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US Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993
Submitted *via: https://www.regulations.gov/document/FDA-2026-N-2526-0001*

Re: Docket No. [FDA-2026-N-2526] for "Butylated hydroxytoluene (BHT); Request for Information FDA

Dear Ms. Grace Graham, Deputy Commissioner for Policy, Legislation, and International Affairs,

The Flexible Packaging Association (FPA) appreciates the opportunity to submit comments in response to the U.S. Food and Drug Administration's (FDA) Request for Information (RFI) concerning the safety of butylated hydroxytoluene (BHT) in food and food contact applications. FPA is the voice of U.S. manufacturers of flexible packaging and their suppliers. The association's mission is connecting, advancing, and leading the flexible packaging industry. Flexible packaging is produced from paper, plastic, film, aluminum foil, or any combination of those materials, and includes bags, pouches, labels, liners, wraps, rollstock, and other flexible products. Flexible packaging is the fastest-growing and second-largest segment of the U.S. packaging industry, representing $51.5 billion in annual sales and approximately 98,000 flexible packaging manufacturing employees in the United States.

Before addressing the individual RFI questions, FPA wishes to emphasize a foundational principle that should guide the FDA's analysis throughout this review: BHT used in food contact materials such as packaging films, adhesives, coatings, and paperboard — has a materially different safety profile than BHT used as a direct food additive. This is not merely a technical distinction; it is a scientifically and regulatorily consequential one that must be preserved throughout the assessment.

This principle is consistent with the framework articulated by the Food Contact Safety Council (FCSC) in its own submission to this docket, which correctly observes that "the presence of a substance in a material does not itself establish meaningful dietary exposure; exposure depends on migration, contact conditions, and the nature of the article in which the substance is used." FPA strongly endorses this view.

Key Distinctions at a Glance

Parameter	Direct Food Additive	Food Contact Material
Regulatory Basis	21 CFR Part 172	21 CFR Parts 175–178

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Parameter	Direct Food Additive	Food Contact Material
Exposure Route	Intentional addition at defined levels	Migration from packaging; inherently limited
Exposure Magnitude	Typically, mg/kg food level	Typically, mg/kg food level (orders of magnitude lower)
Functional Purpose	Antioxidant preservative in food matrix	Stabilizer/antioxidant in packaging matrix
Migration Limiting Factors	N/A	Diffusion kinetics, polymer matrix, contact time/temperature, food simulant
Regulatory Trigger	Safety at intended use level in food	Safety at actual migration level into food

The FDA's own Threshold of Regulation (TOR) policy (21 CFR 170.39) acknowledges that very low levels of migration from packaging may be presumed safe. BHT in many food contact material applications migrates at levels far below concentrations of concern. Applying the same safety scrutiny to food contact uses as to direct food additive uses would be scientifically disproportionate and inconsistent with established risk-based principles.

Consistent with the FCSC's recommendation, FPA also urges FDA to clearly identify circumstances in which BHT is present not as an intentionally added food substance in finished food, but as a constituent of an authorized food contact material or as an incidental component associated with another regulated use — such as certain adhesive systems, can-related preservative systems, or other indirect-use contexts. The regulatory and exposure questions in these scenarios differ materially from direct food use scenarios.

The following comments directly address the questions posed by the FDA within the request for information. FPA’s responses are restricted to the use of BHT within food contact materials, specifically packaging.

Question 1: General Food Categories in Which BHT Is Used Within a Food Contact Material Context

BHT's functional role in food contact packaging is to prevent oxidative degradation of the packaging substrate material during manufacturing, processing, and shelf storage — not to act as a food preservative within the food itself. This technical distinction underscores the importance of a differentiated regulatory analysis from food contact use.

In these applications, BHT is present within the packaging material itself, and consumer exposure occurs only to the extent that BHT migrates from the packaging into food during processing, storage, or use.

BHT is widely used as a functional antioxidant stabilizer in food contact materials across virtually all food categories, including in:

- Polyolefin films (polyethylene, polypropylene) used for snacks, baked goods, frozen foods, and meat products
- Adhesives and coatings used in flexible packaging laminates and multilayer structures
- Rubber gaskets and closures for bottles and jars
- Paperboard and cartonboard used for dry and refrigerated foods
- Wax coatings applied to produce and other foods
- Labels and tapes applied to poultry, dry food, and processed, frozen, or raw fruits and vegetables

Question 2: Typical and Maximum Use Levels of BHT in Each Applicable Food Category

FPA respectfully leaves the direct food additive use level information to other stakeholders with direct knowledge of those formulations, and we encourage the FDA to receive that information separately in order to maintain the analytical distinction between direct and indirect uses.

With respect to food contact materials, BHT is typically present at low concentrations within the substrate — generally well below 0.1% (1,000 ppm) in food contact packaging materials— Migration from these materials is even less. Within packaging, BHT is most often introduced through raw material components rather than as a standalone additive to the finished packaging article. As discussed in Question 3, the presence of BHT at these levels in a packaging material does not translate directly into dietary exposure; the relevant metric for safety assessment is the amount that actually migrates into food under conditions of use.

Question 3: Information on Current Food Contact Uses of BHT, Including Migration Data

A. Current Regulatory Authorizations

BHT is authorized as a food contact substance under multiple federal regulations, including:

- 21 CFR 175.105 — Adhesives
- 21 CFR 175.125 — Pressure-sensitive adhesives (labels/tapes applied to poultry, dry food, and processed, frozen, or raw fruits and vegetables)
- 21 CFR 175.300 — Resinous and polymeric coatings
- 21 CFR 176.170 — Components of paper and paperboard in contact with aqueous and fatty foods
- 21 CFR 176.180 — Components of paper and paperboard in contact with dry foods
- 21 CFR 177.1210 — Closures with sealing gaskets
- 21 CFR 177.2600 — Rubber articles intended for repeated use

- 21 CFR 178.2010 — Antioxidants and/or stabilizers for polymers
- 21 CFR 178.3570 — Lubricants with incidental food contact

In food contact packaging, BHT performs an essential technical function by inhibiting oxidative degradation, thereby maintaining adhesive bond strength, coating durability and clarity, and overall packaging performance under diverse processing, storage, and end-use conditions. These attributes are particularly critical in flexible packaging, multilayer laminates, and coated paperboard structures, which must maintain structural and barrier integrity across a wide range of temperatures and contact durations.

FPA notes that some efforts have been made over the past decade to reduce or replace BHT food contact packaging systems. However, such reformulation efforts typically require:

- Identification of alternative antioxidant systems with equivalent functional performance
- Extensive laboratory and production-scale validation of adhesion, coating durability, aging characteristics, and substrate compatibility
- Comprehensive requalification across the supply chain, potentially involving raw material suppliers, formulators, converters, and brand owners
- Extended requalification timelines — in some cases, up to two years for technical validation alone, and five to ten years for full supply chain transition to on-shelf food packaging

Any regulatory action affecting BHT in food contact applications must account for these practical realities, including transition timelines sufficient to avoid disruption to the food packaging supply chain.

B. Migration Data

Migration of BHT from food contact materials into food has been studied by many international regulatory authorities. The available data consistently demonstrate that migration-based exposure is substantially lower than dietary exposure from direct food additive uses.

The European Food Safety Authority (EFSA) [1] and the German Federal Institute for Risk Assessment (BfR)[2] have published migration data showing BHT levels from packaging at 0.01–0.3 mg/kg food in worst-case scenarios, with typical exposure substantially lower. Publicly available assessments from the European Chemicals Agency (ECHA) [3] and Health Canada's Bureau of Chemical Safety[4] further support the safe use of BHT as applied in food contact materials.

[1] EFSA Panel on Food Additives and Nutrient Sources (ANS), "Scientific Opinion on the re-evaluation of butylated hydroxytoluene (E 321)" (2012; updated assessments)

[2] German Federal Institute for Risk Assessment (BfR), "Migration of BHT from Food Packaging" (various years)

[3] European Commission, Scientific Committee on Consumer Safety "OPINION on Butylated Hydroxytoluene (BHT)" (2021)

[4] Health Canada, Bureau of Chemical Safety, "Safety Assessment of BHT in Food and Food Packaging" (2023)

For many food contact packaging applications, BHT migration falls below the threshold of regulation under 21 CFR 170.39 for non-carcinogens — a level FDA has determined presents negligible risk.

The migration-based exposure from food contact materials is a small fraction of the already conservative safety thresholds established for BHT. This body of data strongly supports the safety of BHT in food contact applications and warrants a clearly differentiated regulatory assessment from direct food additive uses.

Question 4: Subpopulations with High BHT Dietary Exposure or Particular Safety Concerns
With respect to food contact material uses specifically, the contribution of FCM-related BHT migration to total dietary BHT exposure is generally negligible compared to that from direct food additive uses. As such, food contact material uses of BHT do not materially alter the subpopulation exposure profile for risk assessment purposes.

Health Canada's Bureau of Chemical Safety completed a comprehensive, contemporaneous safety assessment of BHT in 2023 and reached the following conclusion:
"Based on the available data and current levels of dietary exposure, BHT used as a food additive and in food packaging materials does not pose a health concern to the general population, including sensitive subpopulations such as children."[5]

This conclusion reached by a peer regulatory authority applying rigorous, science-based standards and a methodology consistent with international best practices is directly relevant to FDA's current review. Health Canada's assessment explicitly encompassed both direct food additive uses, and food packaging material uses, evaluated exposure in sensitive subpopulations including children, and concluded that current exposure levels do not pose a health concern. FDA should give this assessment significant and substantive weight in its own review, consistent with the broader principle of international regulatory concordance.

Question 5: Other Dietary Sources of BHT
FPA's comments are limited to food contact packaging. We note, as discussed under Question 3, that BHT migration from food contact materials represents a small but real source of dietary BHT exposure.

When all sources are considered, total BHT dietary exposure for most consumers remains well below the Acceptable Daily Intake (ADI) of 0.3 mg/kg body weight per day established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)[6]. This finding is consistent with

[5] IBID
[6] JECFA Monograph on BHT (WHO Food Additives Series)

Health Canada's 2023 exposure assessment[7], which concluded that aggregate exposure from food and food packaging does not pose a health concern. BHT exposure from food contact materials occurring from potential migration remains even less, in worse case scenarios.[8] FDA should give appropriate weight to these comprehensive international reviews, which were conducted using a methodology aligned with the exposure-based, risk-proportionate principles FPA urges FDA to adopt here.

Question 6: Market Share of Foods and Food Contact Materials Formulated with BHT

Precise current market share data requires updated industry survey information; however, available market intelligence supports the following characterization of BHT's role in food contact material applications:

- Polyolefin packaging films: High market penetration due to cost-effectiveness and functional performance at low concentrations;
- Paperboard and cartonboard: Use in recycled paperboard is widespread; less common in virgin fiber applications. BHT may be present as a carryover from recycled content rather than as an intentionally added substance.
- Rubber closures and gaskets: Present in a significant portion of bottle caps and jar closures across beverage and food categories.
- Adhesives and coatings: BHT-containing formulations remain prevalent in flexible packaging laminates and coated paper structures, though some transition away from BHT has occurred over the past decade where technically feasible alternatives have been validated.

Question 7: Biomonitoring Data for BHT or Its Metabolites

The absence of systematic BHT biomonitoring in the U.S. general population is an important limitation for this review. While we understand the current scientific evidence to indicate BHT migration from food contact packaging to be of limited exposure to necessitate biomonitoring, we recognize such data would strengthen the scientific foundation for both the current review and future post-market reassessments.

Question 8: Updated Market Disappearance or Poundage Data for BHT

The most recent comprehensive poundage data for BHT in food and food contact applications were compiled by FDA through its Priority-Based Assessment of Food Additives (PAFA) database and through periodic industry surveys. FPA offers the following observations specific to food contact material uses:

- **Food contact material poundage:** BHT use in food contact material applications has been relatively stable over time, as technically equivalent alternatives for polymer stabilization

[7] Health Canada, Bureau of Chemical Safety, "Safety Assessment of BHT in Food and Food Packaging" (2023)

[8] German Federal Institute for Risk Assessment (BfR), "Migration of BHT from Food Packaging" (various years)

are more limited than in direct food applications, and the quantities of BHT required per unit of packaging are inherently small. The functional necessity of BHT as an antioxidant stabilizer in polyolefin films, adhesives, coatings, paperboard, and rubber closure systems continues to support consistent demand at current use levels.

- **Trend context:** While some formulators and converters have investigated alternatives to BHT in adhesive and coating systems over the past decade, the pace of commercial transition has been slow due to the technical complexity, supply chain requalification requirements, and extended timelines described under Question 3. As a result, market disappearance data for BHT in food contact material applications are unlikely to show significant decline and should be interpreted in the context of these practical constraints.

Question 9: Information on Potentially Chemically or Pharmacologically Related Substances
Several substances are chemically or functionally related to BHT and are relevant to the overall safety assessment context. Each of these substances has its own distinct toxicological profile, regulatory authorization, and exposure pathway, and FPA does not suggest that findings for related substances should be conflated with those for BHT.

With specific regard to alternatives to BHT in food contact material applications, FPA has consulted its members and offers the following observations:

- Alternative antioxidant stabilizers are available for certain food contact material applications; however, all currently available alternatives come at increased cost relative to BHT, and each carries its own set of health, safety, and regulatory considerations that must be independently evaluated.
- Reformulation is not a simple substitution. Changing the antioxidant stabilizer system requires comprehensive validation of adhesion performance, coating durability, aging characteristics, thermal stability, and compatibility with diverse food contact conditions. This process frequently involves:
    - Laboratory-scale development and screening of alternative antioxidant systems
    - Production-scale trials and performance validation
    - Regulatory review to confirm that the alternative substance is authorized for the intended food contact application
    - Notification to, and requalification by, customers and downstream supply chain partners, who typically require independent confirmation that substituted formulations meet their own performance and safety specifications
- Supply chain notification and prequalification obligations are a particularly significant practical constraint. In many commercial arrangements, changes to packaging material formulations trigger contractual notification requirements and may require formal customer approval prior to implementation. This means that even where a technically suitable and regulatory-compliant alternative has been identified, commercial

deployment cannot occur until the full supply chain has reviewed and accepted the change.

- Timeline implications are substantial**.** Based on FPA member experience, technical requalification of adhesive and coating reformulations typically requires up to two years. Full supply chain transition — from raw material suppliers through converters and brand owners to on-shelf food packaging — can realistically require five to ten years, depending on the breadth of applications affected and the complexity of customer qualification processes.

The FPA recommends that any transition period established by FDA should reflect realistic commercial timelines to avoid supply chain disruption, packaging performance degradation, or unintended food safety consequences arising from premature changes to validated packaging systems.

Question 10: Safety Data Relevant to BHT in Food or as a Food Contact Substance

Summary of Key Safety Data — Food Contact Material Applications

Given that FPA's comments are focused on food contact material uses, we emphasize the following:

- Exposure differential: As detailed under Question 3, BHT exposure from food contact material migration is typically 100 to 1,000 times lower than exposure from direct food additive uses.[9] This substantially greater exposure margin means that the safety profile for FCM uses of BHT is highly favorable, even applying conservative toxicological assumptions.
- Migration-based risk characterization: BHT migration from food contact materials is low. Under worst-case test conditions, migration levels typically range from 0.01–0.5 mg/kg[10] food simulant — and are expected to be substantially lower under realistic conditions of use. When these values are compared against established acceptable daily intake (ADI) or tolerable intake benchmarks expressed in mg/kg body weight per day, the resulting margins of exposure are large, often by **several orders of magnitude**. This demonstrates a substantial safety margin for consumers even under conservative assumptions.
- This favorable risk characterization — indicating **low risk** — applies consistently across the full range of food contact applications addressed in this submission, including:
- polyolefin films, adhesives, coatings, paperboard, and closures.

[9] Susan P. Felter, Xiaoling Zhang, Chad Thompson, "Butylated hydroxyanisole: Carcinogenic food additive to be avoided or harmless antioxidant important to protect food supply?", Regulatory Toxicology and Pharmacology, Volume 121 (2021) Susan P. Felter, Xiaoling Zhang, Chad Thompson, "Butylated hydroxyanisole: Carcinogenic food additive to be avoided or harmless antioxidant important to protect food supply?"", RegulatoryToxicology and Pharmacology, Volume 121 (2021)

[10] German Federal Institute for Risk Assessment (BfR), "Migration of BHT from Food Packaging (various years).

- Food Contact Notification data: Migration and safety evaluations conducted under actual and worst-case end-use conditions, including studies submitted in support of Food Contact Notifications, confirm that BHT can be used safely within established regulatory limits when present at typical concentrations in food contact packaging materials.

FPA also notes that BHT's authorization as food additive E321 under EU Regulation (EC) No. 1333/2008[11], following EFSA's scientific review, as well as Health Canada's 2023 exposure assessment[12] mentioned in Question 4, represents additional international regulatory support for BHT's safety at current authorized use levels.

Question 11: Documentation of GRAS Conclusions or Prior Sanctions for BHT Uses

BHT has a well-documented and longstanding regulatory history in the United States:

- Prior Sanctioned Status: BHT was in use prior to the 1958 Food Additives Amendment and has been recognized as having prior sanction for certain food uses, providing a foundational basis for its continued authorization independent of the food additive petition process.
- Listed Food Additive: BHT is listed under 21 CFR 172.115 for direct food use as an antioxidant, with specified use limitations by food category and level.
- GRAS Affirmation: BHT has been affirmed as Generally Recognized as Safe (GRAS) under 21 CFR 182.3173 for antioxidant uses, based on its long history of safe use and the scientific evidence available at the time of affirmation.
- Food Contact Material Authorizations: As detailed under Question 3, BHT is independently authorized for food contact material uses under multiple provisions of 21 CFR Parts 175–178, each of which reflects an affirmative regulatory determination that BHT may be safely used in the specified application.

International Regulatory Status

The following table summarizes BHT's regulatory authorization status across major international jurisdictions:

Jurisdiction	Regulatory Status
United States	Listed food additive (21 CFR 172.115); FCM authorized (21 CFR Parts 175–178); GRAS affirmed (21 CFR 182.3173)
Canada	Approved as food additive and food contact substance; 2023 comprehensive safety review confirmed no health concern
European Union	Authorized food additive (E321) under Regulation (EC) No. 1333/2008; FCM uses evaluated by EFSA

[11] https://eur-lex.europa.eu/eli/reg/2008/1333/oj/eng

[12] Health Canada, Bureau of Chemical Safety, "Safety Assessment of BHT in Food and Food Packaging" (2023)

Jurisdiction	Regulatory Status
Codex Alimentarius	INS 321; listed in the General Standard for Food Additives (GSFA) for multiple food categories
Japan	Approved for use in fats, oils, and food contact materials
Australia/New Zealand	Approved under the Australia New Zealand Food Standards Code

The broad international regulatory consensus supporting BHT's safety across multiple major food safety authorities provides compelling additional scientific support for the continued authorization of BHT — particularly in food contact applications, where the exposure profile is even more favorable than for direct food additive uses. FPA urges FDA to take this international concordance into account as a meaningful indicator of the scientific community's collective assessment of BHT safety.

Question 12: Information Supporting the Conclusion That BHT Is No Longer Used for One or More Authorized Intended Uses

While some user have transitioned away from BHT, FPA has no information indicating that BHT has been discontinued for any of its currently authorized food contact material uses. To the contrary, based on FPA member input, BHT continues to be actively and widely used across the full range of food contact applications described in this submission, including polyolefin packaging films, adhesive and coating systems, paperboard and cartonboard, rubber closures, and related articles due to its safety profile, long history of use, and low costs.

CONCLUSION AND POLICY RECOMMENDATIONS

Based on the foregoing analysis and consistent with the principles articulated in this submission, FPA respectfully offers the following recommendations to FDA:

1. Bifurcate the Safety Review

FDA should conduct separate, independent assessments of BHT as a direct food additive (21 CFR 172.115) and as a food contact substance (21 CFR Parts 175–178), reflecting the fundamentally different exposure profiles, risk levels, and regulatory frameworks applicable to each category. Collapsing direct food uses, food contact uses, and constituent or impurity scenarios into a single undifferentiated assessment risk obscuring meaningful scientific differences and producing regulatory conclusions that are disproportionate to actual risk.

2. Recognize the Favorable Risk Profile of Food Contact Material Uses

The body of available migration data overwhelmingly demonstrates that BHT exposure from food contact materials is minimal — typically 100 to 1,000 times lower than exposure from direct food

additive uses — and well within established safety margins.[13] The safety assessment for FCM uses should fully reflect this reality and should not be unduly influenced by concerns arising from high-dose studies conducted in the context of direct food additive exposure. The presence of BHT in a food contact material is not equivalent to BHT in food, and FDA's assessment must preserve this distinction.

3. Prioritize Current-Use Data and Realistic Exposure Estimates

FDA should ground its exposure assessment in current market data, representative use levels, and actual migration information rather than in theoretical maximum-use assumptions or outdated poundage figures. As FCSC has recommended, the central question in a post-market review is whether a substance remains safe under its current conditions of use — an inquiry that should be informed by current commercial realities rather than by highly conservative assumptions untethered from actual practice.

4. Give Substantial Weight to International Safety Conclusions

As noted in Question 11, several countries have already evaluated BHT for use in food and food contact materials and deemed it safe for use in food contact materials. FPA believes international regulatory concordance serves the public interest, reinforces public confidence in the global food safety system, and avoids unnecessary trade and supply chain disruption.

5. Account for Realistic Transition Timelines in Any Regulatory Action

If FDA were to consider any restrictions on BHT uses in food contact materials, the Agency must establish implementation timelines that reflect the practical realities of reformulation and supply chain requalification. Based on industry experience, technical requalification alone may require up to two years, and full supply chain transition — including notification and requalification of raw material suppliers, formulators, converters, and brand owners — may require five to ten years for broad-based packaging applications. Any regulatory action that fails to account for these timelines risks disrupting the food packaging supply chain and could have unintended consequences for food safety and product integrity.

FPA and the flexible packaging industry remain committed to science-based food contact material safety and to constructive engagement with FDA on this and future reviews. The available evidence encompassing migration studies, food contact notification data, and international regulatory assessments consistently and robustly supports the safety of BHT in food contact material applications at current conditions of use. We urge FDA to reflect that evidence

[13] Susan P. Felter, Xiaoling Zhang, Chad Thompson, "Butylated hydroxyanisole: Carcinogenic food additive to be avoided or harmless antioxidant important to protect food supply?", Regulatory Toxicology and Pharmacology, Volume 121 (2021)

accurately in a bifurcated, exposure-driven assessment that appropriately distinguishes the meaningfully different risk profiles of direct and indirect BHT uses.

We appreciate the opportunity to contribute to this important review and welcome further dialogue with the Agency. If you have any questions or require additional information, please don't hesitate to contact us.

Respectfully,

Kyla Fisher
Director of Regulatory Affairs and Sustainability
Flexible Packaging Association (FPA)