CENTER FOR Science IN THE Public Interest
Your Food and Health Watchdog

April 13, 2026

Martin Makary, MD, MPH
Commissioner of Food and Drugs
US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Butylated Hydroxyanisole (BHA); Request for Information (Docket No. FDA-2026-N-0302)

Dear Commissioner Makary,

The Center for Science in the Public Interest (CSPI) respectfully submits these comments in response to Docket No. FDA-2026-N-0302. We appreciate 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 butylated hydroxyanisole (BHA) following its inclusion in the FDA's List of Select Chemicals in the Food Supply Under FDA Review in February.[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 aim to improve the nutritional quality and safety of foods and beverages in the U.S.

At present, BHA is approved for use as an antimicrobial agent, antioxidant, dough strengthener, flavor enhancer, flour treating agent, and oxidizing or reducing agent in a variety of food products in the US[2] despite concerns regarding carcinogenicity. BHA is currently listed in the US National Toxicology Program's (NTP) Report on Carcinogens report as "reasonably anticipated to be a human carcinogen based on sufficient evidence from experimental animal studies."[3] However, the Delaney Clause in the Food, Drug, and Cosmetic Act expressly prohibits the approval of food additives shown to cause cancer in humans or animals.[4] BHA was first listed in the Report on Carcinogens in 1991, meaning the agency has had 35 years to take the statutorily obligatory step to prohibit the use of BHA in foods. NTP found that BHA caused tumors in the forestomach of rats, mice, and hamsters. While the relevance of

[1] US Food and Drug Administration. FDA Launches Assessment of BHA, a Common Food Chemical Preservative. February 10, 2026. https://www.fda.gov/news-events/press-announcements/fda-launches-assessment-bha-common-food-chemical-preservative
[2] US Food and Drug Administration. Substances Added to Food (formerly EAFUS): BUTYLATED HYDROXYANISOLE. https://hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FoodSubstances&id=BUTYLATEDHYDROXYANISOLE
[3] US National Toxicology Program. Report on Carcinogens, Fifteenth Edition: Butylated Hydroxyanisole. https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/butylatedhydroxyanisole.pdf
[4] 21 USC 348(c)(3)(A)

forestomach tumors to human risk assessment is controversial among scientific experts,[5,6,7,8] the Delaney Clause is silent on the matters of tumor site and mechanisms of carcinogenesis, and it does not contain a de minimus exception.[9] Therefore, FDA must conclude that BHA is unsafe and prohibit its use as a food additive even if the agency determines that the risk to humans is small.

Some uses of BHA are also regulated as GRAS which lower-level courts have found are exempt from the Delaney Clause.[10] We argue that this interpretation defies legislative intent; Congress clearly intended for novel food substances to come to market via the FDA pre-market approval process, not the GRAS process, and therefore, clearly intended for carcinogenic substances to be prohibited from use in food. It defies common sense for substances not reviewed by FDA (secret GRAS substances) to be subject to a lower standard than the ones FDA actually reviews. Therefore, FDA should declare that BHA is not GRAS on the basis of the cancer evidence. Additionally, concern has been raised about other adverse effects of BHA. A 2025 evaluation by the European Commission's Scientific Committee on Consumer Safety (SCCS) found that "Available information indicated weak anti-estrogenic activity of BHA. Based on *in vivo* studies of limited quality, some effects on sperm pointing to antiandrogenic modalities can be seen. The SCCS is of the view that the overall evidence is not robust enough to clearly suggest an endocrine mode of action of BHA."[11] In addition, in 1978, the FDA's own Select Committee on GRAS Substances (SCOGS) found that uncertainties regarding liver enzymes induction existed that required additional studies to be conducted.[12] It is unclear whether the FDA has sufficiently resolved those uncertainties. If those uncertainties have not been sufficiently resolved, the agency might conclude that "a reasonable certainty of no harm," the standard for an additive to be FDA-approved or to be a GRAS substance, has not been established for the use of BHA in foods.

Further it is unclear whether the agency has considered the cumulative effects of chemically and pharmacologically related chemicals—as required by statute[13]—such as butylated hydroxytoluene (BHT)

---

[5] International Agency for Research on Cancer (IARC). Predictive Value of Rodent Forestomach and Gastric Neuroendocrine Tumours in Evaluating Carcinogenic Risks to Humans: Views and expert opinions of an IARC Working Group Lyon, 29 November-1 December 1999. IARC Technical Publication No. 39. 2003. https://monographs.iarc.who.int/wp-content/uploads/2022/09/IARC_2003.Tech-Pub_No.39Summary_Reports.pdf.

[6] Labib S., et al. Toxicogenomic Outcomes Predictive of Forestomach Carcinogenesis Following Exposure to Benzo(a)pyrene: Relevance to Human Cancer Risk. Toxicology and Applied Pharmacology. 2013;73:269–280.

[7] Moch, RW. Forestomach Lesions Induced by Butylated Hydroxyanisole and Ethylene Dibromide: A Scientific and Regulatory Perspective. Toxicologic Pathology. 1988; 16(2)

[8] Proctor DM, et al. Mode-of-Action Framework for Evaluating the Relevance of Rodent Forestomach Tumors in Cancer Risk Assessment. Toxicological Sciences. 2007;98(2):313–326.

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

[10] Ctr. for Food Safety v. Becerra, 565 F. Supp. 3d 519, 542-43 (S.D.N.Y. 2021). Available at P. 34 of https://www.cspi.org/sites/default/files/2021-11/GRAS%20District%20Court%20Decision.pdf.

[11] European Commission. Scientific Committee on Consumer Safety (SCCS). Scientific Advice on Butylated Hydroxyanisole (BHA). November 17, 2025. https://health.ec.europa.eu/document/download/502956f3-471d-4e2d-899f-08aa4511bb90_en?filename=sccs_o_306.pdf

[12] US Food and Drug Administration. Select Committee on GRAS Substances (SCOGS) Opinion: Butylated Hydroxyanisole(BHA). https://wayback.archive-it.org/7993/20171031063106/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm260874.htm

[13] 21 USC 348(c)(5)(B).

and tert-butylhydroquinone (TBHQ), a metabolic product of BHA, both of which are sometimes used in conjunction with BHA in food formulations.[14] Such an analysis is necessary before a conclusion of "a reasonable certainty of no harm" can be reached. In making these considerations, the agency should implement its draft post-market assessment framework with the revisions that CSPI proposed in comments we submitted to the agency in January 2025. These included recommendations to improve the quantity and quality of hazard and exposure data available for chemicals under evaluation, exclude non-risk considerations (e.g., cost, feasibility) from its risk assessments to ensure that public health protection is the primary factor driving decision-making, and promote rigor and transparency by developing a centralized database for publishing its completed assessments and subjecting assessments to external peer review.[15]

While we are encouraged that the FDA is requesting information on the use and safety of BHA in food, we hope the FDA will move swiftly through the post-market assessment procedure it has articulated in its draft Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food and fulfill its statutory obligation to ban BHA from food.

Sincerely,

Thomas Galligan, PhD
Principal Scientist for Food Additives and Supplements
Center for Science in the Public Interest

Jannah Tauheed, ScD, MPH, MS
Staff Scientist for Food Additives
Center for Science in the Public Interest

[14] European Food Safety Authority. Scientific Opinion on the Re-evaluation of Butylated Hydroxyanisole–BHA (E 320) as a Food Additive. EFSA Journal 2011;9(10):2392. Available: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2392.

[15] Center for Science in the Public Interest. Comment RE: Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food. January 21, 2025. Available: https://www.cspi.org/sites/default/files/2025-01/CSPI%202025%20Written%20Comments%20Post-market%20Assessment.pdf .