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by enhesa.

What's changing at the US federal level for food contact materials?

A significant recalibration of how substances that come into contact with food are reviewed, authorised and monitored is on the cards, say Alan Sachs, Mark Duvall, Jack Zietman and Emily Schwartz of Beveridge & Diamond

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The US Food and Drug Administration (FDA) has long regulated substances that come into contact with food under the Federal Food, Drug, and Cosmetic Act (FFDCA). However, in recent months, the FDA and Congress have signalled a significant recalibration of how these substances are reviewed, authorised and monitored. These developments have renewed focus on the FDA's post-market review of food contact materials (FCMs) and prompted a re-examination of long-standing assumptions about the safety of these substances.

This article examines the changing regulatory environment, the influence of the new Make America Healthy Again (MAHA) agenda, the FDA's review of select food supply chemicals, and emerging proposals for reform of the Generally Recognized as Safe (GRAS) framework. It concludes with a look at pending federal legislation that would formalise several of these changes and expand the FDA's oversight of food contact materials.

Understanding the regulatory foundation

Under section 409(h)(6) of the FFDCA, a "food contact substance" is defined as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food, provided that such use is not intended to have any technical effect in the food itself". This definition includes, but is not limited to, packaging and processing materials; equipment and surfaces; adhesives and colourants; and certain antimicrobial preservatives and antioxidants.

Unless exempt as GRAS (discussed below), food contact substances are regulated as food additives, which include virtually any substance that may migrate into or affect food. A food additive must be the subject of a food additive regulation or an effective food contact notification (FCN) for that specific use before it is marketed in the US.

For non-GRAS food contact substances, manufacturers typically submit an FCN to the FDA to have their food additives included in the FDA's list of effective pre-market notifications for food contact substances that have been demonstrated to be safe for their intended use. In submitting an FCN, the manufacturer or supplier must notify the FDA of the identity and intended use of the food contact substance, along with the manufacturer's determination and supporting evidence that the intended use is safe.

The FDA then conducts a scientific safety assessment and determines whether the food contact substance is safe within 120 days of receiving the notification (this deadline can be extended if the FDA has questions). Each FCN is proprietary to the notifier, so others must file their own for the same use (21 C.F.R. Part 170, Subpart D).

The FDA maintains a public inventory of effective FCNs, providing transparency about which substances and uses have been reviewed by the FDA without objections. The FDA may subsequently determine that the intended use of a food contact substance is no longer safe, in which case it may determine that the FCN is no longer effective (21 C.F.R. § 170.105). However, questions persist about how often the FDA revisits FCNs and whether legacy notifications remain protective.

The MAHA agenda

The Trump administration's MAHA Commission – established in February of this year – marks the most comprehensive federal effort in recent decades to reform oversight of food and food contact chemicals. After stakeholder consultation, the *MAHA Assessment* was released on 22 May, and the *MAHA Strategy Report* on 9 September.

The assessment identified several priority areas, and the report outlined initiatives across the FDA, the US EPA, the US Department of Agriculture (USDA), and other agencies. Without naming specific substances, the report makes two key FDA reform recommendations relevant to food contact materials:

- first, it should develop and implement an "enhanced evidence-based systematic process" for post-market chemical reviews of food and food contact substances, though the report provides no further specifics; and
- second, it should reform the GRAS programme by adopting a mandatory notification system and eliminating the self-affirmation pathway. The report calls for independent studies evaluating the health impact of self-affirmed GRAS food ingredients, prioritising risks to children and informing transparent FDA rulemaking.

As discussed below, these recommendations align with prior FDA announcements and ongoing plans for regulatory reform.

FDA post-market chemical review

The FDA already has authority to conduct post-market assessments of chemical additives, including food contact substances, either in response to stakeholder petitions or on its own initiative when warranted by new information. The MAHA Commission's call for increased post-market review highlights several high-profile chemical groups already under current reassessment:

Phthalates

Phthalates, used as plasticisers and in various packaging applications, have been under regulatory scrutiny for years. In 2018, environmental and public health organisations petitioned the FDA to revoke the authorisation of 23 phthalates approved for food contact uses. The FDA formally granted that petition in its 2022 final rule, removing those authorisations from the regulations. The FDA simultaneously initiated a request for information to evaluate the remaining nine phthalates that continue to be authorised for food contact use.

In its October 2024 constituent update, the FDA confirmed that it responded to objections to its 2022 final rule and found no basis to alter it. The FDA further noted that the remaining phthalates remain on its "select chemicals under review" list, and it continues an updated safety assessment of the remaining uses, including those reflected in its request for information.

Bisphenols

Bisphenol A (BPA) remains one of the most scrutinised chemicals in the food supply chain. It is used primarily in the production of polycarbonate plastics and epoxy resins, which are found in food and beverage can linings, reusable containers, and other packaging materials.

In 2022, a petition was submitted requesting the FDA to revoke or restrict authorisations for BPA in food contact applications and to establish a migration limit for BPA from authorised uses in food contact articles. The FDA has since been reviewing the petition alongside emerging scientific literature on BPA analogues, such as bisphenol S and bisphenol F, which are increasingly used as replacements in certain applications.

Fluorinated high-density polyethylene

In 2022, the FDA issued a request for information on the current food contact uses of fluorinated high-density polyethylene (HDPE), used in rigid packaging. The FDA sought scientific data on these uses, potential dietary exposure from such materials, and safety information on substances that may migrate from fluorinated polyethylene food containers. The request was prompted by concerns that certain fluorination processes could unintentionally generate PFAS byproducts.

PFAS

In January this year, the FDA announced that 35 FCNs for PFAS-based grease-proofing agents used in paper food packaging are no longer effective. This action marks the completion of a voluntary phase-out that began in 2020, when manufacturers agreed to discontinue sales of these substances. Manufacturers could use existing inventories until 30 June; that grace period has now expired. The FDA has stated that it will continue testing

foods from the general food supply to better estimate consumer exposure to PFAS from foods.

GRAS reform

Few aspects of the FDA's food programme have generated as much controversy as the GRAS framework, which allows substances to bypass pre-market review if they are "generally recognised as safe" among qualified experts under their intended conditions of use. Recognition can be based either on scientific research or experience from common use in food before 1958.

While the GRAS exemption is established under the FFDCA, no statutory framework defines how GRAS status is confirmed. Initially, the FDA conducted its GRAS evaluations. Then, in the 1970s, it created a voluntary affirmation process that allowed manufacturers to perform safety assessments and submit petitions seeking FDA affirmation. This approach later evolved into a self-affirmation option without notice to the FDA. In 2016, the FDA promulgated the GRAS rule to formally implement self-affirmation and voluntary notification. Under this framework, companies may notify the FDA of their GRAS determinations or self-affirm GRAS status without informing the FDA.

If a company chooses to notify the FDA of its GRAS determination, the process is detailed and complex (21 C.F.R. Part 170, Subpart E). Self-affirmation, by contrast, has reduced regulatory barriers for novel ingredients such as alternative sweeteners, functional fibres and plant-based proteins. Although intended to be equally rigorous, self-affirmation shifts the responsibility for safety evaluation to manufacturers, raising concerns about transparency and potential conflicts of interest. The FDA's challenges to some self-affirmed GRAS substances, including partially hydrogenated oils and tara flour, have renewed debate over the adequacy of current self-regulatory practices.

Against this backdrop, the *MAHA Report* directs the FDA to update the current GRAS self-affirmation framework by closing the "GRAS loophole", establishing a mandatory notification programme, and enhancing transparency for consumers regarding substances present in the food supply. If self-affirmation were eliminated, companies introducing new ingredients in foods, or continuing to manufacture or use ingredients previously self-affirmed as GRAS, may be required to notify the FDA publicly of their intended uses and provide supporting safety data.

The FDA's current regulatory agenda lists a proposed rule to amend its regulations to require mandatory submission of GRAS notices for substances used in human and animal food that are claimed to be GRAS, with rulemaking anticipated before the end of 2025.

Pending federal legislation

Congress has also turned its attention to food chemical safety, introducing several bills that would codify stronger oversight and post-market review obligations.

Introduced in the Senate in July, the Ensuring Safe and Toxic-Free Foods Act of 2025 (S 2341) would require GRAS notifications with supporting evidence, provide for public comment, bar certain carcinogenic or reproductive/developmental toxicants, and create an Office of Food Chemical Safety Reassessment with public disclosure requirements.

A companion measure, the Food Chemical Reassessment Act of 2025 (HR 4306), introduced in the House of Representatives around the same time, would require periodic reassessment of chemicals used in food and packaging, mandate review of at least ten substances or classes every three years, and prioritise common dyes and ingredients such as titanium dioxide.

Looking ahead

The FDA is expected to intensify its review of chemicals already in the food supply, moving from ad hoc reassessments towards a more systematic, risk-based approach. Companies should anticipate stricter safety standards and increased pressure to identify safer alternatives.

GRAS reform also appears imminent. The FDA is likely to propose limits on or the elimination of the self-affirmation process through a formal rulemaking, beginning with a notice of proposed rulemaking (NPRM) in the Federal Register, potentially before the end of 2025.

Congress may pursue parallel legislative changes, and public criticism of the "GRAS loophole" is expected to continue. Bipartisan interest in strengthening food chemical oversight could lead to new legislation before the end of the current session. At the same time, states are advancing their own restrictions on food contact materials, creating a rapidly evolving patchwork of requirements.

Together, these developments signal a shift towards an approach to FCMs that is likely to involve more scrutiny and procedural requirements across all levels of government.

The views expressed in this article are those of the authors and are not necessarily shared by Chemical Watch News & Insight.

FURTHER INFORMATION

Inventory of Effective Food Contact Substance (FCS) Notifications →

MAHA Assessment →

MAHA Strategy Report →

Indirect Food Additives: Adhesives and Components of Coatings; Paper and Paperboard Components; Polymers; Adjuvants, Production Aids, and Sanitizers →

FDA Update on Phthalates in Food Packaging and Food Contact Applications →

Fluorinated Polyethylene Containers for Food Contact Use; Request for Information →

Food Contact Notifications That Are No Longer Effective →

S 2341 – Ensuring Safe and Toxic-Free Foods Act of 2025 →

HR 4306 – Food Chemical Reassessment Act of 2025 →