Major Issues with FDA's Proposed GRAS Rule

Federal Register Vol. 91. p 51834| August 11, 2026 | Docket FDA-2025-N-3262

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1. No requirement to notify the FDA *before* marketing a product as GRAS

FDA has touted the proposed rule as a mandatory notice requirement, but the rule explicitly preserves the status quo by stating that: “a company may continue marketing a purported GRAS substance before submitting a GRAS notice or after submitting a GRAS notice before it is filed by FDA.” As such, potentially unsafe substances can be marketed at essentially any time. Substances could be marketed well before the FDA is notified and remain in the food supply for the entire duration of FDA's review. *(Preamble, p. 51851; §170.205, p. 51876)*

2. No compliance, no problem

While the proposed rule requires companies to eventually notify the FDA when it introduces a new GRAS ingredient, there are virtually no consequences for failing to do so. The rule states that failure to comply with the mandatory notification requirement is merely “a factor in FDA's prioritization of food substances for post-market review.” There are no civil or criminal penalties, no injunctive relief mechanism, or requirement that the product be removed from the market until the FDA receives notice. FDA’s post-market review program is chronically underfunded and barely functional. The threat of addition to a queue of chemicals that the FDA may ultimately take decades to review, if ever, is hardly an effective hammer. *(Preamble, p. 51851)*

3. No meaningful deadlines

The proposed rule requires companies to notify the FDA when it makes a GRAS determination, but sets no deadlines for notification. Therefore, companies are welcome to market their substances as GRAS before filing any notice with the FDA. Without a deadline for filing notice, companies could market an ingredient in secrecy indefinitely without any consequence. A mandatory system with no deadline enforcement is unlikely to perform much better than the voluntary system it replaces.

When a company does submit a notice, the proposed rule gives the FDA 45 days to file a notice and states that “within 180 days of filing, we will respond to you by letter.” The FDA has an option to extend 90 days, up to two times. However, the rule does not specify what happens if FDA simply fails to respond. It is unclear if the FDA will list these ingredients as pending review or if substances will be added to the FDA’s GRAS registry at the end of the review period regardless of whether the FDA has reached a determination. The proposed rule also does not allow an opportunity for notice and comment on GRAS determinations. *(§170.265(a)-(b), p. 51877)*

4. Products may be able to stay on the market even when the FDA has concerns

One of the most significant problems with the GRAS system under current law, is that when FDA scientists raise concerns about a GRAS notice, submitters are able to withdraw their notice and continue marketing the substance, usually without consequence. The FDA acknowledges this problem in the preamble to the proposed rule. (p. 51842). Instead of eliminating this practice, the proposed rule codifies it. The proposed rule defines "cease to evaluate" and retains "cease to evaluate" as one of the three potential outcomes of an FDA GRAS review. The other two outcomes are a no questions letter, and a letter stating that there is an insufficient basis for the substance to be considered GRAS (§ 1703.303, p. 51877).

While §170.265(b)(3) of the proposed rule does state that if FDA issues a "cease to evaluate" letter, "we will not consider the notification requirement of §170.205 to be met." However, there does not seem to be any consequence for failure to get a "no questions" letter from the FDA or failure to meet the notification requirements. There is still no market-hold authority, and no explicit requirement to submit additional data to answer the FDA's questions, so the potentially unsafe substance could continue to be sold as GRAS even after FDA has formally stopped evaluating it. *(§170.265(b)(3), p. 51877)*

5. No safety data for ingredients already on the market

The proposed rule creates a new Subpart F (§170.305) which allows substances already in interstate commerce before the rule's effective date to file a "streamlined submission" containing only: company name, substance name, intended conditions of use including amounts, and evidence of prior commerce. No safety data is required. Companies are also not required to disclose if they previously requested that the FDA cease to evaluate a GRAS notice or if FDA scientists had previously raised concerns. FDA will post these submissions, but the rule states explicitly that listing "does not mean that FDA has reviewed the GRAS status of the substance's conditions of intended use." A company can submit a minimal form documenting years of sales and receive an exemption from mandatory GRAS notification without even a cursory safety evaluation. *(§170.305, pp. 51877–51878)*. Subpart F submissions must be filed within one year of the effective date of the final rule.

6. "Streamlined approach" creates perverse incentive to rush to market and gives a halo to unreviewed chemicals

Creating this streamlined, minimal data process incentivizes companies to rush new ingredients to market now to lock in the simplified notification requirements, possibly before the companies even have safety data to support their GRAS determinations. This could lead to an increase in understudied new food chemicals on the market. *(§170.305, pp. 51877–51878)*

Because Subpart F submissions are posted on an FDA-maintained public inventory, consumers, retailers, and downstream manufacturers may infer that listed substances have submitted safety

data to the FDA and received a “no questions” letter. The rule's disclaimer that listing does not mean the FDA has reviewed may not be visible to downstream users who are only trying to verify whether a substance is GRAS. *(§170.305, pp. 51877–51878).* As a result, downstream manufacturers may mistakenly include understudied chemicals in their product under the impression that they are safe.

7. Creates a new “threshold of regulation” loophole

Threshold of Regulation (TOR) is an FDA exemption pathway for food contact materials that allows a food contact substance to be used without going through the FDA’s normal notification and review process for those substances. It is functionally a de minimis loophole.

Under current law, to qualify for the TOR exemption as a food contact substance, a substance must not be a carcinogen, and must not contain any known carcinogenic constituent with a “toxic dose 50” value[1] of less than 6.25 mg/kg bodyweight per day. Qualifying substances must also meet three conditions: (1) the dietary concentration of the substance is 0.5 parts per billion or below, (2) the substance has no technical effect in food, and (3) it has no significant environmental impact. (*§ 170.39; p. 51848; pp. 51875–51876*)

The FDA equates low exposure to safety in the TOR process and does not complete a comprehensive safety evaluation for TOR substances. Companies need to seek a TOR exemption from the FDA, but unlike other food contact substances, once the exemption is received it can be generally applied for all companies wishing to use the substance.

Although TOR was originally designed for food-contact substances expected to migrate into food in trace amounts, the proposed rule expands it to also exempt direct food ingredients from the new mandatory GRAS notification requirement, which is a significant change in scope. (*p. 51848; pp. 51875–51876*)

The proposed rule also changes the criteria for TOR exemptions. It changes the 0.5 ppb dietary concentration threshold to instead an estimated daily intake of 0.025 micrograms per kilogram bodyweight per day, based on the bodyweight of an average person consuming the food. It changes the carcinogenic impurity requirements from less than 6.25 milligrams per kilogram body weight per day to a lifetime cancer risk of 1 in one million. The proposed rule also removes the requirement that TOR substances not have a technical effect in the food. This last change opens the TOR exemption to any kind of direct additive or GRAS substance used in food. (*§ 170.39, p. 51848*)

By equating low exposure to safety, this new framework does not address endocrine disruption, developmental or reproductive toxicity, neurotoxicity, or immunotoxicity — all of which can be

[1] This is defined loosely as the specific chronic dose of a substance required to produce a defined toxic effect or induce tumors in 50% of a test population.
https://derangedphysiology.com/main/cicm-primary-exam/pharmacodynamics/Chapter-413/therapeutic-index-ed50-td50-and-ld50

relevant at very low doses. It also evaluates each substance in isolation, with no cumulative exposure analysis for multiple TOR-exempt substances.

TOR-exempt uses do not appear in the Code of Federal Regulations — only on an FDA-maintained list, a practice which would likely be continued by the proposed rule. When a TOR exemption is revoked due to new safety information, manufacturers using the same substance without having formally requested an exemption are informed only through a general Federal Register notice, not directly. Additionally, it is unclear if information submitted to the FDA, like toxicity data and exposure data, when a company is seeking a TOR exemption will be made public.

We do not know how many substances might be able to take advantage of this new exemption, but some kinds of ingredients that might qualify include flavor ingredients, enzymes, solvents, processing aids, and fermentation by-products.

8. No independent safety review required

Companies may continue to self-affirm GRAS using experts they hire and pay. The mandatory notification requirement changes who must be notified, not who performs the safety review or under what conflict-of-interest standards.

9. Lets food companies hide their safety data

§170.250(d) and (e) allow companies to claim safety-related data in GRAS notices as exempt from disclosure through public records requests. The proposed rule requires companies to explain how a GRAS conclusion is possible when qualified experts don't have access to the data — but this still allows the underlying safety basis to be withheld from the public entirely. *(§170.250, p. 51876)*

10. No requirement to re-notify when new safety evidence emerges

There is no requirement for companies to re-submit a GRAS notification if new safety studies emerge or if the substance's toxicological profile changes.

11. Leaves the supplement back door wide open[2]

Under the Food, Drug, and Cosmetics Act, makers of dietary supplements are required to file a “new dietary ingredient notice” with the FDA 75 days before marketing a new supplement ingredient. The NDI requires, among other things, evidence of safety establishing that the

[2] https://www.acsh.org/news/2026/08/18/kennedy-closes-gras-loophole-leaves-back-door-open-50290

ingredient “will reasonably be expected to be safe” under the recommended conditions of use. (*21 U.S.C. § 350b(a)(2)*). Despite this low safety threshold, the FDA rejects a majority of NDIs.[3]

However, if a supplement ingredient is used in conventional food, then it can bypass the NDI requirements. (*21 U.S.C. § 350b(a)(1)*). Thus, to avoid an FDA objection, supplement makers regularly secretly self-affirm their ingredients as GRAS and then briefly use them in food in order to get around the supplement notification requirements.[4]

The new proposed rule does not change this back door for supplement ingredients. The proposed rule allows companies to market new ingredients as GRAS for an indefinite period of time without any notice to the FDA. The only consequence for failing to notify the FDA is priority for reassessment.

Supplement makers sometimes only want to briefly market their ingredients in conventional food long enough to be able to evade supplement notification requirements.[5] These companies would have little incentive to comply with the so-called mandatory notification requirements. There is nothing in the proposed rule that would prevent a supplement maker from introducing and marketing an ingredient without notice to the FDA, and then simply taking the ingredient out of conventional food, obviating the need to notify the FDA. Even if the FDA notices the absent notification and adds the ingredient to a queue for post-market evaluation, it is unlikely that the substance will be prioritized if not widely being used in food, or if no longer being used in conventional food at all.

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[3] https://www.supplysidesj.com/supplement-regulations/26-years-post-dshea-fda-still-rejects-most-ndi-notifications

[4] https://blogs.edf.org/health/2021/09/27/broken-gras-undermining-the-safety-of-dietary-supplements-and-food/

[5] https://www.nutritionaloutlook.com/view/gras-still-viable-ndi-workaround (“Lawyers I’ve talked to over the years would say, ‘Just get it into a food,’” Endres says. “And I know of companies that literally just start up a new company, put the ingredient into a nutrition bar, sell it on the market, and then shut the company down” just so they can say that the ingredient has been used in the food supply, he adds.”).