

GRAS Under Fire

How FDA or State Rule Changes Might Disrupt the Industry

Presented By: Kevin C. Kenny and Matt Parker

Date: 9 September 2025

Meet the Presenters



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LL.M.**

Senior Advisor
FoodChain ID



Matt Parker

Subject Matter Expert,
Food Contact
FoodChain ID

FoodChain ID Global Service and Reach

Global Technology and Insights Company Serving the Food Industry

Certification, Testing & Consulting

- Food & Feed Safety Certification
- Product Certification
- Sustainability Services
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- Product Development
- Commodity & Ingredient Safety
- Regulatory Compliance & Consulting
- Digital Transformation Consulting



 Office Locations



30,000+
Customers



100+
Countries w/
Customers



220+
Regions & Countries
Regulations Tracked

Introduction & US Federal Situation

Attempted GRAS Legislation

- Intro: Big Picture Food Reg Climate USA 2025
- What is GRAS?
- Elements of GRAS
- History of GRAS
- Two Types of GRAS
- GRAS Notice Summary
- What do we do?



U.S. Big Picture

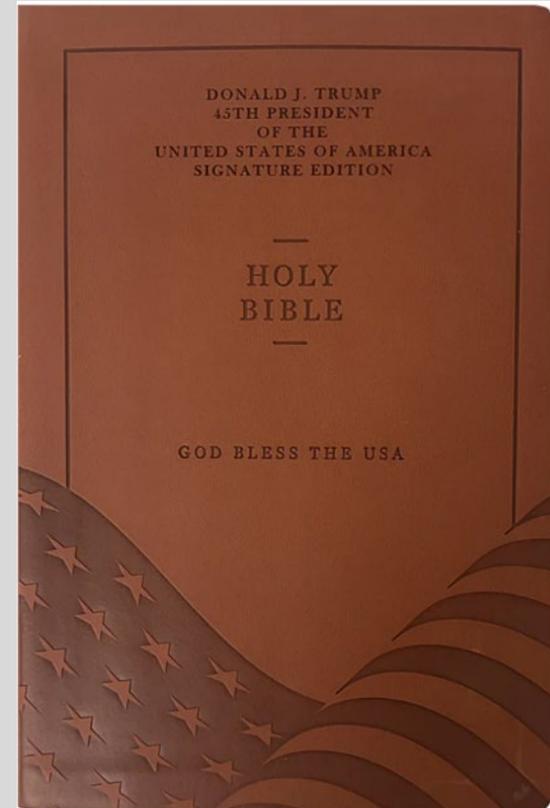
Sep 2025



Courtesy CNN
20 Jan 2025

Today is Day 233 of the Trump Administration.

(1,228 days remaining)



PRESIDENT DONALD J. TRUMP SIGNATURE EDITION GOD BLESS THE USA BIBLE

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Only 1000 Available!
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ADD TO CART

Key Food Players in Trump Administration

Robert F. Kennedy Jr., J.D.

Sworn in: 13 Feb 2025



Secretary of Health and
Human Services

Dr. Marty Makary

Sworn in: 28 March 2025



FDA Commissioner

Kyle Diamantas J.D.

Named 'Acting': 25 Feb 2025



Deputy Commissioner for
Human Foods

Brook Rollins, J.D.

Sworn in: 13 Feb 2025



Secretary of Agriculture

Indirect Challenges

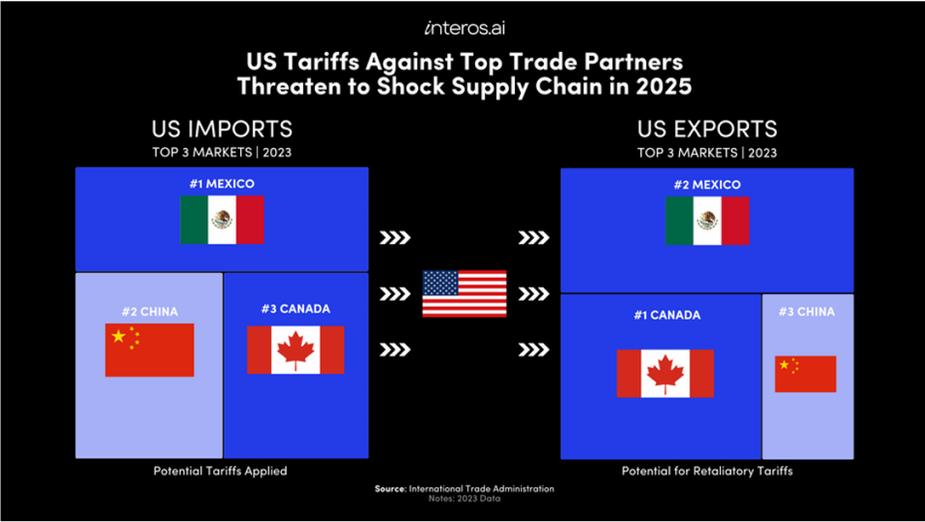
- International Collaboration
- Tariffs
 - On Again. Off Again.(TACO) On Again.
 - Tariffs expected to increase inflation
 - Key ingredients are imported, esp. from China, India, Mexico
- Mass Deportation - Labor shortages:
Undocumented workers represent 50% of farmworkers in the US. (Source: USDA)
- Climate Policy - “its all fake news”
 - Roll back environmental policies including support for renewable energy, pollution regulations, global climate negotiations.
 - EPA (3700 employees, 23%) and FEMA (2000 employees, 33%) RIFS - Capacity Weakness

UNITED STATES
January 21, 2025 1:49 AM UTC
Trump signs executive order withdrawing from the World Health Organization

POLITICS
Trump says 25% tariffs on Canada and Mexico coming on Feb. 1 as he signs several orders on economy

yahoo/finance
China tariffs will 'definitely' increase US inflation: Suntory CEO

Trump launches sweeping border crackdown, mass deportation push
By Ted Hesson and Alexandra Ulmer
January 21, 2025 3:26 AM CST - Updated 3 hours ago



ENVIRONMENT
January 21, 2025 12:26 AM UTC
Trump withdraws from Paris climate agreement, again
By Valerie Volcovici, Jarrett Renshaw

2025 U.S. Food Regulatory Big Picture

Food Additives

- **State vs. Federal:** Patchwork vs. Pre-emption
- **Substance Bans & Restrictions**
 - **Synthetic Dyes:** Red 3, Red 40, Yellow 5 & 6, Blue 1 & 2, Green 3
 - **Preservatives:** BHA, BHT, Propyl Paraben
 - **Sugar & Sweeteners:** Added sugar, HFCS, aspartame, sucralose debates
 - **Other Additives:** Potassium bromate, talc, titanium dioxide
- **School Bans and Labelling Restrictions**
- **Ultra-Processed Foods (UPFs)**
- **GRAS under Threat**
 - Self-GRAS transparency and mandatory notification proposals

Other Food-Related Issues:

- **PFAS & Food Contact:** Packaging bans crossing into additive debates
- **Heavy Metals:** FDA 'Closer to Zero' program shaping reviews
- **SNAP Restrictions**
- **Claims & Labelling:** Greenwashing, 'natural,' and clean label scrutiny
- **Supplements & Novel Foods:** CBD, mushrooms, adaptogens
- **Animal Welfare & Plant-Based Labelling:** Terminology & market access battles

Types of State Actions Currently in Play (2025)

Category	Examples	Potential Federal Conflict
Additive Bans	Red 3, TiO2, Yellow 5, BVO	FDA safety approvals
Ultra-Processed Food (UPF) Restrictions	School bans, UPF labeling, menu disclosure	FDA/USDA authority
School Food Restrictions	Synthetic colors, HFCS	USDA meal standards
SNAP Restrictions	SSB bans, nutrition score thresholds	USDA is approving waivers
GRAS Reform	Labeling or database disclosure laws	FDA GRAS framework
Warning Labels	“Harmful Ingredient” Front-of-Pack	FDA preemption

What is GRAS?

- **Legal Concept:** derived from the FD&C Act, Sections 201(s) and 409.
- Anything intentionally added to food is a “Food Additive” **unless** it is *generally recognized as safe* (GRAS).
- **A substance is GRAS if:**
 - it is **generally recognized** (e.g., via publicly available info)
 - by **qualified experts** (those with scientific training and experience to evaluate safety)
 - **as safe** for its **intended use** (scope, exposure, and context)
 - through **scientific procedures*** (data is equivalent to that required for a food additive petition)
 - * or, in the case of a substance used in food prior to 1 Jan 1958, through either scientific procedures or experience **based on common use.**



What is
not
GRAS?

“GRAS Exemption”

- **Definition:**

“Anything added to food is a food additive unless it is ***generally recognized as safe*** (GRAS).”

- Is a ***Legal concept***, derived from the FD&C Act, Sections 201(s) and 409.
- Is a flexible regulatory tool.

- Congressional intent: Practical approach to allocating resources using scientific judgment without giving away FDA’s post-market authority.
- Provides for the same standard of safety as food additives.*

Food Additive vs. GRAS

Food Additives

- Food Additives **require FDA premarket approval**, a petition process
 - 21 CFR 571.1

GRAS

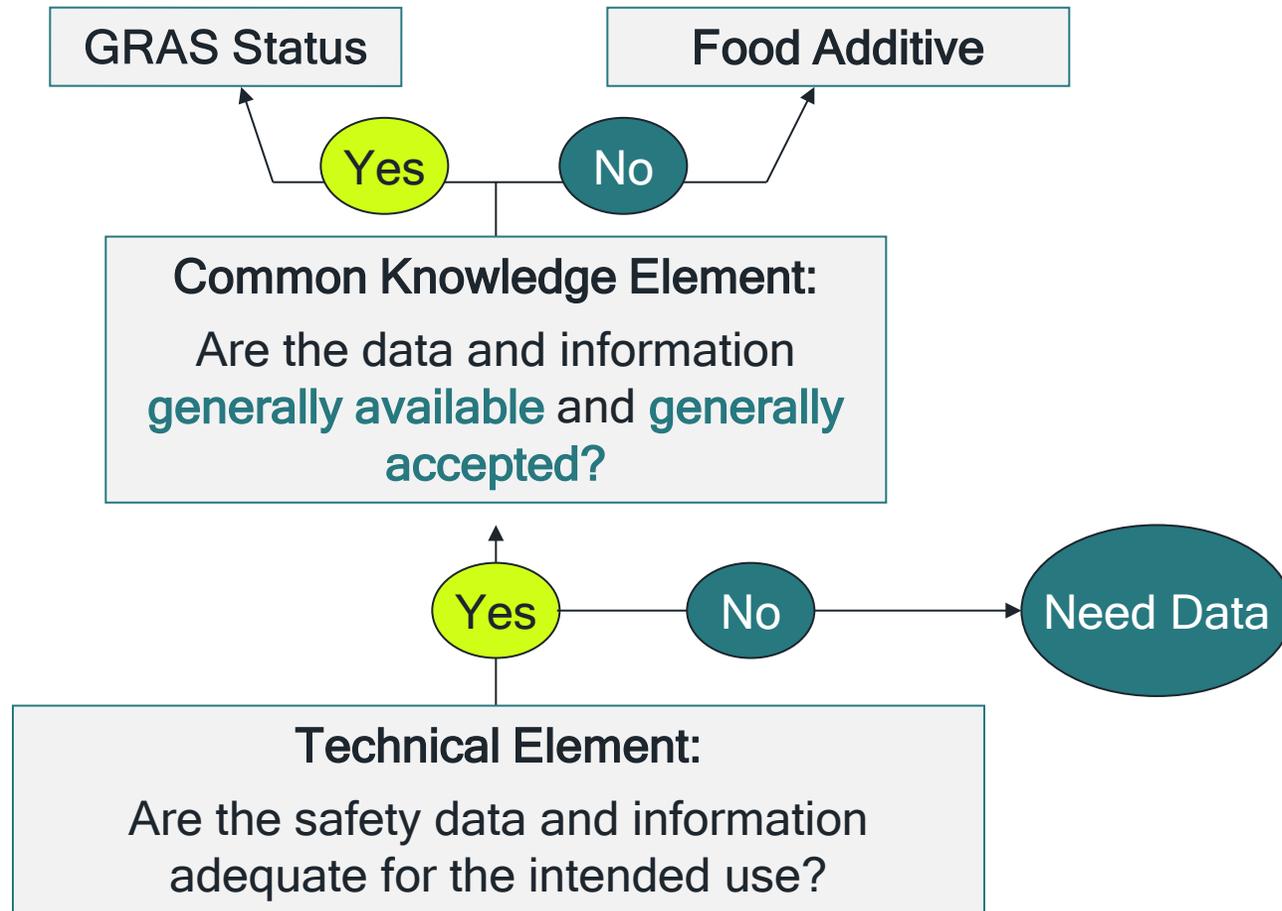
- GRAS Status is an **exemption** to the Food Additive definition.
 - FDA involvement is not required
 - Companies can do their own determination IF requirements of GRAS Status are fulfilled.

GRAS substances excluded from the legal definition of food additives under U.S. law.

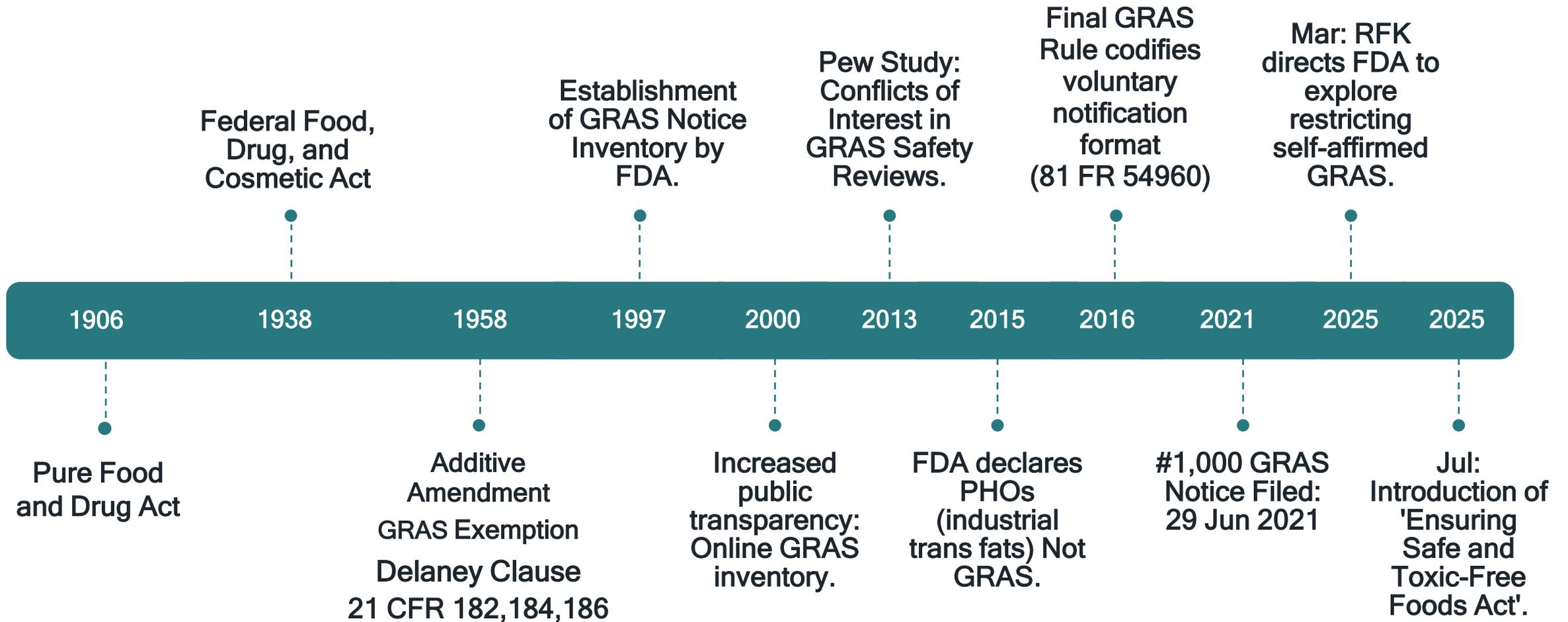
Treated as ordinary food ingredients when their safety is generally recognized by qualified experts.

Common Knowledge

Distinguishes GRAS Substances from Food Additives



History of GRAS



Counts are for Human Food GRNs; FDA tracks Animal Food GRNs separately.

Two GRAS Paths

Self-GRAS

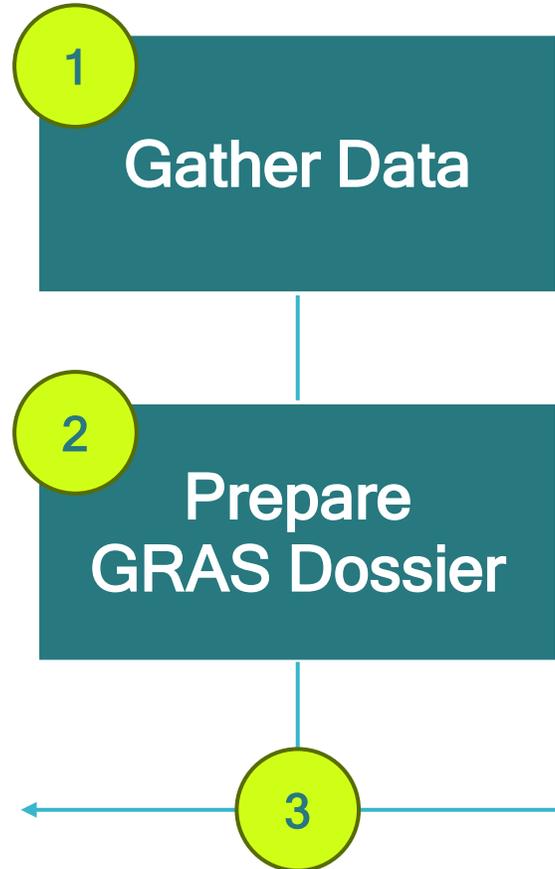
- Reviewed by GRAS Panel
- **Total Timeline:** 5-6 months
- 4-5 months to write and 1 month for panel to review
- **Use:** Lower risk scenarios (only)

Pros:

- Speed/Cost/Flexibility
- Confidentiality of CBI

Cons:

- Cannot market that FDA has blessed this substance.
- Larger CPGS/other Countries may not accept.
- Higher litigation risk
- 2025: Political Risk



Notified GRAS

- Reviewed by FDA
- **Review time:** 6-12 months or more, controlled by FDA
- “No Questions” letter
- **Use:** Moderate risk scenarios
- Enters public database

Pros:

- Regulatory Certainty / CYA
- Market Advantage - proof of acceptance.

Cons:

- Time and Cost
- Public Disclosure of CBI
- Possible FDA Pushback - “insufficient basis”, need more data, etc.)

Self GRAS vs. Notification

- Today: Both processes legally permitted to market in U.S.
- Both require same quality and quantity of data and information

Independent Conclusion

- Info supporting GRAS status held in company files
 - Remains internal and confidential
- May (not always) require a GRAS Panel to sign off on GRAS status

Reasons for Pursuing:

- Substance has a relatively safe profile and existing history of safe use/regulatory approvals
- Due diligence on product-specific safety
- Requires review from GRAS Panel but not necessarily from regulatory authority
- Shorter timeframe (1 month from complete dossier)

FDA GRAS Notice

- GRAS notice is publicly available on FDA website
- FDA “no objections” on GRAS status - business advantage
- Longer timeframe - at least 180 days review following filing

Reasons for Pursuing:

- Required by customers
- Instances where review from regulatory authority necessary
 - Substance does not have an authoritative evaluation
 - GRN required (e.g., infant formula; USDA regulated products)
 - Requirement from regulatory authority in other jurisdictions

Key Elements of a GRAS Notice

21 CFR 170 Subpart E

- Part 1** Signed statements and certification
- Part 2** Identity, method of manufacture, specifications, and physical or technical effect
- Part 3** Dietary exposure
- Part 4** Self-limiting levels of use
- Part 5** Experience based on common use in food before 1958
- Part 6** Narrative (on safety)
- Part 7** List of supporting data and information in your GRAS notice (reference list)

Contents of a GRAS Notice

21 CFR 170.36

- “GRAS exemption claim”
- Identity and properties of the substance
- Discussion of notifier’s reasons for concluding the substance is GRAS for intended use
 - Publicly available Info supporting GRAS determination
 - Information that would appear to be inconsistent with GRAS determination
 - Why, in light of the totality of the info, notifier concludes the substance is GRAS for intended use



GRAS Notification Outcomes

Types of Letters

1

“FDA has no questions”

FDA has no questions;
some uses may require
a color additive listing

2

“Notice does not provide basis”

3

“Notifier stops the process”

GRAS Notice Summary (1 Sep 2025)

Link: [Inventory of GRAS notices](#)

- 1,263 Submitted
- 1,000 “FDA has no questions”
- 216 “At the notifier's request, FDA ceased to evaluate this notice” (75 Resubmitted)
- 32 “Pending”
- 19 “Notice does not provide a basis for a GRAS Determination” (6 Resubmitted)

FDA Responses:

- **Positive Outcome:** 1,000, ca. 80%
- **Negative Outcome:** 19, ca 1.5%

Download data from this searchable database in Excel format. If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Basic Search | **Advanced Search** | **Field Search**

Fill in one or more of the criteria to search for. Separate multiple word (or character string) entries with spaces.
(Character strings may be whole or partial words or numbers, and may include common punctuation as is found in chemical names.)

This Exact phrase:

ALL of these words:

ANY of these words:

NONE of these words:

Show Items Clear Search within these results

Records Found: 1000 Show All Page 1 of 20

GRN No. (sorted Z-A)	Substance	Date of closure	FDA's Letter	Date of add'l correspondence	Resubmitted as GRN No.
1245	<i>Lactiplantibacillus plantarum</i> DSM 21379	Aug 5, 2025	FDA has no questions (in PDF) (173 kB)		
1244	<i>Lactiplantibacillus plantarum</i> DSM 21380	Aug 5, 2025	FDA has no questions (in PDF) (174 kB)		
1243	<i>Bacillus coagulans</i> M2017813 spore preparation	Aug 21, 2025	FDA has no questions (205 kB)		
1242	Short-chain fructooligosaccharides	Jul 14, 2025	FDA has no questions (in PDF) (94 kB)		
1240	<i>Lacticaseibacillus rhamnosus</i> ATCC PTA-126815	Jul 8, 2025	FDA has no questions (in PDF) (92 kB)		
1239	<i>Bifidobacterium animalis</i> subsp. <i>lactis</i> PTA-126817	Jun 11, 2025	FDA has no questions (92 kB)		
1238	2'-fucosyllactose	Jun 17, 2025	FDA has no questions (113 kB)		
1236	Algal oil (≥40% docosahexaenoic acid) from <i>Aurantiochytrium limacinum</i> H Sc-01	Jun 10, 2025	FDA has no questions (240 kB)		
1234	Sansho (<i>Zanthoxylum piperitum</i>) pepper extract	Jul 14, 2025	FDA has no questions (in PDF) (86 kB)		
1233	Sansho (<i>Zanthoxylum piperitum</i>) pepper distillate	Jul 8, 2025	FDA has no questions (in PDF) (85 kB)		
1231	<i>Bacillus velezensis</i> PTA-127359	Jul 11, 2025	FDA has no questions (in PDF) (85 kB)		

Counts are for Human Food GRNs; FDA CVM tracks Animal Food GRNs separately:

[Link: Current Animal Food GRAS Notices Inventory | FDA](#)

USA: State vs. Federal

A Growing Patchwork

US State GRAS Notification Transparency Bills (NY, NJ, PA) - Matt

- Draft laws require public disclosure and/or state-level notification for new Self-Determined GRAS substances Would create state-specific ingredient databases not required by federal law

Federal Activity

- **10 Mar 2025:** RFK directs FDA to explore rulemaking to eliminate or restrict self-affirmed GRAS, citing lack of transparency
- **April:** RFK begins actively chasing states to introduce GRAS Transparency Bills
- **17 Jul 2025:** U.S. Senators Ed Markey (D-MA) and Cory Booker (D-NJ) introduced the “Ensuring Safe and Toxic-Free Foods Act of 2025.” a bill that would fundamentally reshape FDA’s GRAS Framework.
- **12 Aug 2025 - Grocery Reform and Safety (GRAS) Act Introduced in House** Representative Frank Pallone (D-NJ) introduced H.R. 4958, named the **Grocery Reform and Safety (GRAS) Act. (Very similar to Senate bill)**
- **28 Aug 2025** RIN 0910-AJ02 - GRAS Substances Proposed rule requiring mandatory GRAS notice submission; today still in Proposed Rule Stage **FDA proposed revisions** to its GRAS information collection process.
- **4 Sep 2025:** FDA published its [Unified Regulatory Agenda](#) - Notice of Public Rulemaking (NPRM) for GRAS now expected in October, which is when public comment page will open





Examination of U.S. State Bills Covering GRAS Substances

What these bills require & potential industry impacts

An American flag graphic is positioned on the left side of the slide, partially overlapping a teal background. The flag's stars and stripes are visible, with the top left corner showing the blue field with white stars.

Why States Are Acting

1

Public health and consumer protection narratives focus on additive risk and transparency

2

Perceived gaps: self-affirmed GRAS opacity; uneven federal action speed

3

High-profile media attention and advocacy campaigns targeting specific additives

4

High-profile media attention and advocacy campaigns targeting specific additives

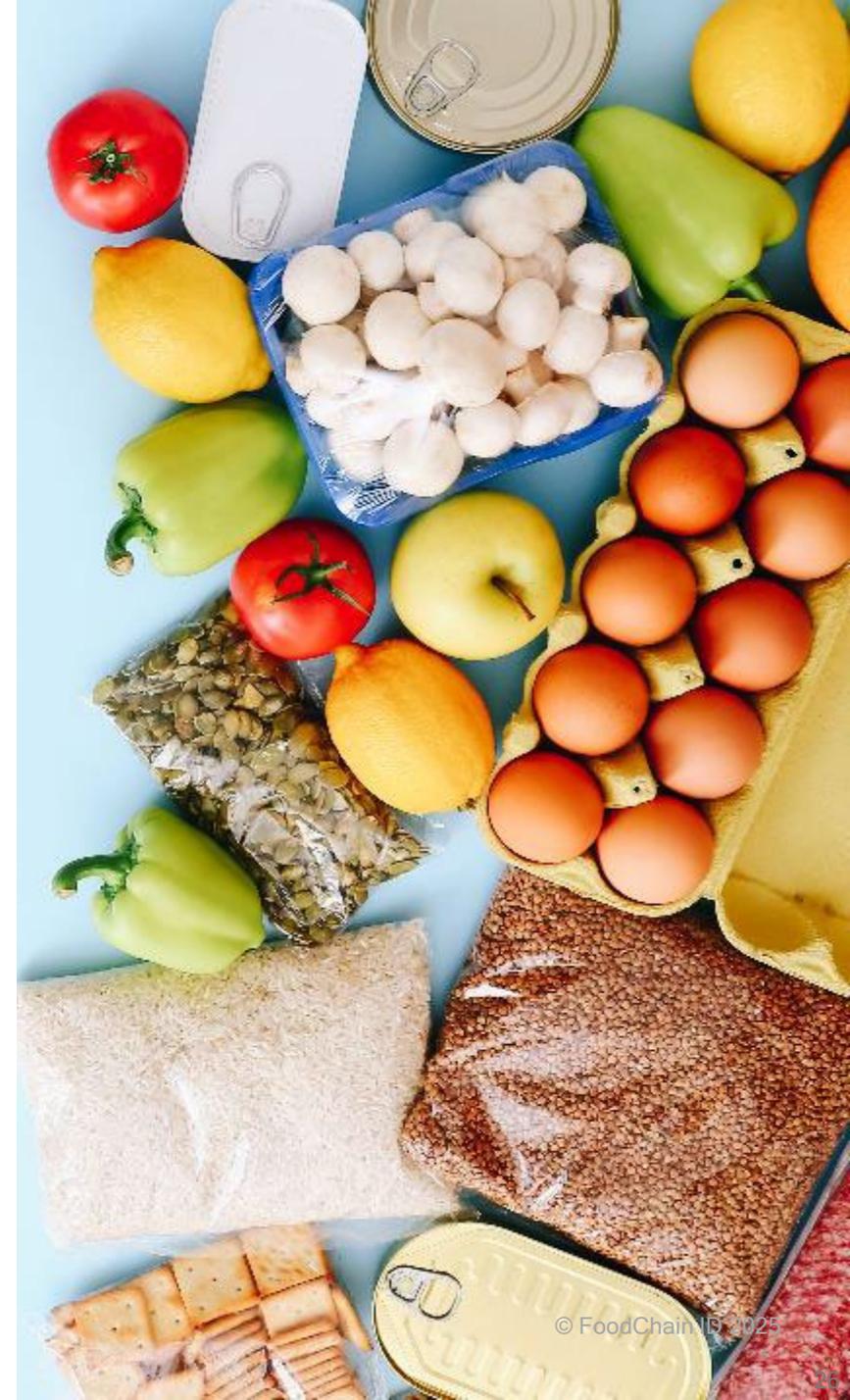
How State Bills Reference GRAS

Common patterns

- Define or reference GRAS under 21 U.S.C. §321(s) and 21 CFR Part 170
- Explicitly distinguish FDA-notified GRAS vs. self-affirmed GRAS
- Require documentation when relying on GRAS for marketability

Targeted scope

- Some bills ban or restrict specific additives regardless of GRAS status





New Jersey A4640

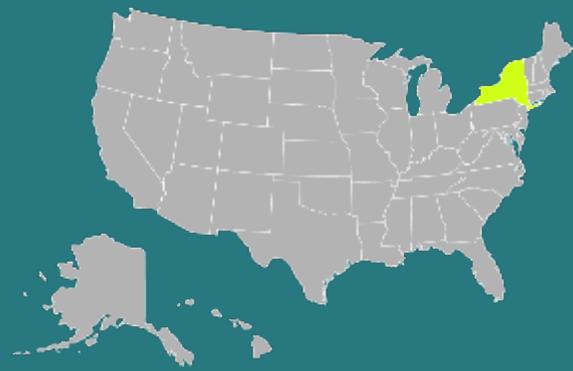


Current Status:

Referred to
Assembly
Consumer
Affairs
Committee on
25 June 2024

- Provides for a Disclosure Requirement
- Requires Detailed Annual Reporting
- Exemptions
- Public Disclosure and Timeline
- Restrictions on Sales and Penalties
- Implementation Timing

[New Jersey A4640](#)



Current Status:

Passed by
Senate 12 June
2025, awaiting
Assembly vote

New York

S.1239-E / A.1556-E

- Provides for a Disclosure Requirement
- Report only new substances/uses
- Exemptions
- Public Disclosure and Timeline
- Restrictions on Sales and Penalties
- Bill Includes Prohibition of Certain Additives and Colours
- Implementation Timing

[New York SB 1239-E](#)



Pennsylvania

S.B. 820

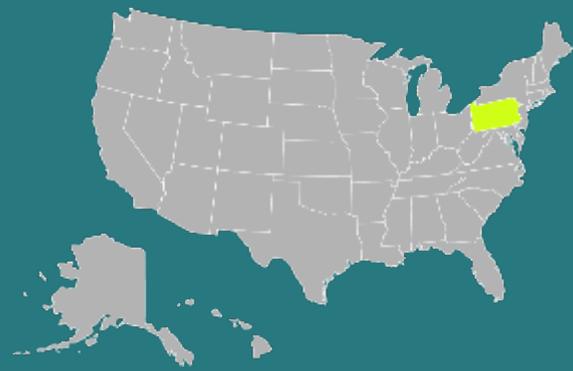


Current Status:

Referred to
Agriculture and
Rural Affairs
Committee 3
June 2025

- Provides for a disclosure requirement
 - No specific requirements listed
- Prohibits 19 food additives/colours
- Effective 1 year after adoption

[Pennsylvania SB 820](#)



Current Status:

Referred to
Consumer
Protection,
Technology
and Utilities on
21 April 2025

Pennsylvania

H.B. 1130

- Provides for a Disclosure Requirement
- Report only new substances/uses
- Exemptions
- Public Disclosure and Timeline
- Restrictions on Sales and Penalties
- Implementation Timing

[Pennsylvania HB 1130](#)



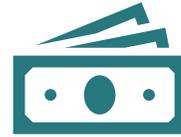
Outlook & Regulatory Best Practices

Food Additive Industry Impacts

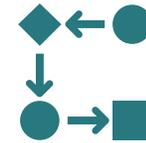
May require additional staffing



Added costs due to submission fees/salaries



Increased ingredient tracking requirements



May require reformulation away from self-determined GRAS substances



Substance bans may require reformulation of products to align with strictest standards



Potential shortages or cost increases for compliant alternatives



GRAS Readiness Checklist



Inventory all additives/ processing aids by SKU, state distribution and use levels



Map regulatory basis: food additive regulation, FDA GRAS notice, or self-affirmed GRAS



Collect/normalize dossiers and supplier attestations; plug gaps



Establish escalation criteria for substitutions and reformulation

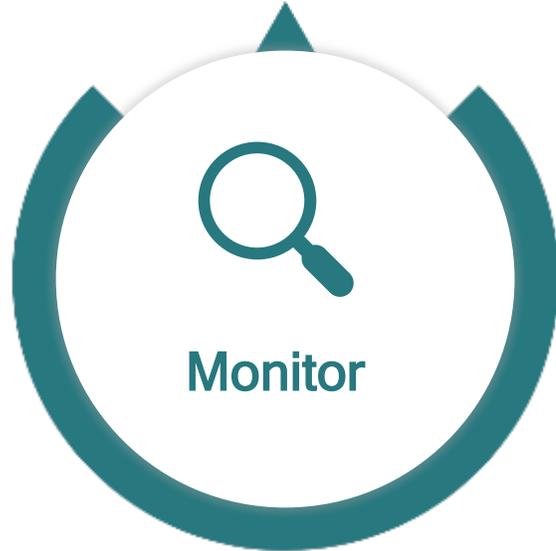


Set up horizon scanning and legislative monitoring workflow



How Industry Can Prepare

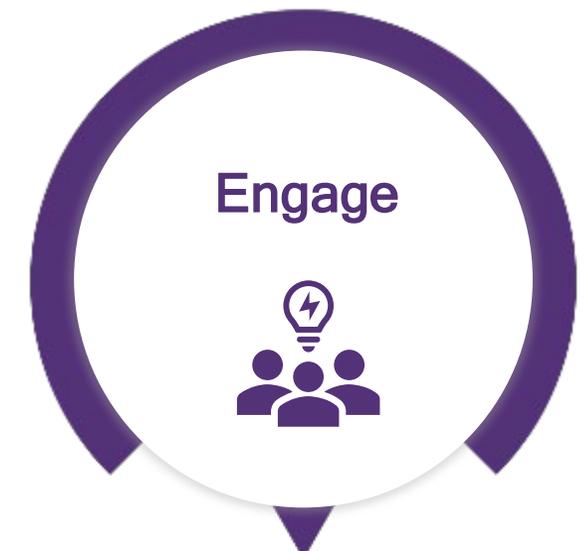
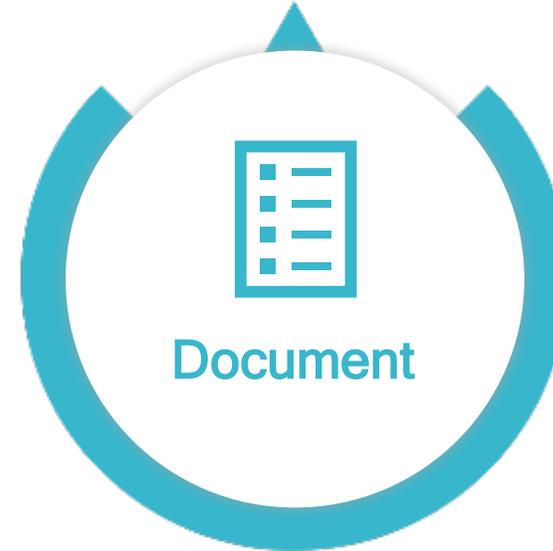
Monitor state legislation & prepare compliance timelines



Strengthen supplier documentation & contractual obligations



Reformulate products to align with strictest state standards



Engage with associations

Our Expectations

- GRAS is critical for U.S. innovation in food
- **Assume GRAS is changing** - transparency at some level is coming - be ready!
- **Better for all involved if done at the FEDERAL Level.**
 - NY does not have the same resources as U.S. FDA. Who can review them in NY?!
 - Federal Actions make it equal across 50 states. If multiple States do GRAS, it will become unmanageable. Do it once, right.
 - We recommend: Federal Notified GRAS (with grandfathering of existing substances - or FDA will be drowned by 500+ new notifications).



GRAS Reform

Takeaways

- Public focus mostly on SELF-GRAS “Loophole” - so expect increased pressure for **transparency**
- Consider transition from self-affirmation to formal **GRAS Notification** to ensure minimal uncertainty
- Reevaluate any ingredients marketed via self-affirmation
- Maintain robust dossiers, origin, toxicological summaries, and use-case assumptions
- Work through trade associations to help shape proposed legislation and rulemaking
- Participate in FDA/public comment periods and respond to GRAS-related RFIs

Example FoodChain ID Experience

Food Contact GRAS

- Customer needed 10-12 self-GRAS determinations for a new series of food contact substances introduced into the market.
 - Working with client, we gathered safety dossier data for each of them, organized a GRAS review panel and delivered over time. Recommended plan was to do self-GRAS to get into the market quicker, then replace with GRAS Notifications or FCNs.
 - After a couple years, we re-evaluated the substances and two of the substances in the meantime had negative new studies published - they were not renewed as GRAS.
- Just because GRAS Status is achieved does not mean it stays GRAS forever.
 - Need to continually re-evaluate in light of new published studies.

U.S. State-Level Package for Food Additives

Interactive Dashboard & Monthly Expert Reports

FoodChain ID USA States and Federal Additive Trends Dashboard

USA States and Federal Additive Trends

Regional Map Current Comparison Long Term Comparison Type & Group Organization & Agency Drilldowns Heatmap

Articles Count by Country

Date Selector

- Select all
- 2015
- 2016
- 2017
- 2018
- 2019
- 2020
- 2021
- 2022
- 2023
- 2024
- 2025

Category Selector

- Select all
- Blog
- General Media
- NGO
- Official Source
- Scientific Journal
- Trade Journal

Type

- Notice
- Proposal
- Regulation

Profile Selector

- Select all
- Artificial Colors - USA: Official
- Artificial Colors - USA: Unofficial
- Artificial Sweeteners - USA: Official
- Artificial Sweeteners - USA: Unofficial
- Colors - USA Federal: Official
- Colors - USA Federal: Unofficial
- Colors - USA States: Official
- Colors - USA States: Unofficial
- Flavors - USA Federal: Unofficial
- Flavors - USA States: Official
- Flavors - USA States: Unofficial
- Food and Beverage Additives - USA: Official
- Food and Beverage Additives - USA: Unofficial
- Natural Colors - USA: Official
- Natural Colors - USA: Unofficial

Powered by FoodChain ID

FOODCHAIN ID®

USA Food Additives Report

FoodChain ID Regulatory Trends (Praedixi)

USA Food Additives Report

June 2025

INDEX BY COUNTRY

- [UNITED STATES](#)
- [USA CALIFORNIA](#)
- [USA LOUISIANA](#)
- [USA NEW YORK](#)
- [USA OKLAHOMA](#)
- [USA TEXAS](#)

EMERGING ISSUES

[Ultra-Processed Food Paradox: When a Protein Shake Equals Candy in Nutrition Science | American Council on Science and Health](#)

[Texas will put warning labels on some foods, but its additives list has inaccuracies](#)

[Senator Thompson Announces Interim Study on Limiting Food Dyes | Oklahoma Senate](#)

[Why 'minimally processed' is the next big thing in snacks](#)

[\(New York\) Enacts the "food safety and chemical disclosure act"; prohibits certain food additives and food color additives; provides that in an action to enforce compliance](#)

Consulting

Consulting

- Scientific and Regulatory Affairs (SARA) Consulting
- Software Implementation and Advisory
- Digital Transformation & AI Consulting
- Cloud Migration Strategy
- Food Safety and Risk Assessment

SARA Consulting

- Food Additives and Ingredients
- Food Contact
- Labelling
- Market Entry
- Expertise as a Service

