



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-2526

RE: Environmental Working Group Comments on FDA's request for information on butylated hydroxytoluene (BHT) in human food (Docket No. FDA-2026-N-2526)

The Environmental Working Group (EWG) urges the FDA to remove butylated hydroxytoluene (BHT) from food. Experimental animal studies provide strong evidence that BHT causes liver toxicity, demonstrates tumor-promoting activity in experimental models and produces liver tumors in long-term rodent studies.^{1,2,3} Animal studies have also found developmental effects and changes in thyroid hormone homeostasis, including altered thyroid hormone levels and thyroid gland weight, suggesting BHT may disrupt endocrine signaling.⁴

Although evidence from long-term human studies is limited, the consistency of the findings in experimental animals raises safety concerns about the continued use of BHT as a food additive.

Considering these findings, the additional studies that have accumulated post-FDA approval, and the current use data provided in this letter, the FDA should conclude that continued use of BHT as a food additive does not meet the statutory standard of reasonable certainty of no harm and should revoke approval for its use in food.

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,

¹EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). (2012). Scientific Opinion on the re-evaluation of butylated hydroxytoluene (BHT) (E 321) as a food additive. *EFSA Journal*, 10(3):2588. doi: [10.2903/j.efsa.2012.2588](https://doi.org/10.2903/j.efsa.2012.2588)

² Vikis HG, Gelman AE, Franklin A, Stein L, Rymaszewski A, Zhu J, Liu P, Tichelaar JW, Krupnick AS, You M. Neutrophils are required for 3-methylcholanthrene-initiated, butylated hydroxytoluene-promoted lung carcinogenesis. *Mol Carcinog*. 2012 Dec.; 51(12):993-1002. doi: [10.1002/mc.20870](https://doi.org/10.1002/mc.20870)

³ Colin T. Shearn, Kristofer S. Fritz & John A. Thompson. 2011. Protein damage from electrophiles and oxidants in lungs of mice chronically exposed to the tumor promoter butylated hydroxytoluene. *Chemico-biological interactions* 192(3), 278-86 doi: [10.1016/j.cbi.2011.04.005](https://doi.org/10.1016/j.cbi.2011.04.005)

⁴ Søndergaard D, Olsen P. The effect of butylated hydroxytoluene (BHT) on the rat thyroid. *Toxicol Lett*. 1982 Feb;10(2-3):239-44. doi: [10.1016/0378-4274\(82\)90081-9](https://doi.org/10.1016/0378-4274(82)90081-9)



water, consumer products and the environment, and on supporting a healthy indoor and outdoor environment for all communities.

The FDA approved BHT for certain uses as a food additive in 1954. In 1959, BHT was also determined to be “generally recognized as safe” (GRAS) for certain uses. Although the U.S. still permits BHT as a food additive, subsequent research has identified concerns regarding chronic toxicity, tumor-promoting activity, and potential endocrine effects that warrant renewed regulatory review.

The European Food Safety Authority (EFSA) identified the liver as a target organ for BHT toxicity and considered evidence of thyroid, developmental, and reproductive harm in its safety evaluation (EFSA, 2012).⁵

Animal studies demonstrate that BHT produces adverse effects in multiple organ systems, with the liver consistently identified as a target organ. Repeated exposure to BHT has been associated with increased liver weight, hepatic enzyme induction, and histopathological changes in rodents (EFSA, 2012; Xu et al., 2021).⁶ Long-term studies have also reported liver tumor findings in rodents, although the mechanisms and human relevance remain under evaluation (EFSA, 2012).⁵

In addition, BHT has demonstrated tumor-promoting activity in experimental models. In a well-established two-stage mouse lung carcinogenesis model, BHT enhanced chemically initiated lung tumor development through inflammatory mechanisms involving neutrophil recruitment, providing a biologically plausible mechanism for tumor promotion (Vikis et al., 2012).⁷ Earlier studies similarly demonstrated that BHT promoted lung tumor formation (Witschi et al., 1983).⁸

BHT has also been associated with potential endocrine-related effects. Animal studies have reported altered thyroid hormone homeostasis, including changes in thyroid hormone levels and thyroid gland weight, suggesting that BHT may disrupt thyroid hormone regulation (EFSA, 2012; Lanigan and Yamarik, 2002).⁹ Developmental and reproductive effects have also been reported

⁵EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). (2012). Scientific Opinion on the re-evaluation of butylated hydroxytoluene (BHT) (E 321) as a food additive. *EFSA Journal*, 10(3):2588. doi: [10.2903/j.efsa.2012.2588](https://doi.org/10.2903/j.efsa.2012.2588)

⁶ Xu, X., Liu, A., Hu, S., Ares, I., Martínez-Larrañaga, M.-R., Wang, X., Martínez, M., Anadón, A., & Martínez, M.-A. (2021). Synthetic phenolic antioxidants: Metabolism, hazards and mechanism of action. *Food Chemistry*, 353, Article 129488. <https://doi.org/10.1016/j.foodchem.2021.129488>

⁷ Vikis HG, Gelman AE, Franklin A, Stein L, Rymaszewski A, Zhu J, Liu P, Tichelaar JW, Krupnick AS, You M. Neutrophils are required for 3-methylcholanthrene-initiated, butylated hydroxytoluene-promoted lung carcinogenesis. *Mol Carcinog*. 2012 Dec.; 51(12):993-1002. doi: [10.1002/mc.20870](https://doi.org/10.1002/mc.20870)

⁸ Witschi HP. Promotion of lung tumors in mice. *Environ Health Perspect*. 1983 Apr.; 50:267-73. <https://pubmed.ncbi.nlm.nih.gov/6873018/>

⁹ Lanigan, R.S., & Yamarik, T.A. (2002). Final report on the safety assessment of BHT(1). *International journal of toxicology*, 21 Suppl. 2, 19–94. <https://doi.org/10.1080/10915810290096513>

in experimental animals, including effects on offspring development and reproductive tissues, although the relevance of these findings to humans remains uncertain (EFSA, 2012).⁵

While long-term epidemiological data in humans are limited, the absence of adequate human studies does not establish safety; rather, it represents a significant uncertainty for a food additive consumed chronically over a lifetime.

Some states have acted in response to concerns about BHT. Indiana proposed to ban BHT and a number of other food additives through a bill, HB 1376, (2026), although the legislation did not advance.¹⁰ Louisiana's 2025 law, SB 14, banned serving foods containing BHT (along with other additives) in school meals.¹¹

Several major food retailers and manufacturers have voluntarily removed BHT from many products, including through ingredient standards and product reformulations. Whole Foods Market prohibits BHT in foods sold in its stores. General Mills committed to removing BHT from cereal and Pizza Hut removed BHT, along with the additive BHA, from its meats in 2016.

EWG maintains a searchable food products database, Food Scores,¹² containing thousands of products with product label information provided by LabelINSIGHT®¹³. In a subset of this data consisting of new product labels recorded between 2023 and 2025, there are 172,000 food products. Of these products, 2,974 contain BHT. The top grocery aisles include snacks, cookies and candy; frozen foods; cereal and breakfast foods; deli; and bakery items (see Figure 1). Further broken down into product categories, the data show the leading product categories containing BHT include frozen pizza; cereal; and chewing gum and mints (see Figure 2).

¹⁰ Indiana General Assembly. (2026). *House Bill 1376: Prohibited food additives* (Second Regular Session, 124th General Assembly). Introduced Jan. 8, 2026.

<https://iga.in.gov/legislative/2026/bills/house/1376/details>

¹¹ Louisiana Legislature. (2025). *Senate Bill No. 14: Public health—Provides relative to nutrition* (2025 Regular Session). Act No. 463. Signed by the governor. <https://legis.la.gov/legis/BillInfo.aspx?i=247976>

¹² EWG's Food Scores. 2026. <https://www.ewg.org/foodscores/>

¹³ NIQ Label Insight. <https://nielseniq.com/global/en/landing-page/label-insight/>

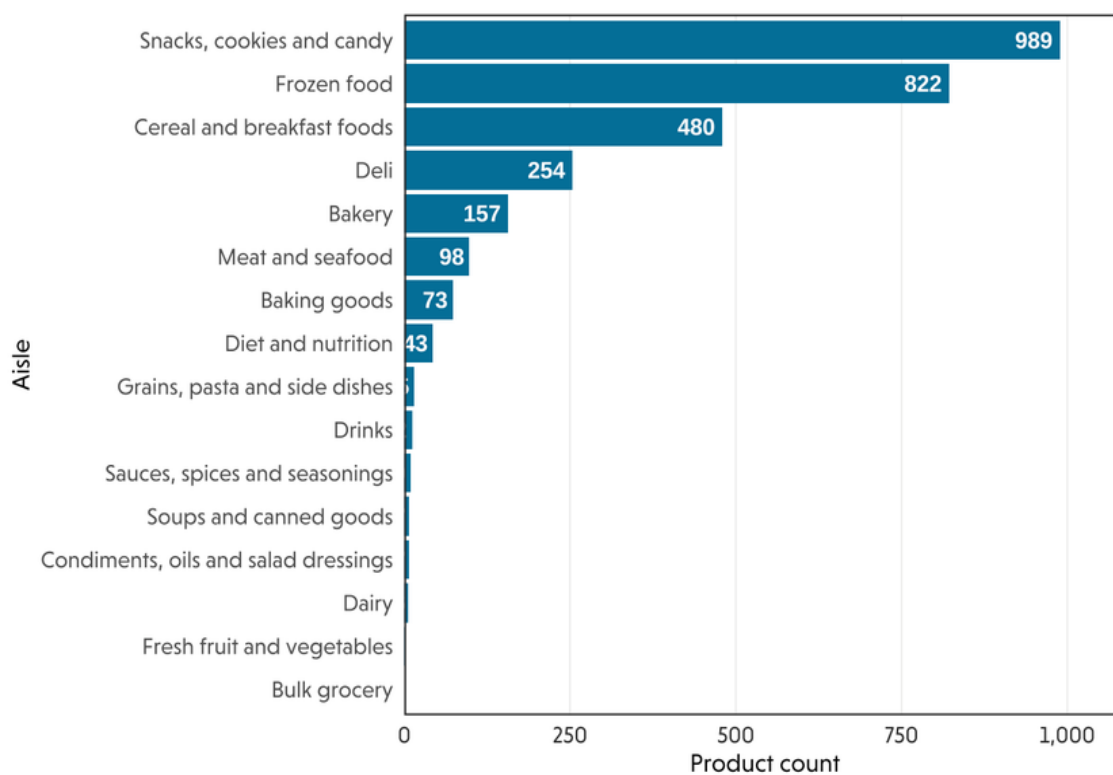


Figure 1. Number of products containing BHT in EWG's Food Scores database by grocery aisle.

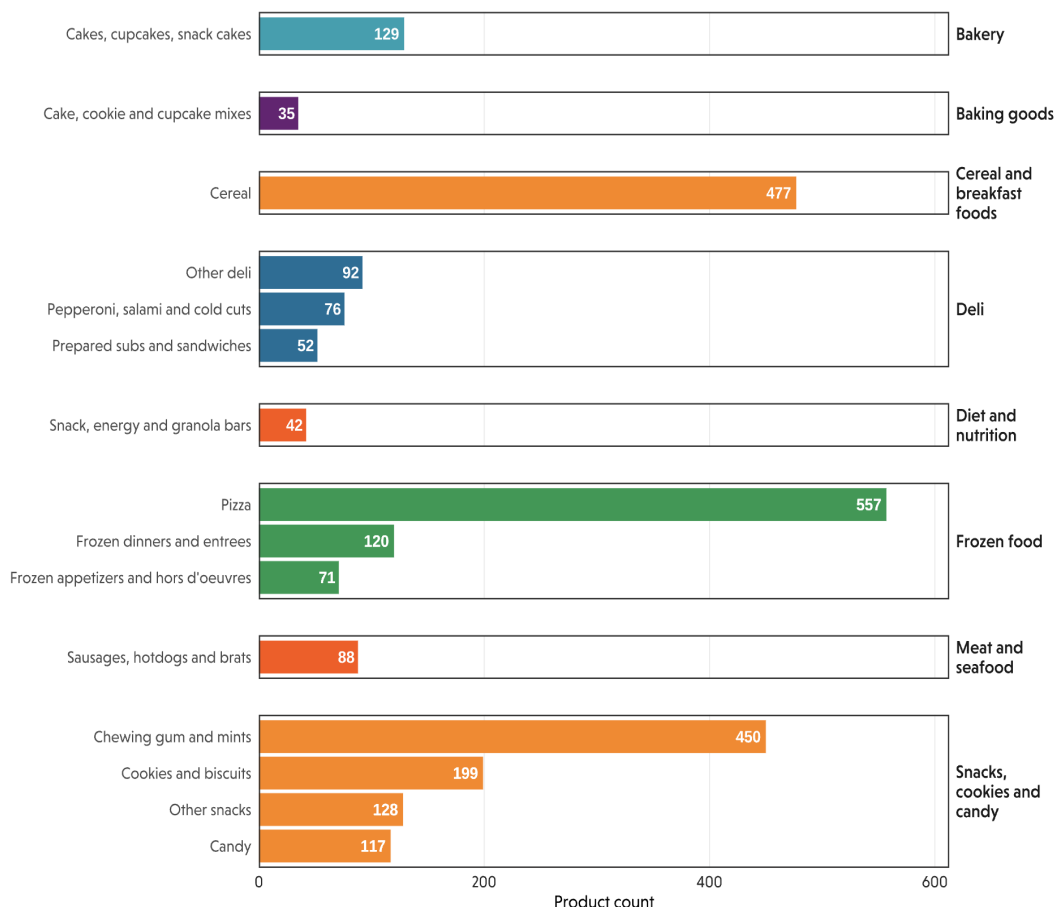


Figure 2. Number of products containing BHT in Food Scores by product category among the top five grocery aisles.

Dietary exposure to BHT is likely non-uniform across populations, as it is primarily present in processed foods such as frozen pizza, cereal, and chewing gum. These food categories are commonly consumed by children, making dietary exposure among children and individuals who consume higher amounts of processed foods an important consideration.



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EWG appreciates the opportunity to provide these comments and strongly urges the FDA to move swiftly to revoke approval for the use of BHT in food.

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