National Pork Producers Council

The Global Voice for the U.S. Pork Industry

National Pork Producers Council
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U.S. Food and Drug Administration
Dockets Management Staff
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: ***Butylated Hydroxytoluene (BHT); Request for Information (Docket. No. FDA-2026-N-2526)***

The National Pork Producers Council (NPPC) appreciates the opportunity to submit comments to the U.S. Food and Drug Administration (FDA) regarding the Request for Information (RFI) on Butylated Hydroxytoluene (BHT). NPPC is the global voice of the U.S. pork industry, representing 42 affiliated state organizations and more than 60,000 pork producers committed to producing safe, wholesome, nutritious, and affordable pork products. Protecting consumer health while maintaining a safe and secure food supply remains the highest priority of the U.S. pork industry.

NPPC commends FDA for conducting a science-based post-market assessment of the current uses and safety of BHT in human food and food-contact materials. We appreciate the Agency's commitment to periodically reviewing food additives using the best available scientific evidence while considering technological necessity, consumer exposure, and public health.

BHT has served as a safe and effective antioxidant in the food supply for decades. When used within FDA-authorized limits, BHT helps prevent oxidative deterioration of fats and oils, maintains product quality, extends shelf life, reduces food waste, and supports domestic and international commerce. Numerous evaluations conducted by FDA, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and other international scientific bodies continue to conclude that BHT is safe for its intended uses.

The regulated use of BHT remains an important component of modern food preservation technologies. Its continued availability supports food safety, product quality, sustainability, and international regulatory harmonization while maintaining appropriate consumer protections through established exposure limits.

NPPC respectfully provides the following responses to FDA's questions.

1. General food categories in which BHT is used

BHT is a synthetic phenolic antioxidant widely used throughout the global food supply to delay oxidation of fats and oils. Oxidative rancidity reduces food quality by producing undesirable flavors and odors, degrading nutrients, shortening shelf life, and increasing food waste. By interrupting free-radical chain reactions, BHT helps preserve product quality throughout manufacturing, storage, transportation, and retail distribution.

Within the United States, BHT is authorized for use in numerous food categories regulated by FDA, including edible fats and oils, breakfast cereals, snack foods, bakery products, dehydrated potatoes, chewing gum, flavoring materials, and select meat and poultry products. In pork production, BHT is commonly incorporated into rendered pork fat, processed pork products, sausage formulations, cured meats, and other fat-containing products where oxidative stability is essential for maintaining flavor, color, texture, nutritional quality, and food safety.

FDA regulations authorize BHT for multiple intended uses, including direct food additive applications, Generally Recognized as Safe (GRAS) uses under specified conditions, animal feed ingredients, and certain food-contact materials. Internationally, Codex Alimentarius also recognizes BHT for use in numerous fat-containing foods, supporting harmonized international food standards and facilitating global trade.

The continued safe use of BHT reflects decades of successful regulatory oversight, scientific evaluation, and technological necessity. Its effectiveness at low concentrations, excellent thermal stability, and compatibility with numerous food systems make BHT an important tool for maintaining food quality while minimizing spoilage and unnecessary food waste.

Because Codex standards frequently serve as international benchmarks for food additive regulation, harmonization of BHT standards provides regulatory consistency for exporters while reducing technical barriers to trade. These harmonized standards are particularly important for U.S. pork exports that require extended refrigerated or frozen storage and long-distance transportation.

2. Typical and maximum use levels of BHT

In both U.S. and Codex regulatory frameworks, BHT safe use levels are clearly defined.

Under 21 C.F.R. § 182.3173, the U.S. permits a maximum of 0.02% (200 ppm) based on the fat or oil content of a food, and its application in meat products is specifically calculated relative to fat rather than total product weight. Under 21 C.F.R. § 181.24, BHT is a prior-sanctioned antioxidant for food-

packaging materials, permitting incidental migration into food up to 0.005% (50 ppm) by weight. Additionally, as stated in Question 1, BHT is codified as being safe for use under a wide variety of regulations with strict safety limits.

Codex standards similarly permit maximum levels of approximately 200 mg/kg (200 ppm) in fats and oils and 100–200 mg/kg (100-200 ppm) in processed meat products, establishing harmonized limits that support consistency across international markets and help facilitate global trade.

Codex Alimentarius similarly establishes maximum use levels for BHT in edible fats and oils, processed meat products, bakery products, snack foods, and other fat-containing foods. These internationally recognized limits promote regulatory consistency while ensuring consumer exposure remains well below established safety thresholds.

Current authorized use levels have proven effective in controlling lipid oxidation while maintaining wide margins of safety. The combination of conservative regulatory limits and relatively low dietary exposure provides continued confidence that BHT can be safely used for its intended technological purposes.

3. Current food-contact uses of BHT

In addition to direct food applications, BHT functions as an antioxidant in food-contact materials, including polymeric packaging, plastic resins, coatings, adhesives, elastomers, and other packaging components. Within these materials, BHT inhibits oxidative degradation of the packaging itself, helping maintain structural integrity and product performance throughout storage and distribution.

Migration studies consistently demonstrate that transfer of BHT from food-contact materials into food is extremely low and contributes only a small fraction of overall dietary exposure. FDA's safety evaluations consider cumulative exposure from both direct food uses and food-contact applications, ensuring total consumer exposure remains within established acceptable intake levels.

The continued use of BHT in food-contact materials contributes to food quality, packaging durability, reduced product spoilage, and overall sustainability throughout the food supply chain while maintaining appropriate consumer safety protections.

4. Subpopulations with high BHT dietary exposure or particular safety concerns relevant to food and food-contact uses of BHT

Dietary exposure to BHT remains low for the general U.S. population because it is used at low concentrations under well-defined regulatory limits. Individuals who consume relatively large quantities of processed foods containing fats and oils—including processed meats, snack foods, cereals, and bakery products—may experience higher dietary exposure than the average consumer. Likewise, infants, children, and adolescents may have higher exposure on a body-weight basis due to greater food consumption relative to body mass.

Despite these differences, comprehensive dietary exposure assessments conducted by national and international regulatory agencies consistently conclude that estimated intakes remain well below the established Acceptable Daily Intake (ADI). The JECFA established an ADI of **0–0.3 mg/kg body weight/day**, incorporating substantial uncertainty factors to ensure protection of sensitive populations. Subsequent evaluations by international scientific authorities have reaffirmed that current dietary exposures are well within these conservative safety margins.

FDA's existing regulations governing BHT use in food and food-contact materials continue to provide appropriate protection for consumers, including individuals with relatively higher dietary exposure.

5. Other dietary sources of BHT, such as dietary supplements, residues in animal products, natural occurrence, or contaminants

Beyond its intentional use as a food antioxidant, BHT may be present in small amounts through several additional exposure pathways. BHT is authorized for use as an antioxidant in certain animal feeds, where it protects feed ingredients from oxidative degradation during storage. Although trace residues may occur in edible animal products, available evidence indicates that these residues contribute minimally to overall human dietary exposure.

BHT may also be used in certain dietary supplements and pharmaceutical formulations to stabilize fat-soluble vitamins and other oxidation-sensitive ingredients. These uses are similarly regulated and generally represent a minor contribution to total exposure.

Unlike naturally occurring antioxidants such as tocopherols, BHT is a synthetic compound and is not naturally present in foods. Background exposure from environmental sources or food-contact materials remains very low compared with intentional food additive uses.

Collectively, these additional exposure sources represent only a small fraction of total dietary intake and have been incorporated into cumulative exposure assessments performed by regulatory agencies.

6. Market share of foods and food-contact materials formulated with BHT

BHT is widely used, in safe amounts, in rendered animal fats and shelf-stable processed pork products, where it serves as a cost-effective antioxidant with strong thermal stability. The ingredient remains especially valuable in products containing animal fats, where oxidative stability is essential for maintaining product quality throughout manufacturing, storage, transportation, and retail distribution.

Within the pork industry, BHT is commonly incorporated into rendered fats, processed pork products, cured meats, sausage formulations, and other shelf-stable products to delay lipid oxidation, preserve flavor and color, and reduce product losses associated with rancidity.

While several alternative antioxidants—including mixed tocopherols, rosemary extract, green tea extract, grape seed extract, and ascorbyl palmitate—are commercially available, each presents limitations that currently prevent complete replacement of BHT across all applications. Industry experience and published scientific literature indicate these alternatives often:

- provide less consistent oxidative protection in high-fat food systems;
- exhibit lower thermal stability during cooking or processing;
- impart undesirable flavor, aroma, or color characteristics;
- require substantially higher inclusion rates to achieve comparable antioxidant performance;
- increase ingredient and formulation costs; and
- demonstrate greater variability among food matrices.

For these reasons, BHT continues to represent a technologically necessary antioxidant for numerous food applications. Its consistent performance allows manufacturers to maintain product quality, reduce food waste, improve supply-chain efficiency, and provide consumers with safe, affordable food products.

7. Biomonitoring data for BHT or its metabolites

Available biomonitoring studies indicate that BHT is efficiently absorbed, metabolized, and eliminated following dietary exposure. After ingestion, BHT undergoes extensive hepatic metabolism to several

well-characterized metabolites that are rapidly excreted, primarily through urine, with smaller amounts eliminated in feces.

Human biomonitoring investigations consistently demonstrate low background concentrations of BHT metabolites in the general population. These findings are consistent with dietary exposure estimates showing that typical intake remains substantially below internationally recognized safety thresholds.

Importantly, available evidence does not indicate bioaccumulation of BHT in human tissues under normal dietary exposure conditions. The compound's rapid metabolism and elimination, combined with conservative regulatory exposure limits, provide additional assurance that authorized uses of BHT do not present a significant public health concern.

Overall, biomonitoring data support the conclusion that current dietary exposure to BHT remains low, predictable, and consistent with the compound's long-established safety profile.

8. Updated market disappearance or poundage data for BHT

BHT continues to be one of the most widely used synthetic antioxidants in the global food industry because of its effectiveness, versatility, and cost efficiency. Although precise U.S. poundage data are considered proprietary and are not publicly reported, market analyses consistently indicate that BHT remains an important ingredient in the manufacturing of processed foods, edible fats and oils, meat and poultry products, animal feeds, food-contact materials, and other oxidation-sensitive products.

Global market reports project continued demand for BHT over the coming decade, driven by increasing food production, expanded international trade, and the need to reduce food loss through improved shelf-life stability. Demand is particularly strong in applications requiring thermal stability and long-term oxidative protection, including rendered fats, processed meats, snack foods, and edible oils.

For the pork industry, BHT remains an effective antioxidant that helps preserve product quality throughout refrigerated, frozen, and export distribution channels. Continued availability of BHT supports manufacturing efficiency, minimizes product losses due to oxidative spoilage, and contributes to a more sustainable food system by reducing unnecessary food waste.

9. Information on potential chemically or pharmacologically related substances used in food or as food-contact substances

BHT belongs to a class of phenolic antioxidants that includes Butylated Hydroxyanisole (BHA), propyl gallate, tertiary-butylhydroquinone (TBHQ), and several naturally derived antioxidants, including mixed

tocopherols and rosemary extract. These compounds function by interrupting free-radical chain reactions that initiate lipid oxidation.

Among these antioxidants, BHT is frequently used in combination with BHA and propyl gallate because their complementary antioxidant mechanisms provide broader protection than any single antioxidant alone. BHT is particularly effective during later stages of lipid oxidation and demonstrates excellent thermal stability during food processing, while BHA provides strong protection during earlier stages of oxidation. Propyl gallate further enhances antioxidant performance by scavenging free radicals and regenerating phenolic antioxidants.

The combined use of these antioxidants allows manufacturers to use lower concentrations of each ingredient while achieving greater oxidative stability in high-fat foods. This synergistic approach has been widely adopted for products such as rendered fats, processed meats, and edible oils where preservation of flavor, color, texture, and nutritional quality is essential.

Although naturally derived antioxidants continue to receive increased commercial interest, currently available alternatives do not consistently provide equivalent oxidative protection across all food systems. Consequently, BHT remains an important component of many antioxidant systems used throughout the food industry.

10. Safety data relevant to use of BHT in food or as a food-contact substance

The safety of BHT has been extensively evaluated for more than six decades by FDA, JECFA, the European Food Safety Authority (EFSA), and numerous independent scientific organizations. These evaluations include acute, subchronic, chronic, reproductive, developmental, and genotoxicity studies, as well as comprehensive dietary exposure assessments.

Collectively, these reviews conclude that BHT can be safely consumed when used within established regulatory limits. Current authorized uses incorporate conservative exposure assumptions and substantial uncertainty factors to ensure protection of consumers, including sensitive populations.

Although some experimental animal studies have reported adverse effects following exposure to very high doses of BHT, these findings generally occurred at exposure levels many times greater than those experienced through normal dietary consumption. Regulatory agencies have consistently concluded that these studies do not demonstrate a meaningful risk to consumers under approved conditions of use because typical dietary exposure remains well below the established ADI.

The extensive toxicological database supporting BHT has been strengthened by decades of practical use in the food supply without evidence of adverse public health outcomes attributable to approved food

additive uses. Continued monitoring by FDA and international regulatory authorities further supports the conclusion that BHT remains safe under existing conditions of use.

11. Additional information relevant to FDA's evaluation

NPPC encourages FDA to continue employing a transparent, science-, and risk-based approach when evaluating food additives. Post-market reviews should consider the totality of available scientific evidence, including hazard identification, dietary exposure, technological necessity, and the substantial public health benefits associated with preventing food spoilage.

In addition to protecting food quality, antioxidants such as BHT contribute to national and global sustainability goals by reducing food waste throughout manufacturing, transportation, retail distribution, and consumer storage. These benefits should be considered alongside toxicological evaluations when assessing the continued authorization of food additives.

12. Information supporting the conclusion that BHT continues to be used for its authorized intended uses

According to available evidence, BHT continues to be used for authorized food and food-contact applications. In fact, BHT continues to serve an important technological function across numerous food categories where oxidative stability is necessary to preserve quality, extend shelf life, and reduce food waste.

Within the pork industry, BHT remains an effective antioxidant for protecting rendered fats and processed meat products against oxidative deterioration during storage and distribution. These applications help maintain product quality while supporting domestic commerce and international exports that require extended transportation and storage times.

Eliminating BHT from these applications without suitable replacements would likely increase oxidative spoilage, shorten product shelf life, increase manufacturing costs, contribute to food waste, and complicate international trade. While alternative antioxidants continue to evolve, currently available options do not consistently match BHT's combination of effectiveness, stability, versatility, and economic value across all food systems.

Accordingly, the available scientific evidence supports FDA's continued authorization of BHT under existing conditions of use.

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Conclusion

NPPC appreciates the opportunity to provide comments regarding FDA's Request for Information on BHT.

The available scientific evidence developed over more than six decades demonstrates that BHT remains a safe, effective, and technologically necessary antioxidant when used in accordance with FDA regulations. Comprehensive toxicological evaluations conducted by FDA, JECFA, EFSA, and other scientific authorities consistently conclude that dietary exposure from approved food and food-contact uses remains well below established safety thresholds.

In the pork industry, BHT provides significant public health and economic benefits by reducing lipid oxidation, preserving product quality, extending shelf life, minimizing food waste, and supporting the safe distribution of pork products throughout domestic and international markets. These benefits are especially important as manufacturers seek to improve sustainability, reduce unnecessary food loss, and maintain affordable food supplies for consumers.

Although alternative antioxidant technologies continue to evolve, no single replacement currently provides the ultimate combination made possible by BHT across the broad range of food applications: oxidative stability, processing performance, versatility, and cost-effectiveness. Consequently, BHT continues to fulfill an important technological function within the U.S. food system.

NPPC encourages FDA to continue applying a transparent, science-based, and risk-based approach to evaluating food additives while considering the totality of available evidence, including toxicological data, dietary exposure, technological necessity, food safety benefits, and international regulatory harmonization.

NPPC also remains concerned about the growing number of state legislative proposals seeking to prohibit or require warning labels for food ingredients authorized by FDA. A patchwork of differing state requirements undermines regulatory consistency, creates unnecessary compliance burdens for food manufacturers, disrupts interstate commerce, and may ultimately increase food costs for consumers.

Congress has entrusted FDA with the responsibility to evaluate the safety of food additives using rigorous scientific standards. NPPC strongly supports FDA's continued leadership in maintaining a nationally uniform, science-based regulatory framework that protects public health while promoting innovation, food security, and consumer confidence in the U.S. food supply.

Thank you for your consideration of these comments.

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Sincerely,

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