Cutting GRAS in 2026? Not Yet

By Suzie Trigg, Kristi Weisner, PharmD | July 16, 2026

RELATED PRACTICES FDA Regulatory and Compliance, Food, Beverage and Restaurant

In the 18 months since the Make America Healthy Again (MAHA)-focused administration began to lead the U.S. Food and Drug Administration (FDA), one of its most significant reforms—closing the so-called GRAS loophole—has not yet materialized. In the meantime, several states have passed new laws to restrict or regulate food additives, and New York has become the first state to take steps to close the GRAS loophole on its own.

What Is FDA Working On?

FDA is working to ensure that it receives information about all substances added to food. Under current law, a food company may, but is not required to, notify the FDA of the company's conclusion that a substance to be added to food is generally recognized as safe (GRAS). In March 2025, Health and Human Services (HHS) Secretary Kennedy directed the FDA commissioner to explore changes to the FDA's final rule on GRAS and related Agency guidance to eliminate the self-affirmed GRAS pathway in an effort to enhance the FDA's oversight of food ingredients and increase transparency for consumers.[1]

In December 2025, the FDA sent the proposed rule to the Office of Management and Budget (OMB) for review, describing the rule as a rule that, if finalized, would amend the FDA's GRAS regulations for human food in 21 CFR part 170 (and for animal feed in 21 CFR part 570) to require the mandatory submission of GRAS notices for both direct and indirect substances (e.g., food packaging).[2] Any substance already listed or affirmed as GRAS by regulation, or by a GRAS notice in the FDA's GRAS notice inventory with an accompanying "no questions" letter, would be exempt. The proposed rule would also clarify the process under which the FDA could determine that a substance is not GRAS.

When Should the Food Industry Expect a Proposed GRAS Rule?

The proposed GRAS rule is currently slated for December 2026—a delay from the anticipated mid-2026 timeline previously projected. In the several months since the FDA sent the proposed rule to OMB, FDA and OMB representatives have held meetings with several industry stakeholders. In July 2026, the White House's Office of Information and Regulatory Affairs (OIRA) released its Unified Agenda, communicating that the GRAS rule is now slated for December 2026.

Additionally, certain existing GRAS substances may receive alternative treatment to avoid significant delays, with available cost information now stating: "Other one-time per manufacturer costs of the proposed rule are preparing and submitting streamlined submissions related to uses of substances introduced into interstate commerce under the GRAS provision of section 201(s) of the FD&C Act before the effective date of a final rule, for firms that choose to submit this information during the window of availability for this time-limited option for such submissions."[3]

© 2026 Haynes and Boone, LLP

All signs indicate that a final GRAS rule may still be years away, with a final compliance date for mandatory GRAS submissions even further into the future.

What Have States Done Without FDA Action?

States have forged ahead with MAHA priorities, like mandatory GRAS notice to FDA, with a dozen states moving to ban specified additives from school meals or more broadly, and two states—Texas and Louisiana—aiming to provide on-pack information to consumers about certain color additives and food additives. Over the past 18 months, while the FDA has considered how to eliminate the self-affirmed GRAS pathway, post-market safety reviews of various food additives, how to define ultraprocessed food (UPF) and similar issues related to food additives, state laws have proliferated. Among states considering action with respect to GRAS substances in food, New York has taken the lead with the passage of the Food Safety and Chemical Disclosure Act, Senate Bill S1239F (the "Act" or SB 1239).

How Has New York Tackled Changes to GRAS?

SB 1239, while passed by the New York State Legislature, awaits approval after its passage by the New York State Assembly on April 21, 2026.[4] If signed into law by Governor Hochul, not only will New York follow suit with other states banning certain food additives, but it will be the first state in the U.S. to require entities to publicly disclose the basis for substances self-affirmed to be generally recognized as safe (GRAS).[5] Still, it is important to underscore that SB 1239 has not been signed into law by Governor Horchul, nor assigned a Chapter number, and therefore is not effective law as of the time of this writing.

Food and Color Additive Prohibitions

The Act amends the New York Agriculture and Markets Law to make it unlawful "for any person, firm, association or corporation to manufacture, compound, brew, distill, produce, process, sell, deliver, distribute, hold, offer or expose for sale…any food or food product" containing FD&C Red No. 3, potassium bromate or propylparaben.[6]

GRAS Substance Reporting Requirements

The Act requires a person, firm, association or corporation to submit a report to the commissioner and to ensure it is available in a public database before the person, firm, association or corporation is allowed to:[7]

- Sell or offer or expose for sale any GRAS substance or combination of GRAS substances for use in or on food, or to use any GRAS substance or combination of GRAS substances in the manufacturing, compounding, brewing, distilling, producing or processing of any food or food product;
- Make any new use of any GRAS substance or combination of GRAS substances in or on food; or
- Sell or offer or expose for sale any food or food product containing any GRAS substance or combination of GRAS substances.

The report must contain:[8]

© 2026 Haynes and Boone, LLP

- Signed statements and a certification, including the intended conditions for use and the statutory basis for concluding that the substance is GRAS;
- The identity, method of manufacture, specifications and physical or technical effect of the substance;
- Dietary exposure to the substance, such as the amount that consumers are likely to eat or drink as part of a total diet;
- Self-limiting levels of use in circumstances where the amount of the substance added to human food or animal food is limited because the food containing over certain levels of the substance would be unpalatable or technologically impractical;
- Evidence of a substantial history of consumption of the substance's use in food by a significant number of consumers prior to Jan. 1, 1958, if applicable;
- A narrative description of the basis for the conclusion of GRAS status;
- A list of the generally available data, information and methods the notifier cites in the GRAS notice;
- Any previous GRAS substance notices submitted to the FDA on the substance and the FDA's responses; and
- All relevant currently available safety information.

The Act defines a "generally recognized as safe substance" or "GRAS substance" in a way that echoes federal law as "any substance added to food that is exempted from the definition of 'food additive' … because it is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use" based either on the same scientific procedures required for food additive approval or on common use if the substance was used in food prior to Jan. 1, 1958.[9]

Exceptions

The Act clearly targets new or previously self-affirmed GRAS substances, with exclusions from the Act's reporting requirements for:[10]

- GRAS substances for which the FDA issued a "no questions" letter;
- Substances listed in federal regulations as prior sanctioned or GRAS for use in food or food packaging;
- Food contact substances with an effective premarket notification demonstrating safety for the intended use;
- Substances subject to regulations approving their intended use for food;
- Food ingredients that have been widely consumed in the U.S. prior to Jan. 1, 1958, without known detrimental effects, that are subject only to the conventional processing practiced prior to Jan. 1, 1958, and for which there are no known safety hazards;
- Substances for which the FDA issued a letter of acknowledgement without objection that the substance is safe under its intended conditions of use; and
- Substances determined by the commissioner to be safe to add to foods.

The Act also excepts an entity that, "in the regular course of business, sells food at retail directly to the public on premises located in the state[,]" as long as "such food or food product was acquired for sale within the state" by such entity before the effective date.[11]

Under this exception, retail food stores, food service establishments, food relief organizations, supermarkets, grocery stores, specialty stores, farmers markets and other vendors may sell, deliver, distribute, hold, offer or expose for sale food or food products containing potassium bromate

© 2026 Haynes and Boone, LLP

or propylparaben until the product's expiration, "best by" or "sell by" date on the packaging, and up to three years after the effective date of the Act.[12]

Supermarkets, grocery stores, specialty food stores, farmers markets and other vendors selling or offering or exposing for sale any food or food product containing an unreported GRAS substance or combination of GRAS substances are also shielded from enforcement if they have a valid written contract or renewal agreement from their manufacturer, producer, distributor or supplier containing assurances of compliance with the Act.[13] The Act also provides an outright exemption from GRAS reporting requirements for small businesses that are independently owned and operated and that have fewer than 100 employees.[14]

---

[1] HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients Are Safe, March 10, 2025.

[2] Substances Generally Recognized as Safe, RIN: 0910-AJ02.

[3] *Id.*

[4] *Food Safety and Chemical Disclosure Act*, S1239F, Reg. Sess. (N.Y. 2026) (to be codified at N.Y. Agric. & Mkts. Law §§ 198(7-a), 199-a(5), 199-h).

[5] N.Y State Senator Brian Kavanagh, *Kavanagh, Kelles, Healthy Food Advocates Announce Passage of Landmark Law to Require Disclosure of Chemical Ingredients and Safety Data for Processed Foods* (Apr. 21, 2026).

[6] N.Y. Agric. & Mkts. Law § 199-a(5(a)), as amended by S1239F.

[7] N.Y. Agric. & Mkts. Law § 199-h(1(a)), as amended by S1239F.

[8] N.Y. Agric. & Mkts. Law § 199-h(1(b)), as amended by S1239F.

[9] N.Y. Agric. & Mkts. Law § 198(7-a), as amended by S1239F.

[10] N.Y. Agric. & Mkts. Law § 199-h(2), as amended by S1239F.

[11] N.Y. Agric. & Mkts. Law §§ 199-a(5(b)), 199-h(3), as amended by S1239F.

[12] N.Y. Agric. & Mkts. Law §§ 199-a(5(b)), 199-h(3), as amended by S1239F.

[13] N.Y. Agric. & Mkts. Law § 199-h(4), as amended by S1239F.

[14] N.Y. Agric. & Mkts. Law § 199-h(6), as amended by S1239F.

© 2026 Haynes and Boone, LLP