

Ensuring Safe and Toxic-Free Foods Act of 2025

GRAS Designation Reform (Section 409A)

The bill establishes stricter requirements for substances that manufacturers wish to classify as GRAS. It mandates that:

- GRAS determinations must be submitted to the FDA along with extensive scientific evidence, including toxicological data, exposure analysis, and proof the substance is not carcinogenic or linked to reproductive or developmental toxicity.
- The FDA must publicly post submitted GRAS notices and allow for a 60-day public comment period.
- The FDA can object to GRAS claims if documentation is incomplete, the experts involved have conflicts of interest, or the evidence does not support safety.
- Substances can be reassessed and GRAS status withdrawn at any time.
- Certain toxic or untested substances—including those not marketed before the Act's enactment—are excluded from GRAS eligibility.

FDA Oversight and Review

- The FDA must review at least 50 GRAS notices per year until a full backlog is addressed.
- All decisions (approval or objection) must be made public, including scientific documentation used in assessments.

Expert Standards and Conflict of Interest

The Act requires the FDA to update its guidance on how GRAS expert panels are convened, emphasizing the need for independence and transparency to prevent biased safety evaluations.

Food Chemical Reassessment Program (Section 409B)

- The FDA is required to reassess the safety of at least 10 food substances or substance classes every three years.
- Manufacturers must provide data for these reassessments when requested.
- Priority is given to substances that are subject to petitions, regulatory concern, or citizen complaints.
- The same rigorous scientific standards outlined in Section 409A must be applied during reassessments.

Implementation Timeline

- The changes become effective two years after the bill's enactment.
- FDA guidance updates must be issued within 180 days.