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Mandatory GRAS Notification and the New Ultra-Processed Foods Definition

WHAT FDA'S 2026 PROPOSALS MEAN FOR FUNCTIONAL FOOD AND BEVERAGE COMPANIES

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On August 10, 2026, the U.S. Department of Health and Human Services (HHS) announced two significant food policy initiatives that could reshape the regulatory landscape for functional food and beverage companies. First, the U.S. Food and Drug Administration (FDA) published a proposed rule that would transform its longstanding voluntary Generally Recognized as Safe (GRAS) notification program into a mandatory reporting system. Second, HHS and the U.S. Department of Agriculture (USDA) submitted the federal government's first proposed definition of "ultra-processed foods" (UPFs) for final review.

Although neither initiative will take effect immediately, both signal a broader movement toward increased transparency and oversight of food ingredients and product formulations. For companies developing and marketing functional foods and beverages, including products containing adaptogens, botanicals, nootropics, probiotics, and other novel ingredients, these developments warrant close attention.

A Potentially Significant Change to the GRAS Framework

Under the Federal Food, Drug, and Cosmetic Act, substances intentionally added to food generally require FDA review as food additives, unless they qualify as GRAS. Historically, manufacturers have been permitted to reach their own GRAS conclusions, based on publicly available scientific data and expert review, without notifying the FDA. This "self-affirmed GRAS" pathway

has played a critical role in bringing innovative ingredients to market, particularly in the functional food and beverage industry.

The FDA's proposed rule would not eliminate the GRAS pathway but , rather, would require companies to notify the FDA whenever they rely on a "self-affirmed GRAS" conclusion to market an ingredient. The agency is essentially proposing a framework under which manufacturers would be required to submit information supporting their GRAS determinations, providing the FDA with greater visibility into ingredients entering the food supply.

Importantly, the proposal does not establish a ***premarket*** approval requirement. Companies would still be able to continue marketing products before the FDA completes its review. However, failure to submit a required notification could increase the likelihood of regulatory scrutiny or enforcement action.

The latest proposal also includes a streamlined pathway for ingredients already on the market. During a one-year transition period, companies could submit a shorter notification containing basic information such as ingredient identity, intended use, and evidence of prior commercial use, rather than a comprehensive package of safety data. Several categories of ingredients would also be exempt from the new notification requirement, including certain ingredients that have already received FDA "no questions" letters.

For many functional food and beverage companies, the proposed rule represents less of a scientific challenge and more of a documentation and compliance exercise. Companies should begin identifying which ingredients in their portfolios rely on self-affirmed GRAS determinations and evaluating what support may be needed if the rule is finalized.

Key Dates to Watch

While the proposal has generated substantial interest, implementation would occur over several years. Based on the FDA's proposed framework, food and beverage companies should be aware of the following milestones:

Comment Period: Public comments are due by December 9, 2026. Electronic comments may be submitted through Regulations.gov under Docket No. FDA-2025-N-3262. Husch Blackwell can assist with drafting and submitting comments.

Final Rule: The FDA must review and respond to public comments before issuing a final rule.

Effective Date: The FDA has proposed that any final rule become effective 60 days after publication in the Federal Register.

Compliance Date: Mandatory GRAS notifications would not be required immediately. The FDA has proposed an 18-month compliance period following the effective date.

Streamlined Submission Window: Companies marketing ingredients pursuant to existing self-affirmed GRAS determinations would have a one-year window, beginning on the effective date of the final rule, to submit streamlined notifications.

This timeline provides companies with a meaningful opportunity to prepare. Companies that begin inventorying ingredients and organizing supporting documentation now will be better positioned if and when the rule becomes final.

The Federal Government's First Attempt to Define "Ultra-Processed Foods"

At the same time the FDA announced the proposed GRAS rule, HHS revealed that the FDA and USDA submitted a proposed federal definition of "ultra-processed foods" for review by the Office of Management and Budget.

At this stage, the proposed UPF definition is not a regulation and does not impose any new labeling, formulation, or marketing requirements. The definition itself has not yet been publicly released. Even so, the announcement is significant because it signals growing governmental and public interest in food processing practices and ingredient composition.

Even a nonbinding federal definition of "ultra-processed foods" could have meaningful effects beyond federal regulation, as state legislatures, retailers, and advocacy organizations frequently look to federal guidance when shaping their own policies and standards. A federal UPF definition could therefore become an influential benchmark long before any formal regulatory requirements are adopted.

The proposed UPF definition is particularly relevant for functional food and beverage manufacturers. Many products in the category contain specialty ingredients, flavors, processing aids, or fortified nutrient blends that could attract attention under future UPF frameworks. In addition, states such as California have already begun advancing their own approaches to defining ultra-processed foods, while lawmakers in Congress continue to propose competing legislative frameworks.

What Functional Food and Beverage Companies Should Do Now

Although both initiatives remain in development, food and beverage companies should not wait for final rules to prepare. Now is the time to inventory ingredients backed by self-affirmed GRAS determinations, confirm supporting documentation is complete, flag any gaps, and consider what additional information a streamlined FDA notification process might require.

Beyond GRAS, companies should take a fresh look at how their products may be viewed under existing and emerging ultra-processed food frameworks. Understanding potential classification risks now can help inform decisions around formulation, ingredient sourcing, product positioning, labeling, and marketing as the regulatory landscape continues to evolve.

Companies should also review their supplier agreements to confirm responsibility for GRAS substantiation, notification obligations, and access to underlying safety data.

Finally, stakeholders should consider participating in the rulemaking process. The FDA is accepting comments on the proposed GRAS rule through December 9, 2026, providing industry participants with an important opportunity to shape the final framework.

Looking Ahead

Taken together, the proposed GRAS notification requirement and the emerging federal UPF definition reflect a broader shift toward increased transparency in the food system. Neither measure is expected to create immediate compliance obligations, and substantial regulatory activity would need to occur before either initiative materially changes the marketplace. However, the direction of travel is becoming increasingly clear.

For functional food and beverage companies, now is the time to evaluate ingredient portfolios, strengthen documentation practices, and monitor evolving regulatory expectations. Companies that begin preparing early will be better positioned to respond as these initiatives continue to develop.

Husch Blackwell is actively tracking these developments and is available to assist with related GRAS and UPF compliance matters. Contact the authors or visit our team's page for ongoing updates.

Contact Us

For more information about the legal and regulatory decisions affecting your institution, please contact Megan Beebe, Tracey Gonzalez, Stevie Matheny, or your Husch Blackwell attorney.

This article is intended for general informational purposes and does not constitute legal advice. The regulatory landscape described above is evolving rapidly, and specific legal questions should be addressed in consultation with qualified counsel.