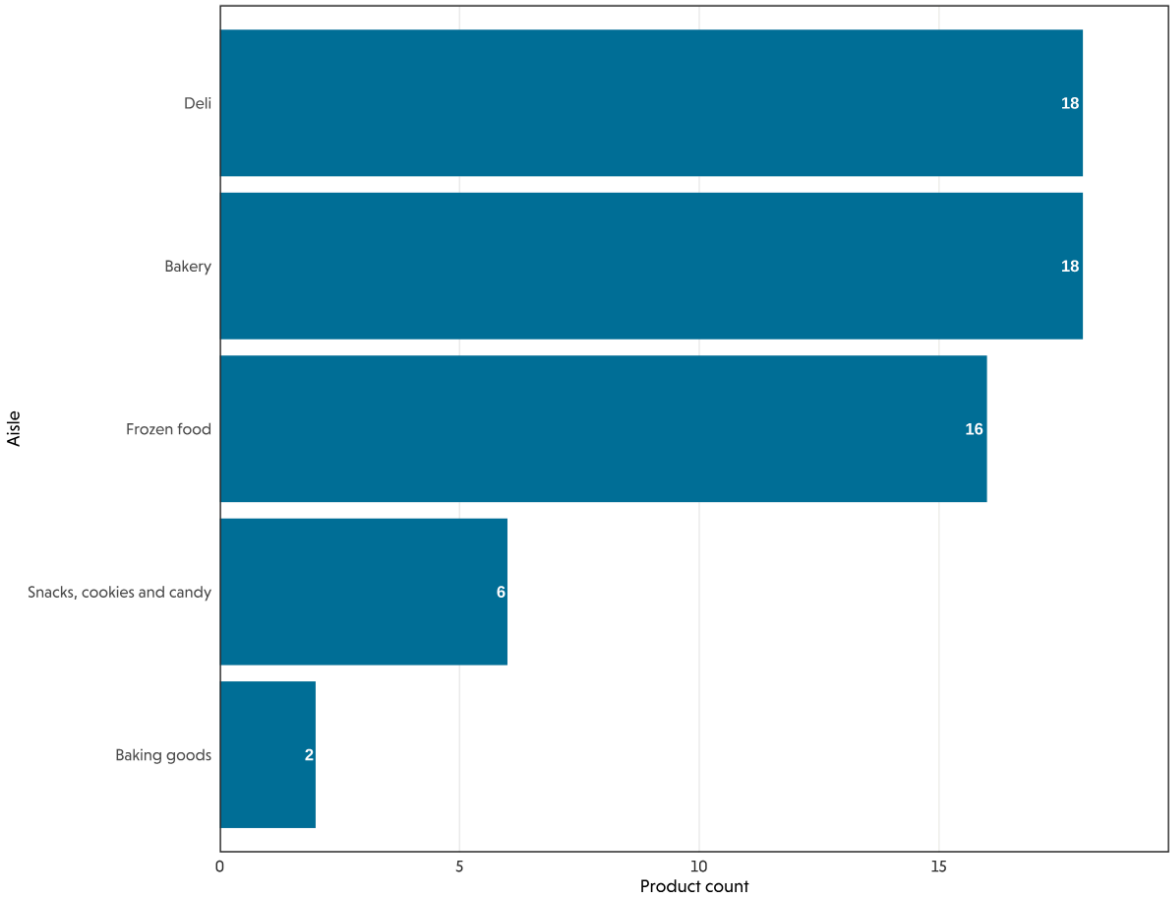

Figure 1. Number of products containing ADA in EWG's Food Scores database grocery aisles.

[15] EWG 2014. https://www.ewg.org/research/nearly-500-ways-make-yoga-mat-sandwich

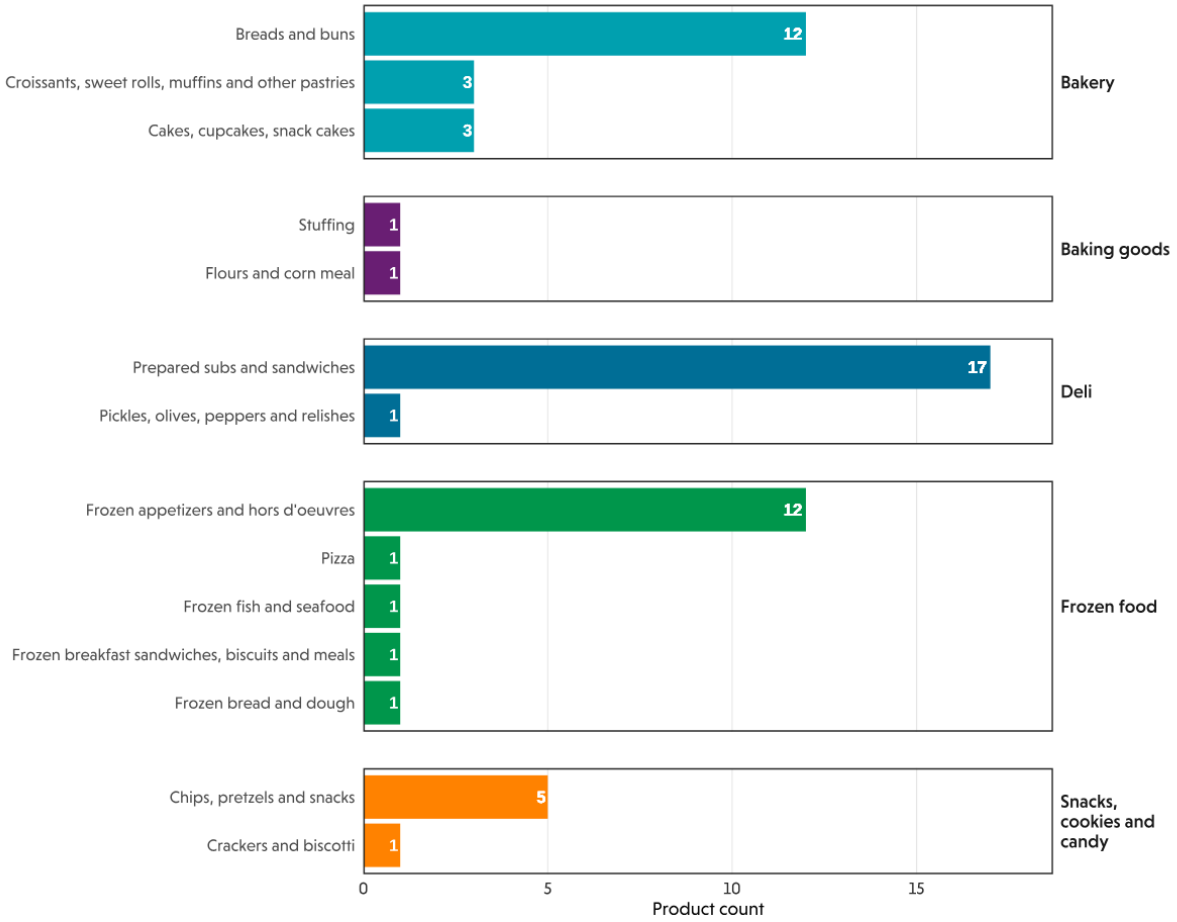

Figure 2. Number of products containing ADA in Food Scores by product categories from the top five grocery aisles.

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EWG appreciates the opportunity to provide these comments and strongly urges the FDA to move swiftly to ban the use of ADA as a direct and indirect additive in foods.

Submitted on behalf of EWG,

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