Policy Backgrounder

New Food Safety Rules – and the Administration's Regulatory Policy

The Administration is proposing a significant change to Federal oversight of food ingredients, requiring manufacturers to notify FDA about safety determinations that are currently voluntary. This Backgrounder outlines the proposal – and how it fits into overall Administration policies on regulation.

Trusted Insights for What's Ahead®

- FDA proposes to replace voluntary notification with mandatory disclosure of most manufacturer determinations of ingredients "generally recognized as safe" (GRAS), while stopping short of requiring premarket FDA approval. Manufacturers would remain responsible for safety and could market qualifying uses before FDA completes its review.
- FDA seeks greater visibility into substances already in use. The proposal would make previously undisclosed safety determinations visible to FDA and, in many cases, the public.
- The rule highlights a broader regulatory tradeoff: despite its broader deregulatory agenda, the Administration is willing to impose new compliance costs to advance its other priorities.
- Greater Federal oversight would not necessarily mean greater regulatory uniformity. Companies could face new FDA notification requirements while continuing to navigate differing state restrictions on food ingredients, raising a classic issue of the extent of states' powers in regulation and the extent of Federal preemption.

GRAS and Food Safety

The current Federal food safety framework reflects a regulatory structure Congress established nearly seven decades ago and adapted by the Food and Drug Administration (FDA). Congress enacted the Food Additives Amendment of 1958,[1] amending the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act),[2] amid concern that an increasing number of chemicals were entering the food supply without adequate safety review. The legislation established the basic regulatory framework: a substance intentionally added to food generally requires FDA authorization before use unless it falls outside the statutory definition of a food additive.

An exception applies for the use of a substance Generally Recognized as Safe (GRAS). Under the FD&C Act, qualified experts must generally recognize the substance as safe under its intended conditions of use on an appropriate scientific basis.[3] GRAS excludes a qualifying use from the food additive premarket approval process, but a use must still be safe.

FDA's administration of this framework has changed over time. After relying on regulatory lists, informal opinions, and a formal GRAS process, FDA proposed a voluntary notification system in 1997 and finalized that framework in 2016.[4] Manufacturers remain responsible for safety, while FDA provided scientific standards, guidance, consultation, and voluntary review. A company submitting a notice may receive a "no questions" response or an insufficient-basis response or ask FDA to cease its review. Because the system is voluntary, manufacturers may make independent GRAS conclusions without notifying FDA.[5] From the business perspective, the system has worked well for decades.

From Voluntary Notification to Mandatory Oversight

The proposed rule would convert voluntary GRAS notification into a mandatory system for most qualifying uses in human and animal food while preserving the statutory GRAS exclusion.[6] Manufacturers would generally have to provide the basis for their safety conclusion. Failure to notify FDA would not automatically convert a substance into an unapproved food additive; FDA instead proposes to treat noncompliance as a factor in prioritizing substances for review.

Importantly, the proposal stops short of requiring premarket approval. Manufacturers would continue to make the initial GRAS determination, and a legitimately qualifying use could enter commerce before a notice is submitted or while FDA evaluates it.

The proposal includes two broad tracks: a streamlined inventory and risk-based review process for current uses and full mandatory notification for new uses. For new uses, companies generally would submit detailed information on the substance's identity and manufacturing, intended conditions and levels of use, dietary exposure, and the scientific basis for safety and general recognition. The agency would have up to 45 days to determine whether a notice is sufficiently complete to file. Once filed, the manufacturer's notification obligation would be satisfied. FDA would ordinarily respond within 180 days after filing, with the ability to extend review by up to two additional 90-day periods.

Existing uses would have a lighter transition. During a one-year window, manufacturers could submit basic information identifying qualifying uses already in commerce, their conditions and levels of use, and evidence of existing market presence without initially providing a full scientific dossier. FDA would publish those uses without formally determining they are GRAS. The agency could later require a full GRAS notice or, where appropriate, a food-additive petition.

A Broader Change in Regulatory Policy?

For business, the implications of this change to mandatory disclosure extend beyond the administrative cost of filing notices. Mandatory disclosure could affect ingredient-safety decisions, product development, commercialization timelines, supplier relationships, customer behavior, and the durability of longstanding regulatory practices.

The change stands at odds against the Administration's broader deregulatory policy. Executive Order 14192 states that Federal policy is to "significantly reduce the private expenditures required to comply with Federal regulations" and generally requires agencies issuing new regulations to identify ten regulations for repeal.[7] FDA, however, concludes that the GRAS proposal would have a "significant economic impact on a substantial number of small entities."[8]

The proposal therefore illustrates that other important Administration priorities may, in some cases, outweigh the Administration's broader deregulatory objectives. For businesses, it is a reminder that regulation in particular industries may follow a different trajectory from the Administration's overall regulatory posture. For the food industry, this regulatory policy extends beyond GRAS. HHS announced the proposal alongside a separate HHS-USDA initiative to establish the Federal government's first definition of ultra-processed foods (UPFs), intended to provide a more consistent foundation for nutrition research and future policy.[9]

Food manufacturers and other firms across the supply chain may need stronger scientific review, exposure analysis, manufacturing specifications, supplier documentation, and recordkeeping. Firms also may need to inventory existing independent GRAS conclusions and determine whether supporting records are adequate for a system in which those determinations may become Federal submissions and public information. These fixed costs—and any resulting effects on product-development timelines—could weigh particularly heavily on smaller ingredient developers and emerging food-technology companies. FDA itself acknowledges that an insufficient-basis determination could shift market share and revenue among manufacturers using competing ingredients.

If significant backlogs in FDA processing develop, customers may hesitate to use ingredients with unresolved notices. A system that remains post-market as a matter of law could therefore develop some de facto premarket effects through private supply-chain decisions. FDA's streamlined pathway for existing uses appears intended, in part, to limit that risk.

Informal guidance and agency control

The proposal also raises a broader issue for businesses that rely on agency guidance and longstanding regulatory accommodations. FDA and other regulatory agencies routinely use guidance and consultation to translate broadly worded statutes into workable compliance practices. Those arrangements can provide substantial stability, but they do not equal protections Congress placed in law. GRAS illustrates the distinction particularly well: the statutory exemption Congress enacted remains in place, while a decades-old administrative practice permitting independent conclusions without notification is being revised.

The Administration's approach to agency control makes that distinction more relevant. Its 2025 Executive Order on agency accountability provides that only the President and Attorney General supply "authoritative interpretations of law for the executive branch" and constrains contrary agency positions through regulations, guidance, and litigation.[10]

Greater control can produce more consistent policy within an Administration, but it can also make regulatory expectations more sensitive to changes in Administration priorities. Importantly, stronger White House oversight does not expand FDA's authority beyond what Congress has provided. The FD&C Act allows qualifying ingredients to avoid the food additive approval process, but it does not expressly require the mandatory notification system FDA now proposes. FDA is instead relying on its broader statutory authorities to establish that requirement. The proposal appears designed to preserve that distinction: manufacturers would continue to make their own safety determinations, notification would not amount to FDA approval, and companies would not need to wait for an affirmative FDA response before entering the market. For business, the central issue is whether this approach provides a clear and durable regulatory framework for future compliance, investment, and product decisions.

State regulation and preemption

A separate challenge is state law. Stronger Federal oversight of GRAS determinations would not prevent states from restricting ingredients that Federal law permits. At least 37 states introduced legislation addressing food dyes or additives in 2025, with significant variation in the substances covered and regulatory approaches used.[11]

For firms, that patchwork affects many aspects of business operations and serves as a reminder that greater Federal oversight does not necessarily produce national uniformity. Only Congress could resolve the issue, if it chose, by adopting a national standard and some form of preemption. The proposal therefore ultimately reflects a regulatory tradeoff rather than a simple turn toward greater regulation. In the meantime, however, this industry and its supply chains face greater regulation. For the food industry, this will reduce innovation and increase costs, adding to inflationary pressures on food prices.

About the Authors

David Young, President, The CEO Center, The Conference Board

John Gardner, Head of Public Policy & Research, The CEO Center, The Conference Board

Anthony Reyes, Senior Economic Policy Analyst, The CEO Center, The Conference Board

---

The Conference Board is the Member-driven think tank that delivers Trusted Insights for What's Ahead®. Founded in 1916. TCB.org | Learn about Membership

The CEO Center, founded in 1942 as the Committee for Economic Development, is the public policy center of The Conference Board. Members of The CEO Center are chief executive officers, key executives of leading US companies, and university Presidents. Collectively they represent 30+ industries, over 5 million employees, and more than $2T in annual revenues. The nonprofit, nonpartisan, business-led policy center delivers ***Reasoned Solutions in the Nation's Interest™.*** **TCB.org/ceo-center**

Endnotes

[1] https://www.congress.gov/bill/85th-congress/house-bill/13254/text

[2] https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act

[3] https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras

[4] https://www.federalregister.gov/documents/2026/08/11/2026-16296/substances-generally-recognized-as-safe

[5] https://www.hhs.gov/press-room/hhs-announces-ultra-processed-foods-gras-reforms.html

[6] https://www.federalregister.gov/documents/2026/08/11/2026-16296/substances-generally-recognized-as-safe

[7] https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-prosperity-through-deregulation/

[8] https://www.federalregister.gov/documents/2026/08/11/2026-16296/substances-generally-recognized-as-safe

[9] https://www.hhs.gov/press-room/hhs-announces-ultra-processed-foods-gras-reforms.html

[10] https://www.whitehouse.gov/presidential-actions/2025/02/ensuring-accountability-for-all-agencies/

[11] https://www.ncsl.org/state-legislatures-news/details/new-commission-lays-out-maha-priorities-for-food-and-health-policy